IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 645 OF 2022

IN THE MATTER OF:

INDIAN MEDICAL ASSOCIATION & ANR.

...PETITIONER

VERSUS

UNION OF INDIA & ORS.

...RESPONDENTS

AFFIDAVIT IN TERMS OF ORDER DATED 23.04.2024 ON BEHALF OF RESPONDENT NO. 1: UNION OF INDIA

ADVOCATE FOR THE RESPONDENT

G. S. MAKKER

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
WRIT PETITION (CIVIL) NO. 645 OF 2022

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AFFIDAVIT IN TERMS OF ORDER DATED 23.04.2024 ON BEHALF OF RESPONDENT NO. 1: UNION OF INDIA

I, B.K.Singh, S/o Late Shri Baleshwar Prasad, aged about 59 years, presently working as Joint Secretary, in the Ministry of Ayush, New Delhi do hereby solemnly state and affirm as follows:-

I state that I am authorized in my official capacity to swear and depose to the present affidavit on behalf of the Respondent No. 1 and as such, I am fully conversant with

NOTARY PUBLIC K. BANDANA Delhi Regn. No. 19718 Date of Exp. 26.02.2025 Govt of India

the facts and the circumstances arising in W. P. (C) 645 of 2022 (hereinafter referred to as "the Petition") based on the records of the case.

2. That I have gone through the contents of the Petition and deny each and every one of the averments and allegations contained therein save those that have been specifically admitted herein.

3. That the answering respondent has filed the Counter Affidavit and Additional affidavit to the present petition on 18.03.2024 and 08.04.2034 respectively. The present Affidavit is being filed in compliance of direction of this Hon'ble Court vide its order dated 23.04.2024 in order to clarify the position with regard to withdrawal of Rule 170 of Drugs & Cosmetics 1945.

4. That the answering respondent is filling the present additional affidavit and seeks the liberty of this court to file additional affidavits if required.

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RULE 170 OF DRUGS & COSMETICS RULES, 1945.

5. Is respectfully submitted that in the year 2018, the present answering respondent vide gazette notification no. G.S.R. 1230 (E) on 24.12.2018 notified Rule 170 of the Drugs and Cosmetic Rules, 1945 regarding prohibition of advertisements of Ayurvedic, Siddha or Unani Drugs. As per Rule 170 of Drugs and Cosmetic Rules, 1945-

(1) The manufacturer or his agent, of Ayurvedic, Siddha or Unani drugs, shall not participate in the publication of any advertisement relating to any drug for the use of diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or condition.

(2) The Ayurvedic, Siddha or Unani drug shall be advertised for the purpose other than specified in sub-rule (1) after the allotment of the Unique Identification Number.

(3) The manufacturer of the Ayurvedic, Siddha or Unani drug shall apply for the Unique Identification Number for the advertisement issues or aired before this notification, within the period of three months from the date of publication of this notification.

(5) The application for allotment of the Unique Identification Number for an advertisement shall be

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submitted to State Licensing Authority or Drug Controller specifying therein the claims such as textual references, rational from the authoritative books, indication(s), or use(s), evidence regarding safety, effectiveness and quality of drug.

A copy of the Gazette Notification of Rule 170 of Drugs and Cosmetic Rules, 1945 issued by Ministry of Ayush, dated 21.12.2018 is annexed herewith and marked as **Annexure R-1 (Pg. 17 to 24)**.

6. The aforesaid Rule 170 of the Drugs & Cosmetics Rules, 1945 was challenged in proceedings before various High Courts. The details of such proceedings challenging Rule 170 of the Drugs & Cosmetics Rules, 1945 before different High Courts are as follows–

1.	W.P. (C) 321/2019 & CM APPL. 1529/2019
2.	W.P.(C) 502/2019 & CM APPL.2375/2019
3.	W.P.(C) 505/2019 & CM APPL.2395/2019
4.	W.P.(C) 985/2019 & CM APPL.4412/2019
5.	W.P.(C) 5755 & CM APPL.20805/2020
6.	W.P.(C) 15712 & CM APPL.48899-48900/2022

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PETITIONS FILED BEFORE THE BOMBAY HIGH COURT	
7.	W.P (C).No.289 of 2019
PETITIONS FILED BEFORE THE KERALA HIGH COURT	
8.	W.P (C) No.10079 of 2019
9.	W.P (C) No. 12426 of 2019

7. It is respectfully submitted that the Delhi High Court vide order dated 15.01.2019 in *W.P. (C) 321/2019 & CM APPL. 1529/2019*, directed the answering respondent to not take any coercive action against the petitioners till the next date of hearing.

   A copy of the Order dated 15.01.2019 in *W.P. (C) 321/2019 & CM APPL. 1529/2019*, passed by the Delhi High Court is annexed herewith and marked as **Annexure R-2 (Pg. 25 to 26)**.

8. It is respectfully submitted that the Delhi High Court vide order dated 18.01.2019 in *W.P.(C) 502/2019 & CM APPL.2375-76/2019* and *W.P.(C) 505/2019 & CM APPL.2385-86/2019* clarified that the lead proceedings in these cases would be *W.P. (C) 321/2019*, i.e., *Reckit Benckiser India Private Limited & Ors. V. Union of India* for the purposes of pleadings and the hearing.

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A copy of the Order dated 18.01.2019 in *W.P.(C) 502/2019 & CM APPL.2375-76/2019* and *W.P.(C) 505/2019 & CM APPL.2385-86/2019* passed by the Delhi High Court is annexed herewith and marked as **ANNEXURE R-3 (Pg. 27 to 28).**

9. It is respectfully submitted that the Bombay High Court vide order dated 11.02.2019 in *W.P. (C) No. 289 of 2019*, had directed Respondent (Ministry of Ayush) not to take coercive action against members of the petitioner's association.

A copy of the Order dated 11.02.2019 in *W.P. (C) No. 289 of 2019* passed by the Bombay High Court is annexed herewith and marked as **ANNEXURE R-4 (Pg. 29 to 30).**

10. It is respectfully submitted that the Kerala High Court vide interim order dated 10.04.2019 in *W.P. (C) 10079/2019*, directed the respondents not to take any coercive action against the petitioner therein for a period of three months.

A copy of the Order dated 10.04.2019 in *W.P. (C) 10079/2019* passed by the Kerala High Court is annexed herewith and marked as **Annexure R-5 [Pg. 31 to 32].**

11. It is respectfully submitted that Section 33-C of Drugs & Cosmetics Act, 1940 provides for constitution of Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB), to advise the Central Government and the State Governments on

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technical matters arising out of Chapter IV A i.e. Provisions relating to Ayurvedic, Siddha and Unani Drugs.

12. It is respectfully submitted that based on the recommendation of expert committee to revisit Rule 170 of the Drugs & Cosmetics Rules, 1945, in the meeting held on 15.03.2021 by ASUDTAB, a draft gazette notification was placed before the ASUDTAB wherein Rule 170 was proposed to be omitted. The ASUDTAB recommended for omission of Rule 170 of the Drugs & Cosmetics Rules, 1945, considering the fact that whatever action is to be taken with respect to misleading advertisements of ASU drugs will be considered under the Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954.

A copy of Minutes of the online Meeting of Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held on dated 15.03.21 is annexed herewith and marked as **ANNEXURE R-6** **[Pg. 33 to 97]**.

13. It is respectfully submitted that subsequent to this, the Ministry of Ayush vide G.S.R no. 473(E) dated 02.07.2021 had published gazette notification of draft rules for the objections or suggestions by the stakeholders. These draft rules inter-alia include that "*The Rule 170 shall be omitted.*"

A copy of the Gazette Notification issued by Ministry of Ayush, dated 02.07.2021 is annexed herewith and marked as **ANNEXURE-R-7 [Pg.98 to 180].**

14. It is respectfully submitted that in the meeting held on 15.03.2021 by ASUDTAB, the then Drugs Controller General of India, who is a member of ASUDTAB, has observed that "it may not be appropriate to omit Rule 170" regarding "Prohibition of advertisements of Ayurvedic, Siddha or Unani drugs" in anticipation of its inclusion to the similar provisions in the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

A copy of Minutes of the Meeting of Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held on dated 27.06.2022 is annexed herewith and marked as **ANNEXURE –R-8 [Pg.181 to 234].**

15. It is respectfully submitted that the aforesaid Writ Petition i.e. *Writ Petition (C) 321 of 2019* came up for hearing before the Delhi High Court wherein vide order dated 01.05.2023, the High Court passed the following directions -

"1. On 16th February 2023, Mr. P. Chidambaram, learned senior counsel for the petitioners ***had stated that the***

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petitioners shall be satisfied in the event Rule 170 and Form 26 E4 were re-examined by the respondents.

2. Today, Mr. Kirtiman Singh, learned counsel for the Union of India on instructions states that the writ petitions of the AYUSH stakeholders regarding Rule 170 of the Drugs and Cosmetics Rules, 1945 will be placed before the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) for reconsideration

3. The statements made by learned counsel for the parties are accepted by this Court and the parties are held bound by the same.

4. With the view to balance the equities. This court directs that any decision taken by the Union of India in pursuance to the decision of ASUDTAB shall not be implemented for a period of four weeks from the date of its communication to the learned counsel for the petitioners. It is clarified that in the interregnum, the interim made by the court shall be continued."

A copy of the Order dated 01.05.2023 in *Writ Petition (C) 321 of 2019* passed by the Hon'ble High court of Delhi at New Delhi is annexed herewith and marked as **ANNEXURE R-9 [Pg. 235 to 238].**

16. It is respectfully submitted that in its last meeting held on 25.05.2023 abiding to the aforesaid direction of the Delhi High Court to reconsider the matter of the Rule 170 of Drugs and Cosmetics Rules, 1945, the ASUDTAB recommended to proceed with final notification for omission of the Rule 170 and its related Forms mentioned in the D & C Rules, 1945.

A copy of the amendment in the Minutes of the Meeting of Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held on dated 25.05.2023 is annexed herewith and marked as **ANNEXURE R-10 [Pg. 239 to 270]**.

17. It is respectfully submitted that after obtaining approval of Hon'ble Minister on 19.07.2023, the draft of final notification was sent to Ministry of Law & Justice for legal vetting. In this regard, Ministry of Law & Justice had referred twenty-first and twenty-third reports of Committee on Subordinate Legislation and informed that after the pre-publication of a notification, the final notification should be published within three months if no objections/ suggestions are received and within six months if large numbers of objections/ suggestions are received on the draft notification. Further, Ministry of Ayush was suggested to go for pre-publication of the proposal in the Gazette notification.

18. It is respectfully submitted that as the process of final gazette notification will take further time, in order to avoid confusion among the various State/ UT SLAs and to prevent avoidable litigations, Ministry of Ayush vide letter no. T-13011/1/2022-DCC-Part (2) dated 29.08.2023 directed all State/ UTs Licensing Authorities not to take any action under Rule 170 of the Drugs & Cosmetics Rules, 1945 as the final notification is under process.

A copy of the letter dated 29.08.2023 issued by the Ministry of Ayush is annexed herewith and marked as **ANNEXURE R-11** **[Pg. 291 to –]**.

19. It is respectfully submitted that Ministry of Ayush vide G.S.R no. 98(E) dated 02.02.2024 had published gazette notification of draft rules for the objections or suggestions of the stakeholders. These draft rules include the omission of Rule 170 and its provisions.

A copy of Gazette Notification issued by the Ministry of Ayush, dated 02.02.2024 is annexed herewith and marked as **ANNEXURE-R-12 [Pg. 292 to 293]**.

20. That it is further respectfully submitted that Ministry of Ayush has also constituted an expert committee to examine the comments of various stakeholders on the aforementioned

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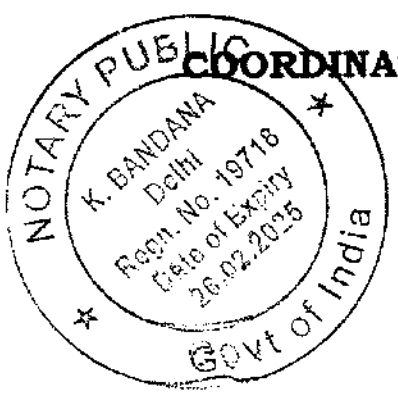
gazette notification G.S.R no. 98(E), dated 02.02.2024. The report of the said expert committee will be placed before the ASUDTAB in its upcoming meeting.

MOU BETWEEN MINISTRY OF AYUSH AND ADVERTISING STANDARDS COUNCIL OF INDIA (ASCI)

21. That it is respectfully submitted that Ministry of Ayush had signed a MoU with Advertising Standards Council of India (ASCI) on 20.01.2017, to report misleading advertisements related to Ayush systems in the print and electronic media. The duration of this MoU was for a time period of one year and later, this MoU was further renewed for a period of one year i.e. from 01.04.2018 to 31.03.2019. In 2017-18, ASCI reported 732 cases, and in 2018-19, 497 cases of misleading Ayush advertisements. The reported cases were examined in the Ministry and forwarded to respective State Licensing Authority for taking necessary action.

REPORTING OF MISLEADING ADVERTISEMENT OF AYUSH DRUGS BY NATIONAL PHARMACOVIGILANCE COORDINATION CENTRE.



22. That it is respectfully submitted that in the year 2018, the matter of misleading advertisement was included under the umbrella of pharmacovigilance in addition to compiling and reporting of Adverse Drug Reaction (ADR). The National Pharmacovigilance Coordination Centre is established at All India Institute of Ayurveda (AIIA) New Delhi along with Five Intermediary Pharmacovigilance Centres (one each at National Institutes in the cities of Jamnagar, Jaipur, Chennai, Bangalore, and Kolkata), and 99 Peripheral Pharmacovigilance Centres (PPvCs) established and functioning across the country. These pharmacovigilance centres report misleading advertisement to respective State/ UT authorities from time to time. The National Pharmacovigilance Coordination Centre was established at All India Institute of Ayurveda (AIIA) at New Delhi along with Five Intermediary Pharmacovigilance Centres (one each at National Institutes in the cities of Jamnagar, Jaipur, Chennai, Bangalore, and Kolkata), and 43 Peripheral Pharmacovigilance Centres (PPvCs). Thereafter, 21 new centres were approved in August 2019, 11 new centres in June 2020 and 25 new centres were approved in January 2022. At present, 99 Peripheral Pharmacovigilance Centres (PPvCs) established and functioning across the country. Year-wise data

of misleading advertisement reported by National Pharmacovigilance Coordination Centre along with action taken, is as follows –

Name of the State/ UT	2018	2019	2020	2021	2022	2023	2024	Total
Assam	-	130	190	346	22	363	153	1204
Andhra Pradesh	-	-	7	13	26	268	26	340
Bihar	-	-	2	6	56	9	5	78
Chattisgarh	6	67	77	78	52	74	26	380
Gangtok	-	-	2	7	-	-	-	9
Goa	-	-	0	36	10	1	-	47
Gujarat	-	130	209	346	219	358	153	1415
Haryana	-	-	2	17	18	62	7	106
Himachal Pradesh	37	146	190	115	144	202	64	898
Imphal	-	-	0	6	9	-	-	15
Jammu & Kashmir	-	25	44	577	375	-	43	1064
Jharkhand	-	-	-	-	3	1	-	4
Karnataka	93	859	830	612	546	330	149	3419
Kerala	-	11	21	107	283	191	30	643
Madhya Pradesh	26	242	517	731	727	554	236	3033
Manipur	-	-	0	2	7	4	2	15
Maharashtra	16	264	431	558	466	548	97	2380
Meghalaya	-	-	0	27	7	12	4	50
Nagaland	-	-	0	7	23	7	8	45
New Delhi	139	453	642	698	402	482	78	2894
Odisha	-	-	1	1	1	9	5	17
Punjab	-	-	37	321	183	200	7	748
Puducherry	-	11	2	3	4	8	-	28
Rajasthan	25	322	811	825	778	754	168	3683
Sikkim	-	-			3	4	6	13
Tamil Nadu	9	803	739	782	767	866	264	4230
Telangana	-	65	44	154	399	334	128	1124
Tripura	-	-	-	-	-	10	-	10
Uttar Pradesh	13	261	207	243	259	304	90	1377

Uttarakhand	-	80	68	168	224	264	46	850
West Bengal	47	510	464	560	201	402	139	2323
	411	4249	5347	7000	6192	6258	1781	31238
Remaining*	-	146*	514*	1144*	1175*	1513*	310*	4802*
Total Reports	411	4395	5861	8144	7367	7771	2091	36040

*Remaining: These are the advertisements that are seen on various social media e-platforms. In such cases, a specific state cannot be identified, however, recorded.

23. Action taken on misleading advertisements of Ayush drugs as reported by State Licensing Authorities upto March, 2024 –

S.no.	State	Reported action taken by SLA
1	Karnataka	79
2	Madhya Pradesh	21
3	Rajasthan	206
4	Tamil Nadu	31
5	Uttarakhand	12
6	West Bengal	5
	Total	**354**

24. In view of the above submissions, the answering respondent humbly prays that the above affidavit be taken on record.

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DEPONENT

बिश्वजीत कुमार सिंह
BISHWAJIT KUMAR SINGH
संयुक्त सचिव/Joint Secretary
आयुष मंत्रालय, भारत सरकार
Ministry of Ayush, Government of India
आयुष भवन, बी-ब्लॉक, जीपीओ कॉम्प्लेक्स, आई.एन.ए., नई दिल्ली
Ayush Bhawan, B-Block, GPO Complex, INA, New Delhi

VERIFICATION:

I, the deponent named above, do hereby verify that the contents of the above affidavit are believed to be true and correct on the basis of the information derived from the record of the case and nothing material has been concealed there from.

06 MAY 2024

Verified at Delhi on this the____ day of May, 2024.

IDENTIFIED

06 MAY 2024

विश्वजीत कुमार सिंह
BISHWAJIT KUMAR SINGH
संयुक्त सचिव/Joint Secretary
आयुष मंत्रालय, भारत सरकार
Ministry of Ayush, Government of India,
आयुष भवन, बी-ब्लॉक, जीपीओ कॉम्प्लेक्स, आई.एन.ए., नई दिल्ली-23
Ayush Bhawan, B-Block, GPO Complex, INA, New Delhi-23

DEPONENT

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K. BANDANA
Delhi
Regn. No. 19718
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Govt of India

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Govt. of India
Mob.: 9654768498

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रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 917] नई दिल्ली, सोमवार, दिसम्बर 24, 2018/पौष 3, 1940
No. 917] NEW DELHI, MONDAY, DECEMBER 24, 2018/PAUSHA 3, 1940

आयुर्वेद, योग व प्राकृतिक चिकित्सा, यूनानी, सिद्ध एवं होम्योपैथी (आयुष) मंत्रालय

अधिसूचना

नई दिल्ली, 21 दिसम्बर, 2018

सा.का.नि. 1230(अ).—औषधि और प्रसाधन सामग्री नियम 1945 का और संशोधन करने के लिए कतिपय प्रारूप नियम औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 33ढ की उप धारा (1) द्वारा यथापेक्षित, सा.का.नि. सं. 396(अ), 4 अप्रैल, 2016 द्वारा भारत के राजपत्र, असाधारण भाग II, खंड 3, उप-खंड (i) में तारीख 04 अप्रैल, 2016 को प्रकाशित किया गया था; और उन सभी व्यक्तियों जिनके इससे प्रभावित होने की संभावना है, से उस तारीख से जिसको भारत के राजपत्र में प्रकाशित इस अधिसूचना की प्रतियां जनता को उपलब्ध कराई गई हैं, से पैंतालिस दिन की अवधि के समाप्त होने से पूर्व आपत्तियां या सुझाव मांगे गए थे।

और जबकि, उक्त राजपत्र 04 अप्रैल, 2016 को जनता को उपलब्ध करा दिया गया था;

और जबकि उक्त प्रारूप नियम पर जनता से प्राप्त आपत्तियां और सुझावों पर केंद्रीय सरकार द्वारा विचार कर लिया गया है;

अत:, अब केंद्रीय सरकार, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 33ढ की उप धारा (1) के साथ पठित उक्त धारा की उप धारा (2) के खंड (ङ) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए आयुर्वेद, सिद्ध और यूनानी औषधि तकनीकी सलाहकार बोर्ड से विचार-विमर्श करने के पश्चात औषधि और प्रसाधन सामग्री नियम, 1945 में निम्नलिखित और संशोधन करती है, अर्थात:-

नियम

1. (1) इन नियमों का संक्षिप्त नाम औषधि और प्रसाधन सामग्री(ग्यारहवाँ संशोधन) नियम, 2018 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख को प्रवृत्त होंगे।

(18)

2. औषधि और प्रसाधन सामग्री नियम, 1945 में-

(i) नियम 169 के पश्चात, निम्नलिखित नियम अंत:स्थापित किया जाएगा, अर्थात:-

"170 आयुर्वेद, सिद्ध और यूनानी औषधों के विज्ञापनों का प्रतिषेध-

(1) आयुर्वेद, सिद्ध अथवा यूनानी औषधों के विनिर्माता या उसका अभिकर्ता किसी रोग, विकार, लक्षण अथवा दशा के निदान, इलाज, शमन उपचार या निवारण के उपयोगार्थ किसी औषध संबंधी किसी विज्ञापन के प्रकाशन में भाग नहीं लेगा।

(2) विशिष्ट पहचान संख्या आवंटित किए जाने के पश्चात उप नियम (1) में विनिर्दिष्ट प्रयोजन के लिए आयुर्वेद, सिद्ध अथवा यूनानी औषध का विज्ञापित किया जाएगा।

(3) आयुर्वेद, सिद्ध अथवा यूनानी औषध विनिर्माता इस अधिसूचना से पूर्व जारी अथवा प्रसारित विज्ञापन के लिए इस विज्ञापन के प्रकाशन की तारीख से तीनमास पूर्व की अवधि के भीतर विशिष्ट पहचान संख्या के लिए आवेदन करेगा।

(4) विज्ञापन के लिए आवेदन को अस्वीकार कर दिया जाएगा, यदि

(i) वह अपूर्ण हो; अथवा

(ii) आशयित विज्ञापन के विनिर्माता का संपर्क विवरण न दिया गया हो; अथवा

(iii) विज्ञापन की विषय-वस्तु में प्रत्यक्ष या अप्रत्यक्ष रूप से अभद्रता अथवा अश्लीलता झलकती हो।

(iv) किसी ऐसे आयुर्वेद, सिद्ध अथवा यूनानी औषध के बारे में हो जो उस औषध या औषधि के उपयोग से पुरुष अथवा महिला के यौनांगों की लंबाई अथवा आयाम या क्षमता के निष्पादन में वृद्धि का सुझाव देता हो; अथवा

(v) यह प्रतिष्ठित व्यक्तियों अथवा सरकारी पदधारियों के फोटो या प्रशंसा पत्र प्रदर्शित करता हो; अथवा

(vi) यह किसी सरकारी या सरकार के स्वायत्त संगठन का संदर्भ देता हो;

(vii) यह किसी आयुर्वेद, सिद्ध अथवा यूनानी औषध के वास्तविक स्वरूप के बारे में मिथ्या प्रभाव डालता हो; अथवा

(viii) यह उक्त औषध की प्रभावकारिता के बारे में भ्रामक या अतिरंजित दावा करता हो।

(5) विज्ञापन के लिए विशिष्ट पहचान संख्या के आवंटन के लिए आवेदन राज्य अनुज्ञापन प्राधिकारी अथवा औषधि नियंत्रक को प्ररूप 26ङ-4 में प्रस्तुत किया जाएगा जिसमें पाठ्य संदर्भ, अधिकाधिक पुस्तकों में से तर्क, संकेत अथवा उपयोग, सुरक्षा, प्रभावशीलता तथा औषधि की गुणवत्ता संबंधी प्रमाण, जैसे दावों को विशिष्ट तौर पर दर्शाया गया हो।

(6) प्ररूप 26ङ-4 के साथ एक हजार रुपए प्रति विज्ञापन आवेदन फीस तथा अन्य समर्थक दस्तावेज जमा किये जाएंगे।

(7) यदि आयुर्वेदिक सिद्ध अथवा यूनानी औषधि के उत्पादन के लिए एक से अधिक राज्य में अनुज्ञापन दिए गए हैं तो विज्ञापन के लिए आवेदन राज्य के अनुज्ञापन प्राधिकारी के यहां प्रस्तुत किया जाएगा जहां पर विनिर्माता का कारपोरेट कार्यालय स्थित है।

(8) राज्य अनुज्ञापन प्राधिकारी आवेदन के निपटान के लिए (यदि अपेक्षित हो, संबद्ध तकनीकी विशेषज्ञों के परामर्श से) इसकी प्राप्ति की तारीख से तीस दिनों के भीतर पूर्ण सूचना सहित आवेदन की प्रक्रिया पर कार्रवाई करेगी और विज्ञापन के लिए विशिष्ट पहचान संख्या आवंटित करेगी।

(9) आयुर्वेदिक, सिद्ध अथवा यूनानी औषधि के विनिर्माता उप-नियम (8) के अधीन विशिष्ट पहचान संख्या के आवंटन के आवेदन का निपटारा तीस दिन के अंतराल में न होने की स्थिति में, राज्य आयुष अथवा स्वास्थ्य सचिव को निर्देश जारी करने हेतु अपील कर सकते हैं।

(10) आवेदक, अनुज्ञापन प्राधिकारी अथवा औषधि नियंत्रक को अपेक्षित सूचना जब कभी भी मांगी जाए, प्रस्तुत करेगा। ऐसा न करने की स्थिति में आवेदन अस्वीकृत किया जाएगा तथा आवेदन फीस जब्त कर लिया जाएगा।

(11) राज्य अनुज्ञापन प्राधिकारी अथवा औषधि नियंत्रक आवेदन से समाधान होने पर अथवा अन्यथा, विज्ञापन की दर्ज की हुई विषय-सूची, आवेदन को अस्वीकृति के कारण अथवा आवेदक की ओर से अपेक्षित कोई स्पष्टीकरण को प्ररूप 26ङ-5 में दर्ज तथा संप्रेषित करेगी।

(12) अनुज्ञापन प्राधिकारी अथवा औषधि नियंत्रक द्वारा प्ररूप 26ङ-5 में अभिलिखित विज्ञापन विनिर्माता को उस औषधि की बिक्री हेतु अनुज्ञप्ति की वैधता की तारीख तक विधिमान्य होगा और उसके पश्चात नवीकरण किया जा सकता है।

(13) उप-नियम (11) के अधीन केंद्र राज्य अनुज्ञापन प्राधिकारी के विनिश्चय के विरुद्ध केंद्रीय सरकार के समक्ष अपील फाइल कर सकेगी और केंद्रीय सरकार का आदेश अंतिम और अपीलार्थी और राज्य अनुज्ञापन प्राधिकारी के लिए बाध्यकारी होगा।

(14) राज्य सरकार आयुर्वेद, सिद्ध अथवा यूनानी प्रणाली के मुद्रण, इलैक्ट्रॉनिक, इन्टरनेट तथा ऑडियो-विजुअल मीडिया में विज्ञापन का अनुवीक्षण कार्य करने हेतु आयुर्वेद, सिद्ध अथवा यूनानी प्रणाली के अधिकारियों को राजपत्र में अधिसूचित करे और विज्ञापनों का मुद्रित रजिस्टर तथा ऑनलाइन रजिस्टर भी बनाए जिसमें अनुपयुक्त या अविधिमान्य पाई गई प्रविष्टियों सहित सभी प्रविष्टियां करे तथा इस प्रकार के दोषी विज्ञापनों के खिलाफ की गई कार्रवाई का उल्लेख करे। राज्य सरकार विज्ञापनों की सूचना केंद्रीय सरकार को तिमाही आधार पर तथा केंद्रीय सरकार द्वारा यथाबांछित प्रदान करेगी।

(15) यदि उक्त प्राधिकारी द्वारा दिए गए निर्देशों का अनुपालन न किया गया हो तो राज्य अनुज्ञापन प्राधिकारी आयुर्वेद, सिद्ध अथवा यूनानी औषधियों के विनिर्माताओं के अनुज्ञप्ति को नियम 159 के उपबंधों के अनुसार निलंबित अथवा रद्द करें।

(16) केंद्रीय सरकार राजपत्र में अधिसूचित करते हुए लोकहित में किसी भी आयुर्वेद, सिद्ध अथवा यूनानी औषधि के विज्ञापन का निषेध करे।

(ii) अनुसूची क में प्ररूप 26ङ3 के पश्चात निम्नलिखित प्ररूपों को अंत:स्थापित किया जाएगा अर्थात्:-

"प्ररूप 26 ङ4

[नियम 170 देखें]

आयुर्वेद, सिद्ध और यूनानी औषध के विज्ञापन हेतु आवेदन प्ररूप

(टिप्पण: आवेदन केवल एक विज्ञापन के लिए किया जाए)

1. मैं ..... (पदनाम सहित आवेदक का नाम) ....., ... तक विधिमान्य अनुज्ञप्ति सं ..... धारी ..... (निर्माता कंपनी का नाम व पूरा पता) ..... का प्राधिकृत हस्ताक्षरकर्ता हूं और एतद्द्वारा आशयित विज्ञापन की निम्नलिखित विषय-वस्तु के विचारार्थ आवेदन करता हूं:

आयुर्वेद/सिद्ध/यूनानी औषधि का नाम	चित्र/ऑडियो/विडियो सहित विज्ञापन की विषयवस्तु (प्रति संलग्न करें)	प्रयोग संकेत के संदर्भ	विज्ञापन की भाषा	विज्ञापन का माध्यम (प्रिंट/इलैक्ट्रॉनिक/इंटरनेट/दृश्य श्रव्य)

2. एक हजार रुपए की विहित फीस सरकारी खाते के शीर्ष..... में जमा करा दी गई है और संगत राजकोष चालान संलग्न है।

3. निम्नलिखित दस्तावेजों की प्रतियां संलग्न हैं:

i) विधिमान्य अनुज्ञप्ति

ii) लक्षणों/दावों के संदर्भ

iii) सुरक्षा का सबूत

iv) प्रभावकारिता का सबूत

v) गुणवत्ता के मानक

vi) अन्य कोई (कृपया विनिर्दिष्ट करें)

क. .....
ख. .....
ग. .....

तारीख..... *हस्ताक्षर*.....

(आवेदक)

पता और संपर्क विवरण

प्ररूप 26 ड5

[नियम 170 देखें]

आयुर्वेद, सिद्ध अथवा यूनानी औषध के लिए राज्य अनुज्ञापन प्राधिकारी

राज्य अथवा संघ राज्य क्षेत्र का नाम.....

[टिप्पण: (क), (ख) और (ग) पैराग्राफों में से केवल एक पर टिक किया जाए और भरा जाए]

अभिलेखित किया जाता है कि .....(पता)....., स्थित मैसर्स.....(विनिर्माता/कंपनी का नाम) के पास आयुर्वेद/सिद्ध/यूनानी औषध विनिर्माण का अनुज्ञापन सं....., ...तक विधिमान्य है और यह संप्रेषित किया जाता है कि-

(क) .....(औषधि का नाम) के लिए आशयित विज्ञापन की निम्नलिखित विषय-वस्तु विशिष्ट पहचान सं.....(राज्य/संख्या/वर्ष का नाम)..... के अंतर्गत रजिस्टर में नोट की गई है:-

"..... ....."

विज्ञापन की उपर्युक्त विषयवस्तु चालू अनुज्ञापन की विधिमान्य तक वैध है। अविधिमान्य विज्ञापन अथवा विज्ञापन की विषय-वस्तु में कोई भी तोड़-मरोड़ करने पर नियमानुसार विधिक कार्रवाई की जा सकती है।

(ख) इस पत्र के जारी होने के तीस दिन के भीतर सुगत सहायक सूचना सहित निम्नलिखित स्पष्टीकरण देना आवश्यक है जिसके ना हो सकने पर आवेदन पर विचार नहीं किया जाएगा और आवेदन फीस जब्त कर ली जाएगी:-

.....

(ग) आवेदन तारीख.....पर निम्नलिखित कारणों से विचार नहीं किया गया है-

.....
.....

टिप्पण: *विज्ञापन में अनुमति किसी भी रूप में प्रतिबिंबित या प्रदर्शित नही की जाएगी।*

तारीख: जारीकर्ता अधिकारी की मुहरबंद (हस्ताक्षर और नाम)

राज्य अनुज्ञापन प्राधिकारी/औषधि नियंत्रक

राज्य या संघ राज्य क्षेत्र का नाम"

[फा.सं. के.11024/03/2013-डीसीसी (आयुष)]

पी.एन. रणजीत कुमार, संयुक्त सचिव

पाद टिप्पण:- मूल नियम भारत के राजपत्र में अधिसूचना संख्यांक एफ. 28-10/45-एच(आई) तारीख 21 दिसम्बर, 1945 को प्रकाशित किए गए थे और अंतिम संशोधन सा.क.नि.सं. 1193 (E) तारीख 12 दिसम्बर, 2018 द्वारा किया गया था।

MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY

NOTIFICATION

New Delhi, the 21st December, 2018

G.S.R 1230(E).—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by sub-section (1) of section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940) in Part II, Section 3, Sub-section (i) of the Gazette of India, Extraordinary, *vide* number G.S.R 396 (E), dated the 4th April, 2016 inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

and whereas, the said Gazette was made available to the public on the 4th April, 2016;

and whereas, objections or suggestions received from the public on the said draft rules have been considered by the Central Government;

now, therefore, in exercise of the powers conferred by sub-section (1) of section 33-N read with clause (e) of sub-section (2) of the said section of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

RULES

1. (1) These rules may be called the Drugs and Cosmetics (Eleventh Amendment) Rules, 2018.

   (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, -

   (i) after rule 169, following rule shall be inserted, namely:-

"170 Prohibition of advertisements of Ayurvedic, Siddha or Unani drugs-

(1) The manufacturer or his agent, of Ayurvedic, Siddha or Unani drugs, shall not participate in the publication of any advertisement relating to any drug for the use of diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or condition.

(2) The Ayurvedic, Siddha or Unani drug shall be advertised for the purpose other than specified in sub-rule (1) after the allotment of the Unique Identification Number.

(3) The manufacturer of the Ayurvedic, Siddha or Unani drug shall apply for the Unique Identification Number for the advertisement issued or aired before this notification, within the period of three months from the date of the publication of this notification.

(4) The application for advertisement shall be rejected if,

   (i) it is incomplete; or

   (ii) the intended advertisement does not contain the contact details of the manufacturer; or

   (iii) the contents of the advertisement directly or indirectly tantamount to vulgarity or obscenity; or

(iv) it refers to any Ayurvedic, Siddha or Unani drug in terms which suggest or calculated to lead to the use of that drug or medicine for the enhancement of height and dimensions or capacity of performance of male or female sexual organs; or

(v) it depicts photographs or testimonials of celebrities or government officials; or

(vi) it refers to any Government or Autonomous organization of the Government; or

(vii) it gives a false impression about the true character of Ayurvedic, Siddha or Unani drug; or

(viii) it makes a misleading or exaggerated claim about the effectiveness of the said drug.

(5) The application for allotment of the Unique Identification Number for an advertisement shall be submitted in Form 26 E-4 to the State Licensing Authority or Drug Controller specifying therein the claims such as textual references, rationale from the authoritative books, indication(s) or use(s), evidence regarding safety, effectiveness and quality of the drug.

(6) The application fee of rupees one thousand per advertisement shall be deposited along with Form 26E-4 and other supporting documents.

(7) The application for the advertisement shall be submitted to the Licensing Authority of the State where the corporate office of the manufacturer is located, in case the Ayurvedic, Siddha or Unani drug is licensed for manufacturing in more than one State.

(8) The State Licensing Authority shall process the application (if required, in consultation with the concerned technical experts) for disposal within thirty days from the date of receipt of application along with complete information and shall allot Unique Identification Number for the advertisement.

(9) The manufacturer of Ayurvedic, Siddha or Unani drug may appeal to the State AYUSH or Health Secretary for the direction in case the application for allotment of Unique Identification Number under sub-rule (8) is not disposed off within the period of 30 days.

(10) The applicant shall furnish the required information to the Licensing Authority or Drugs Controller as and when called for, failing which the application shall be rejected and the application fee shall stand forfeited.

(11) The State Licensing Authority or Drugs Controller on being satisfied with the application or otherwise, shall record and convey in Form 26 E-5 the recorded contents of advertisement, reasons for rejection of application or any clarification required from the applicant.

(12) The advertisement recorded by the Licensing Authority or Drugs Controller in Form 26 E-5 shall be valid till the date of validity of license to manufacture for sale of that drug and can be renewed thereafter.

(13) An appeal may be filed before the Central Government against the decision of the State Licensing Authority under sub-rule (11) and the order of Central Government shall be final and binding on the appellant and the State Licensing Authority.

(14) The State Government may notify in the Official Gazette the officers of Ayurvedic, Siddha or Unani system to undertake the monitoring of the advertisements of Ayurvedic, Siddha or Unani drugs in the print, electronic, internet and audio-visual media and maintain printed register as well as online register of the advertisements with appropriate entries including those found inappropriate or invalid and action taken against such faulty advertisements and the State Government shall provide information of the advertisements to the Central Government on quarterly basis and also as and when sought by the Central Government.

(15) The State Licensing Authority may suspend or cancel the license of the manufacturer of the Ayurvedic, Siddha or Unani drug as per the provisions of Rule 159, in case the directions given by the said authority is not complied.

(16) The Central Government shall, in the public interest, prohibit any advertisement of the Ayurvedic, Siddha or Unani drugs, by notification in the Official Gazette.

(ii) in Schedule A, after Form 26 E3, the following Forms shall be inserted, namely:-

"FORM 26 E4

[See rule 170]

Application Form for Advertisement of Ayurvedic, Siddha and Unani drugs

(Note: Application may be made only for one advertisement)

1. I .....(name of the applicant with designation)am the authorised signatory of.....(name and full address of the manufacturing company) License number..... valid up-to .....hereby apply for consideration of following contents of the intended advertisement:

Name of the Ayurvedic/Siddha/ Unani drug	Contents of the advertisement including picture/audio/ video (s) (Enclose copy)	Reference of indication(s)	Language of advertisement	Medium of advertisement (print/electronic/ internet/ audio-visual)

2. The prescribed fee of rupees one thousand has been deposited to the Government under the head of account.....and the relevant Treasury Challan is enclosed herewith.

3. Copies of the following documents are attached-

   i) Valid license

   ii) References of indications/claims

   iii) Proof of safety

   iv) Proof of efficacy

   v) Quality standards

   vi) Any other (please specify)

      a. ...

      b. ...

      c. ...

Date.....

Signature.....

(Applicant)

Address and contact details

FORM 26 E5

[See rule 170]

State Licensing Authority for Ayurvedic, Siddha or Unani Drugs

Name of the State or Union territory .....

[Note: Out of (a), (b) and (c) paras, only one shall be ticked and filled]

It is recorded that M/s..... (Name of the manufacturer / company) situated at..... (Address), is holding Ayurvedic / Siddha / Unani drug manufacturing License Number ..... valid upto ..... and it is conveyed that-

(a) Following contents of the intended advertisement for the ..... (name of the drug) are noted in the register vide Unique Identification Number ..... (Name of the State/ number/ year):-

".....
....."

The advertisement contents as above are valid till the validity of the current license. Invalid advertisement or any distortion in the contents of advertisement shall be liable for legal action as per rules.

(b) Following clarification with relevant supporting information is needed within thirty days of issue of this communication, failing which application shall be declined and application fee forfeited.-

---

(c) Application dated ..... is hereby declined due to following reason(s)-

---

Note: *The permission shall not be reflected or shown in the advertisement in any form.*

Date: Seal of issuing Officer (Signature and Name)

State Licensing Authority/Drug Controller

Name of State or Union Territory".

[F.No.K.11024/03/2013-DCC (AYUSH)]

P. N. RANJIT KUMAR, Jt. Secy.

Foot Note.—The Principal Rules were published in Official Gazette of India *vide* Notification No. F.28-10/45-H(I), dated 21st December, 1945 and was last amended *vide* notification G.S.R. No.1193(E) dated 12th December, 2018.

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

(25)

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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ W.P.(C) 321/2019, C.M. Appl. No. 1529-1530/2019

RECKITT BENCKISER INDIA PRIVATE LIMITED AND ORS.
..... Petitioner

Through: Mr. Kapil Sibal, Senior Advocate with Mr. Amar Gupta, Mr. R. Jawahar Lal, Mr. Siddharth Bawa and Mr. Shayamal Anand, Mr. Ashish Joshi, Advocates

versus

UNION OF INDIA AND ANR.
..... Respondent

Through: Mr. Ravi Prakash, Senior Standing Counsel, Ms. Aakanksha Kaul, Ms. Anshula Laroiya, Mr. Farman Ali, Mr. Akash Mohan, Advocate for UOI

CORAM:
HON'BLE MR. JUSTICE S. RAVINDRA BHAT
HON'BLE MR. JUSTICE PRATEEK JALAN

ORDER

% 15.01.2019

Issue notice of the petition as well as of the stay application to the respondents.

Mr. Ravi Prakash, Senior Standing Counsel, accepts notice on behalf of the respondents.

List on 20.02.2019.

(26)

In the meanwhile, respondents are directed not to take any coercive action against the petitioner till the next date of hearing.

S. RAVINDRA BHAT, J

PRATEEK JALAN, J

JANUARY 15, 2019
pkb

27

$~38 & 39

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ **W.P.(C) 502/2019 & CM Nos.2375-76/2019**

MAGNET LABS PVT. LTD. ..... Petitioner

versus

UNION OF INDIA AND ANR. ..... Respondents

\+ **W.P.(C) 505/2019 & CM Nos.2385-86/2019**

MANKIND PHARMA LIMITED & ANR ..... Petitioners

versus

UNION OF INDIA & ANR ..... Respondents

Present : Mr. R. Jawahar Lal, Mr. Siddharth Bawa and Mr. Shyamal Anand, Advs. for petitioner.
Ms. Maninder Acharya, ASG with Mr. Kirtiman Singh, CGSC along with Mr. Waize Ali Noor, Mr. Viplav Acharya, Mr. Parth, Ms. Shruti Dutt, Mr. Prateek Dhanda, Mr. Sahil Sood and Mr. Harshul Choudhary, Advs. for UOI.

CORAM:
HON'BLE MR. JUSTICE S. RAVINDRA BHAT
HON'BLE MR. JUSTICE PRATEEK JALAN

ORDER

% **18.01.2019**

Issue notice to the respondents.

Mr. Kirtiman Singh, Central Government Standing Counsel accepts notice on behalf of the respondents.

(28)

List on 20.02.2019.

In the meanwhile, the respondents are directed not to take any coercive action against the petitioners till the next date of hearing.

It is clarified that the lead proceedings in these cases would be W.P.(C)No.321/2019, Reckitt Benckiser India Private Limited & Ors. v. Union of India & Anr. It is open to the respondents to file counter affidavit in W.P.(C)No.321/2019 and pleadings in W.P.(C)No.321/2019 shall be treated as the lead case for the purposes of hearing.

S. RAVINDRA BHAT, J

PRATEEK JALAN, J

JANUARY 18, 2019
aj

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION

WRIT PETITION NO.289 OF 2019

Ayurvedic Drug Manufacturers Association & Anr. ..Petitioners

V/s.

Union of India & Ors. ..Respondents

Mr.Virag Tulzapurkar, Senior Counsel a/w Mr.Adheesh Nargolkar, Mr.Nishad Nadkani, Mr.Pranav Sampat and Ms.Prajakta Joshi i/b Khaitan and Co. for the Petitioners.

Mr.R.S. Apte, Senior Advocate i/b Mr.Girish J. Paryani for Respondent No.1-Union of India.

Ms.Reeta Shastri, AGP for the Respondent-State.

CORAM : RANJIT MORE &
SMT.BHARATI H. DANGRE, JJ.

DATE : 11th FEBRUARY 2019

P.C.

1. Heard Mr.Tulzapurkar, learned senior counsel for the petitioners for some time. Mr.Apte, learned senior counsel for respondent No.1-Union of India, prays for time to take instructions to file written submission. Time is granted. Stand over to 18th March 2019.

2. Mr.Tulzapurkar, learned senior counsel for the

N.S. Kamble

petitioners pray for ad-interim protection. He submits that Delhi High Court has granted interim protection in similar facts. He has placed on record the interim order passed by the Delhi High Court. This fact is not disputed by the learned senior counsel Mr.Apte, appearing for respondent No.1. In view of the fact of the matter, by way of interim relief we direct that the respondent shall not take coercive action against members of the petitioners association.

3. At this stage Mr.Tulzapurkar, learned senior counsel for the petitioners submits that there are 264 members of the petitioners association and he will place list of the members on record of this petition within a period of one week.

(SMT.BHARATI H. DANGRE, J.) **(RANJIT MORE, J.)**

(31)

IN THE HIGH COURT OF KERALA AT ERNAKULAM
Present:

THE HONOURABLE MR. JUSTICE SHAJI P.CHALY Wednesday, the 10th day of April 2019/20th Chaithra, 1941 WP(C) No.10079/2019(H)

PETITIONER

PANKAJAKASTHURI HERBALS (PVT) LTD.,
POOVACHAL, THIRUVANANTHAURAM-695 575,
REPRESENTED BY ITS MANAGING DIRECTOR,
DR.J.HAREENDRAN NAIR

RESPONDENTS

1. UNION OF INDIA,
REPRESENTED BY THE SECRETARY TO GOVERNMENT,
MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMEOPATHY (AYUSH) AYUSH BHAVAN,
B'BLOCK GPO COMPLEX, INA NEW DELHI-110 023.

2. STATE OF KERALA,
REPRESENTED BY ITS SECRETARY TO GOVERNMENT,
DEPARTMENT OF AYUSH, GOVERNMENT SECRETARIAT,
THIRUVANANTHAPURAM-695 001.

3. THE DEPUTY DRUGS CONTROLLER (AYURVEDA/SIDDHA/UNANI),
AROGYA BHAVAN, THIRUVANANTHAPURAM-695 001.

Writ Petition (civil) praying inter alia that in the circumstances stated in the affidavit filed along with the WP(C) the High Court be pleased to stay all further proceedings pursuant to Exhibit P3, pending disposal of the above Writ Petition.

This petition coming on for orders upon perusing the petition and the affidavit filed in support of WP(C) and upon hearing the arguments of M/S P. NANDAKUMAR, AMRUTHA SANJEEV, S. ANEESH, Advocates for the petitioner, SRI. P. VIJAYAKUMAR, ASSISTANT SOLICITOR GENERAL OF INDIA for respondent 1 and of SENIOR GOVERNMENT PLEADER for respondents 2 & 3, the court passed the following:

(32)

SHAJI P. CHALY, J
W.P. (C) Nos. 10073, 10079 & 10927 of 2019
Dated this the 10th day of April, 2019

ORDER

These writ petitions are basically connected in respect of Ext. P2 Rules brought by the Ministry of Ayurveda, Yoga and Naturopathy introducing prohibition of advertisements of Ayurvedic, Siddha or Unani Drugs by incorporating Rule 170 to the Drugs and Cosmetic Rules, 1945. Therefore, I heard them together for the purpose of considering the interim relief sought for by the petitioners.

2. Various contentions are raised by learned senior counsel as well as counsel for the petitioners and the learned counsel appearing for the respondents. However, I am of the considered view that they are all larger questions to be adjudicated after counter affidavits are received from the respondents. But taking into account the interim orders passed by various High Courts in the subject issue, and other facts and circumstances, I am of the opinion that an interim order can be passed. Therefore, the prohibitions contained under Rule 170 introduced to the Rules will be subject to Rule 170 (2) and there will be a direction to the respondents that, if the petitioners are carrying out the advertisements in accordance with law, and subject to orders passed in the application submitted or hereafter submitted by them before the State Drug Licensing Authority seeking unique identification number as is contemplated under rule 170(2) of rules 1945 no coercive action shall be taken against them, for a period of three months. I also make it clear that, the State authority will be at liberty to consider the applications for unique identification number irrespective of the pendency of the writ petitions.

Respondents to file counter affidavit.

SHAJI P. CHALY, JUDGE

(True Copy)

ASSISTANT REGISTRAR

WP(C) No.10079/2019(H)

EXHIBIT P2: TRUE COPY OF NOTIFICATION DATED 04-04-2016 ISSUED BY IST RESPONDENT.
EXHIBIT P3: TRUE COPY OF NOTIFICATION DATED 21.12.2018 ISSUED BY I[ST] RESPONDENT

This is the true copy of document
Marked as Ext. P in the W.P.

Advocate

True typed copy

Minutes of the Meeting of Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held through Video Conferencing on 15th March, 2021 at 04:00 PM.

A meeting of the ASUDTAB was held through video conferencing on 15.03.2021 at 04:00 PM under the Chairmanship of Dr. Sunil Kumar, Director General Health Services, MoHFW. List of participants is placed at Annexure 1.

Dr. J.L. N. Sastry, CEO(NMPB), I/c Drug Policy Section and Secretary (ASUDTAB) welcomed the Chairman, members of the Board, the co-opted members, Special invitees and the participants and briefed the mandate and background of the Board and its last meeting. The Chairman of the Board expressed his pleasure to chair the meeting online as the agenda items framed for the meeting were quite relevant and very important as per the directions of the Cabinet Secretariat to reduce compliance burden. He then requested Dr. J.L. N. Sastry to start the agenda items one by one and asked the Board members to express their views independently so as to take a considered view and make recommendations to the Government for consideration with the permission of the Chair, Dr. J.L. N. Sastry discussed following agenda items and outcomes of the meeting were as follows;

Agenda Item No.1: Confirmation of the last ASUDTAB meeting held on 21.5.2020.

The minutes of the last ASUDTAB meeting held on 21.05.2020 was circulated on 23.06.2020 to all members of ASUDTAB and co-opted members of ASUDTAB for information and comments within 15 days. Since there were no comments received from the members and hence the minutes were confirmed unanimously.

Agenda Item No.2: Action Taken Report (ATR) on the recommendations of ASUDTAB.

The action taken report was placed before the Board. Dr. Sastry explained all the ATR one by one and following was recommended;

(a) Final Notification for the proposed merger of central appellate laboratories for ASU&H drugs Pharmacopoieal Laboratories of Indian Medicine and Homoeopathy (PLIM and HPL) into Pharmacopoiea Commission of Indian Medicine & Homoeopathy has been vetted from the Department of Legal Affairs and will be notified shortly.

(b) Inclusion and standardization of Ayush Kwath formulation under Ayurvedic, Siddha and Unani Formulary and Pharmacopoiea have been published effective from 1st January, 2021 for regulation as classical/shastriye drug.

(c) Standards of excipients as mentioned in IP, FSSAI, BIS Act are already permitted for ASU drugs as per Rule 169 of the Drugs and Cosmetics Rules, 1945. However it was also discussed that the in-house standards for manufacturing of classical ASU drugs with the use of excipients may be seen in the light of GMP provisions and no separate provision in the rules is required.

(d) On account of divergent views on the exemption/relaxation for the use of permitted sweeteners in place of sugar/jaggery in Avleha and Churna formulations of ASU drugs in the last meeting the matter is put up for further discussion at Agenda item no. 4.

(e) Necessary amendment in the Rule 161B of the Drug and Cosmetics Rules, 1945 will be provided for Admissibility of Real Time Stability Study Data and/or Accelerated Stability Study data for the licensing of ASU drugs.

(f) Regarding harmonization of the mechanism, Forms, labelling template & timelines for disposal of ASU drug manufacturers' applications for license and formulations approval and adoption of online system it was informed to the members that the e-aushadhi portal is functional and processing of application though this portal is being brought under the D&C Rules, 1945. As of now 33 State Licensing Authorities from 29 States have registered on the portal and more are under process.

(g) The matter of inclusion of Sowa Rigpa drugs under Drugs & Cosmetics Rules, 1945 was taken up by the subcommittee constituted for amendment in the Act and review committee for amendment in the Rules and appropriate changes will be made in the Drugs and Cosmetics Rules for inclusion of Sowa-Rigpa drugs. Accordingly Draft amendments is prepared and placed at Annexure 3 to the minutes.

<u>Agenda Item No.3:</u> Regulatory Compliances by ASU drugs Industry under Drugs and Cosmetic Act 1940 & Rules 1945.

Dr. Sastry explained that as per directions of the Cabinet Secretariat the necessity of preparing action plan for reduction of compliance burden on business/citizens was initiated. Ministry of AYUSH after thorough analysis of the Rules, Forms and Schedules under the Drugs and Cosmetics Rules, 1945 have identified 35 compliances which can be reduced and accordingly prepared a draft notification for consideration by the ASUDTAB members, before seeking public comments on the draft notification for implementation. Dr Sastry also highlighted the salient reforms in the proposed action plan.

The members discussed one by one the proposed amendment and unanimously supported the action plan of the Ministry for reduction of compliance burden. The provision of perpetuity of licenses as proposed was welcomed.

Accordingly Draft amendments of Rules as notified on 17.3.2021 is placed as Annexure 2 to minutes.

Chairman of the board raised concern about the mushrooming of innumerable ASU proprietary products in the market and will the token amount of mere Rs. 5000 for licensing of proprietary products will curb such substandard products or not. He also suggested having a strong regulatory mechanism to put a check on unethical practices. The Secretary of the board informed that the hike in the product license fee will be utilised for generating product specific license number and QR code in the State licensing process, which in turn will help in tracing and taking action against the product and manufacturers not maintaining the standards.

Agenda Item No. 4: AYUSH specific suggestions for amendments in D&C Act 1940.

Dr. Sastry mentioned that in the Ministry a committee was constituted to provide suggestions for amendments in D&C Act 1940 for AYUSH drugs. And Secretary of the board requested the members to provide comments on the recommendations of the Committee and accordingly draft amendmaent in the Act will be made.

Dr. C.K. Katiyar and Dr Thirunarayanan commented that the definition of integrated medicine has no legal sanctity. New ASU drug, OTC Drugs definition should be firstly shared for comments. The member did not support the recommendation of common DTAB for all type of drugs.

Dr. Anil Khurana, DG, CCRH also insisted that the definitions/draft amendment under each recommendation should be first proposed then only the members will be able to comment.

It was thus decided that the draft amendment will be circulated and comprehensive comments will be taken. The Secretary of the Board informed the members that the idea of placing it here was to let the members know that the amendment in the Act is also underway as the amendment in the Rules have already been proposed for meeting up the action plan for reducing the compliance burden and other matters.

Agenda Item No.5: Recommendations of Expert Committee and review committee for amendments in the Drugs and Cosmetics Rules, 1945.

The Ministry of AYUSH has constituted an expert committee under the Chairmanship of Prof. S.S. Savirkar, Chairman PCIM&H for considering the amendment to the Drugs and Cosmetic Rule 1945 relating to provisions of Ayurveda, Siddha, Unani (ASU) drugs. The recommendations of the expert committee were further placed before a review committee constituted for preparing the draft amendment to the Drugs and Cosmetic Rule 1945. The members were requested to go through the draft amendment and provide their comments.

Dr C.K. Katiyar enquired the concept of reducing the alcohol content in Asava and Aristas under Rule 161 and Rule 168 from 12% to 11.42% which was explained by the Secretary of the Board and the proposed amendment was agreed as per the logic provided.

It was resolved that to address the issue of artificial sweeteners, new dosage forms, new indications etc, the provisions under Rule 158B needs to be revisited and accordingly the comments of the members which emerged during the meeting will be considered in the draft amendment and will be circulated with the minutes of the meeting.

It was suggested that under Rule 157 for qualification of competent technical staff involved in manufacturing of ASU drugs along with the proposed qualifications MD Bhaishajya Kalpana/ Dravyaguna may also be considered.

The members welcomed the decision of omission of Rule 170. The Secretary of the Board also informed the members that since the amendment in the Drugs and Magic Remedies Act is also been taken up by the MoHFW and Ministry of AYUSH has sent the inputs/comments after considering the representations from AYUSH industry and whatever action is to be taken with respect to misleading advertisements of ASU drugs will be considered under DMR Act.

Some members also requested to include provision of test drug license for the purpose of clinical trials or pre clinical research and third party manufacturing along with loan license. It was also requested by the members that the previous approved minutes of the ASUDTAB should be uploaded on either e-aushadhi portal or ministry's website for public as is done by DTAB also and it was unanimously agreed by the members and secretary of the board.

Accordingly Draft amendments is prepared and placed as Annexure 3 to minutes.

<u>Agenda Item No. 6:</u> Recommendations of Expert Committee of Homoeopathy drugs for amendments in the Drugs and Cosmetics Rules, 1945.

Secretary of the board informed to the Chair and ASUDTAB members that as it was resolved in the last ASUDTAB meeting that the Exert Committee on Homoeopathy will be presenting its report and recommendations about technical matters of Homoeopathy drugs to

ASUDTAB. It was also resolved in the last ASUDTAB meeting that henceforth the notifications pertaining to amendment of the Drugs & Cosmetics Rules for Homoeopathy Drugs can be issued by Ministry of AYUSH being the part of Central Government following the stipulated procedure of interdepartmental consultation. Concurrence on the matter is also sought from Ministry of Health and Family Welfare and in anticipation to it, the agenda of homoeopathy drugs and subsequently draft amendment to homoeopathy rules will be a part of this meeting.

The invited members from Homoeopathy side suggested that the recommendations of the expert committee on homoeopathy has already been provided and it would be better if amendment rules of homoeopathy be prepared and kept in draft form of rule and clause wise for comments. Homoeopathy representatives also unanimously agreed that the Homoeopathy drug matters be considered in ASUDTAB and accordingly ASU&HDTAB be constituted.

Accordingly, Draft amendments for Homoeopathy drugs rules as per the recommendations of expert committee on Homoeopathy is also prepared and placed as Annexure 3 to the minutes.

It was also recommended by Director General CCRH to consider Homoeopathy representation in the Pharmaexcil. It was informed by Secretary of the board that a separate Ayush Export Council is underway and the recommendation will be considered in it.

Agenda Item No. 7: Recommendations of sub-committee for Sowa-Rigpa drugs for amendments in the Drugs and Cosmetics Act, 1940.

The matter of inclusion of Sowa Rigpa drugs under Drugs & Cosmetics Rules, 1945 was taken up by the subcommittee constituted for amendment in the Act and review committee for amendment in the Rules. The members of the board unanimously adopted the proposal of inclusion of Sowa-Rigpa in the Drugs and Cosmetics Rules alongwith the existing ASU rules. Accordingly Draft amendments is prepared and placed at Annexure 3 to the minutes.

Agenda Item No. 8: Recommendations of sub-committee of ASUDCC for regulatory guidelines for sale and sellers of ASU medicines products.

As of now there are no regulatory provisions for sale of ASU drugs in the Drugs & Cosmetics Act, 1940 and Rules thereunder. Recommendations of the subcommittee of ASUDCC for regulatory guidelines for sale and sellers of ASU medicines products were not adopted. The members of the board instead recommended that voluntary online registration of sellers through e-aushadhi portal may be initiated for selling ASU drugs containing Schedule E-1 ingredients only. Such certificate may be issued without any cost with a validity period of one year.

Agenda Item No. 9: Recommendations of ASUDCC for amendments of the existing GMP provisions.

The members of the Board discussed the recommendations of ASUDCC for amendments of the existing GMP provisions and expressed concern on the draft GMP guidelines for ASU drug manufacturing submitted by the subcommittee of ASUDCC as the micro and small entities may not be in a position to comply and then number of them will be more than 7000. Instead, the members suggested that provision of GMP at two levels, Level (a) and Level (b) be prepared. Level (a) the existing GMP provisions for micro and small entities and GMP provision as recommended by the subcommittee of ASUDCC will be adopted as such for Level

(b) GMP for medium and large entities and placed at Annexure 4.

Agenda Item No. 10: Any other agenda with the permission of Chair.

Amendment in rule 158B of the Drugs and Cosmetics Rules, 1945: The members of the board recommended that necessary amendments are required under Rule 158B of the Drugs and Cosmetics Rules for bringing in clarity with respect to requirement of safety and efficacy study of various raw materials, intermediates, extracts, volatile oils, aushadghanas etc prepared both under ASU Classical and Proprietary medicines. It was also suggested that the new dosage forms, new indications, new ingredients of ASU drugs should also be defined for clarity under this rule.

Accordingly, Draft amendments is prepared and placed at Annexure 3 to the minutes.

The meeting ended with vote of thanks to the chair.

****

Annexure 1

ATTENDENCE SHEET FOR THE MEETING OF AYURVEDA, SIDDHA & UNANI DRUGS TECHNICAL ADVISORY BOARD (ASUDTAB) HELD ON 15th MARCH, 2021 AT 4:00PM ONLINE AT MICROSOFT TEAMS APP

S. No.	Name& address of ASUDTAB member	Phone & Email
1.	**Prof. Dr. Sunil Kumar,** The Director General of Health Services (Chairman ASUDTAB) Nirman Bhawan, New Delhi-110011	dghs@nic.in
2.	**Representative of Drugs Controller General of India,** DCG(I) FDA Bhawan, Kotla Road, ITO, Delhi-110002	dci@nic.in
3.	**Dr. J. L.N. Sastry,** CEO NMPB and I/c Head Drug Policy Section, Ministry of AYUSH (Secretary ASUDTAB)	dpsjln.65@gov.in
4.	**The Director,** Central Drugs Laboratory. 3. Kyd Street Kolkatta-700016	Tel: 033-22299541, Fax:033-22299380 Email: cdikol@gmail.com
5.	**Dr C K Katiyar,** CEO Health Care (Technical) Emami Ltd, 687, Anandpur EM Bypass, Kolkata-700 007	ck.katiyar@emamigroup.com +91 33 66136509
6.	**Dr. Rabinarayan Acharya,** Professor and Head, Dept. of Dravyaguna, IPGT&RA Director Pharmacy, Gujarat Ayurved University, Jamnagar, Gujarat, 361008	drrnacharya@gmail.com Phone/Fax: 0288 2553936 Cell: 0.9924585855
7.	**Dr. N. Kabilan,** MD(S), Ph.D., Professor & Head, Department of Siddha, The Tamil Nadu Dr.MGR. Medical University, 69, Anna Salai, Guindy, Chennai-600032	kabilan.n@tnmgrmu.ac.in
8.	**Shri. Sanjay Srivastav,** Maharishi Ayurveda Private Limited, Road No. 17-18 NEPZ, Noida(U.P.)	mapplnoida@maharishiavurvedaindia.com
9.	**Dr. L. Sivakumar,** SKM Siddha and Ayurveda Company Ltd., Saminathapuram, Erode, Tamilnadu	skmgmo@gmail.com 6380937172
10.	**Shri Mohsin Dehlvi,** Dehlvi Naturals, 125, F.I.E, Patpargarj Industrial Area, Delhi-110092	dehlvim@gmail.com
11.	**Dr. T. Thirunarayanan,** Centre for Traditional Medicine & Research 4A, 4th Cross Street, Mahalakshmi Nagar Adambakkam, Chennai-600088	thiru64@gmail.com 9444018158 91-44-22533399

(40)

12.	**Dr Anil Khurana,** Director General, CCRH, 61-65, Institutional Area, Opp. D-Block, Janakpuri, New Delhi	anil23101961@gmail.com ccrhindia@gmail.com
13.	**Dr. GVR Joseph** Joint Director, HPL	gvrjoseph@gmail.com
14.	**Dr. S.R. Chinta** Deputy Advisor(H) Ministry of AYUSH	sr.chinta@nic.in
15.	**Sh. S.C. Gupta,** Secretary, Homoeopathic Pharmaceutical Association of India And Dr. Mudita Arora, representing Homoeopathy Industry	hpaofindia@gmail.com
16.	**Dr. Rachna Paliwal,** Assistant Advisor(H.) Drug Policy Section	rachna.paliwal@nic.in
17.	**Dr. G.C. Gaur,** Consultant Drug Policy Section	drgg1955@gmail.com

(41)

Annexure – 2

To be published in the Gazette of India,
Extraordinary, Part II, Section 3, Sub-section (i)
Government of India
Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy

NOTIFICATION

New Delhi, dated the March , 2021

G.S.R.—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said section, for the information of all persons likely to be affected thereby; and notice is hereby given that the objections or suggestions of the stakeholders on the said draft rules will be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Any objection or suggestion, which may be received from any person with respect to the said draft rules within the period specified above, will be taken into consideration by the Central Government;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi – 110023 or emailed at dec-ayush@nic.in.

DRAFT RULES

1. Short title, extent and commencement.

(1) These Rules may be called the draft Drugs and Cosmetics (Amendment) Rules, 2021.
(2) They shall come into force from the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to be as the principal Rules) the title under "**PART XVI MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS**" shall be substituted, namely:-" PART XVI MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS".

3. In rule 151, for the words" Ayurvedic (including Siddha)", the following words shall be substituted, namely- "Ayurvedic, Siddha".

4. The rule 153, shall be substituted with the following rule, namely,-
"153. Application for license to manufacture Ayurvedic, Siddha or Unani drugs.-(1) An application for the grant of a licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs falling under clause (a) of section 3 of the Act shall be made in Form 24D to the licensing authority along with a fee of rupees five thousand.

(2) An application for the grant of a licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs falling under clause (h) of section 3 of the Act shall be made in Form 24D to the licensing authority along with a fee of rupees five thousand per product.

(3) The application shall be made through portal e-AUSHADHI (www.eaushadhi.gov.in) as per the format provided in the said portal, pertaining to the license for manufacture for sale of Ayurvedic, Siddha or Unani drugs.

Provided that this rule shall not be applicable to licence obtained under Form 25D prior to the date of commencement of this Amendment Rules, 2021. Such licence holders having a valid Good Manufacturing Practices Certificate have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence."

5. The rule 153A, shall be substituted by the following rule, namely,—
" **153A. Application for loan licence to manufacture Ayurvedic, Siddha or Unani drugs.**- 1) An application for the grant of a loan licence to manufacture for saleAyurvedic, Siddha or Unani drugs falling under clause (a) of section 3 of the Act shall be made in Form 24E to the licensing authority along with a fee of rupees five thousand.

(2) An application for the grant of a loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs falling under clause (h) of section 3 of the Act shall be made in Form 24E to the licensing authority along with a fee of rupees five thousand per product.

(3) The application shall be made through portal e-AUSHADHI (www.eaushadhi.gov.in) as per the format provided in the said portal, pertaining to the loan license for manufacture for sale of Ayurvedic, Siddha or Unani drugs.

Provided that this rule shall not be applicable to licence obtained under Form 25E prior to the date of commencement of this Amendment Rules, 2021. Such licence holders having a valid Good Manufacturing Practices Certificate of the manufacturing facilities he intends to avail have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence.

Explanation—For the purpose of this rule, a loan licence means a licence which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licensee in **Form 25-D**.".

6. After rule 153A, the following rule shall be inserted, namely,—

"153B. Application for Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing unit-(1) An application for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing unit shall be made in Form 24E-1 to the licensing authority along with a fee of rupees five thousand and inspection fee of rupees one thousand.

(2) Every application in Form 24E-1 shall be made for a unit having premises and other requirements as prescribed under Schedule T.

(3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units.".

7. The rule 154, shall be substituted with the following rule, namely. —

"154. Form of licence to manufacture Ayurvedic, Siddha or Unani drugs. — (1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale of any Ayurvedic, Siddha or Unani drugs shall be issued in Form 25-D. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfilmentby the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic, Siddha or Unani Systems of medicine as the case may be, which the State Government may approve in this behalf.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 25D issued online as per the format provided in the said portal.".

8. The rule 154A, shall be substituted with the following rule, namely,- -

"154A. Form of loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs.—

(1) A loan licence to manufacture for sale of any Ayurvedic, Siddha or Unani drugs shall be issued in **Form 25E**. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfilment of shortcomings if any highlighted by the licensing authority as the case maybe.

(2) A licence under this rule shall be granted by the Licensing Authority after consulting such expert in Ayurvedic, Siddha or Unani systems of medicine, as the case may be, which the State Government may approve in this behalf.

(3) The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit licensed under Form 25 D has adequate equipment, staff, and capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.

(4) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 25E issued online as per the format provided in the said portal.".

9. The rule 155, shall be omitted.

10.The rule 155A, shall be omitted.

11.(i). In sub clause (1) of rule 155B for the words "for a period of five years" the words "in form 26 E-1" shall be substituted.
(ii). The sub clause (2) shall be omitted.

12. The rule 156, shall be substituted with the following rule, namely, —
"156. Duration of licence—(1) A licence issued in Form 25D shall remain valid perpetually.

Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every three years from the date of issue of license in form 25 D or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within one month of completion of three years from the date of issue of license in form 25 D or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled.".

13. The rule 156A, shall be substituted with the following rule, namely, —
"156A. Duration of loan licence—(1) A loan licence issued in Form 25E shall remain valid perpetually.

Provided that the licencee, submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every three years from the date of issue of license in form 25 E or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within one month of completion of three years from the date of issue of license in form 25 E or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration license shall be deemed to have been cancelled.".

14. After rule 156A, the following rules shall be inserted, namely, —
"156AA. Duration of Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units -(1) A certificate issued in form 26E-1 shall remain valid if the licencee deposits a certificate retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is cancelled by the licensing authority.

(2) The certificate retention fee referred to in sub-rule(1) shall be rupees two thousand.

(3) If the licensee fail to pay certificate retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay certificate retention fee alongwith a late fee calculated at the rate of two per cent of the certificate retention fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the certificate shall be deemed to have been cancelled.

156AB. Inspection for grant of license and verification of compliance.-(1) Before a certificate in Form 26E-1 is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more inspectors appointed by the State Government under this Act, with or without an expert in the field concerned. The inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The establishment licensed under sub-rule (1) shall be inspected by the drug inspectors appointed by the State Government under this Act to verify the self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules not less than once in three years or as needed as per risk based approach.

(3) Provided the drug inspectors are allotted the inspection duty in a randomized manner ensuring same drug inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than three years duration.

156AC. Report by Inspector.– (1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and the Requirements of Plant and Equipments as laid down in Schedule T.

(2) The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the sub- rule (1), to the Licensing Authority.

156AD.-Procedure of Licensing Authority.-(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the licence and the Rules under the Act shall be observed, he shall issue a licence under this Part.
(2) If the Licensing Authority is not satisfied, he shall issue a memorandum of shortcoming, and the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.
(3) Such memorandum of shortcomings as under sub-rule (2) is to be replied back by the applicant within two months of issue of such memorandum.
(4) On non submission of requirements in sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.
(5) For this purpose, the licensing authority shall intimate the applicant and process the application through portal e-AUSHADHI (www.e-aushadhi.gov.in).

156AE.- Further application after rejection. - If within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices as the case may be, the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees one thousand the Licensing Authority may after causing a further inspection to be made, he is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part.".

15. In rule 157, (i) the words "or renewed in Form 26-D" shall be omitted.

(ii) In sub clause (1) for the words "Ayurvedic (including Siddha)" the words "Ayurvedic, Siddha" shall be substituted.

(iii) In sub clause (1A), the words "or renewal" shall be omitted.

(iv) In sub clause (1D) for the words "period for renewal" the words "perpetuity"; for the words "renewal" the words "perpetuity"; and for the words "Drugs and Cosmetics (4th Amendment) Rules, 2015" the words "Drugs and Cosmetics Rules, 2021" shall be substituted.
(v) The proviso under sub clause (1D) shall be omitted.

16. In rule 157A, the following proviso "For this purpose the applicant shall submit the record online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal." shall be inserted.

17. In rule 158, the sub-clause (c) shall be substituted, namely, "(c) For this purpose the applicant and inspector shall submit the record online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal."

18. In rule 158A, the sub-clause (e) shall be substituted, namely, "(e) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed." The following sub-clause "For this purpose the applicant and inspector shall submit the record online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal.".

19.In rule 158C, the following proviso shall be inserted, namely,- "For this purpose the applicant or licensing authority shall apply or issue certificate online respectively through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal.".

20. In sub-rule (1) of rule 160B after the words "shall be granted in Form 48" the following words shall be inserted, namely,- "The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment of shortcomings if any highlighted by the licensing authority as the case maybe.".

21. After rule 160J the following rule shall be inserted, namely,—

"160K.-Information to be uploaded by the licensee on online portal.- (1) The applicant or licensee under this part shall register with portal, e-AUSHADHI (www.e-aushadhi.gov.in) and upload information, as per the format provided in the said portal, pertaining to license application, renewal, tests carried out and other such information as required and shall be updated from time to time.

(2) The information uploaded by the licensee in the portal under sub-rule (1) shall be verified by the concerned licensing authority.".

22. The Form 24 D, shall be substituted, namely,—

"FORM 24D

(See rule 153)

Application for the grant of a licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

I / We ..... of.....hereby apply for the grant of a licence to manufacture Ayurvedic, Siddha or Unani drugs onthe premises situated at.....
.....

2. Names of drugs categorized according to Schedule T to be manufactured (with details)

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic, Siddha or Unanidrugs .....

4. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date..... Signature .....

(applicant)

Note—The application should be accompanied by a Plan of the premises"

23. The Form 24 E, shall be substituted, namely,-

"FORM 24E

(See rule 153A)

Application for the grant of a loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

(46)

1. I / We* ..... of**.....hereby apply for the grant of a loan licence to manufacture Ayurvedic, Siddha or Unani drugs on the premises situated at.....C/o***.....

2. Names of drugs categorized according to Schedule T to be manufactured (with details).

3. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic, Siddha or Unani drugs in the manufacturing premises.

4. I / We* enclose.

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me / us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.

(c) Specimen of labels, cartons of the drugs proposed to be manufactured.

5. A fee of Rs ..... has been credited to Government under the head of account .... and the relevant Treasury Challan/online transaction slip is enclosed herewith.

Date .... *Signature* .....

(applicant) "

24. After Form 24 E the following Form, shall be inserted, namely,-

"FORM 24E-1

(See rule 153B)

Application for the Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units.

1. I / We ..... of.....hereby apply for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing on the premises situated at..... .....

2. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date.....

Signature .....

(applicant)

Note—The application should be accompanied by a Plan of the premises"

25. The Form 25D, shall be substituted, namely.-

"FORM 25D

(See rule 154)

Licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

No. of Licence and date of issue.....

1. .... is / are hereby licensed to manufacture the following Ayurvedic, Siddha or Unani drugs on the premises situated at..... ..... under the direction and supervision of the following competent technical staff: —

(a) Competent Technical staff (Names).

(b) Names of drugs categorized as per Schedule T (each item to be separately specified).with Product Code/QR Code for each approved drug.

2. The licence shall be in force from .....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ..... Signature .....

Designation .....

***Conditions of Licence*

1. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

5. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

6. The license is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha or Unani drugs as laid down in Schedule T of the Drugs and Cosmetics Rules, 1945. "

26. The Form 25E, shall be substituted, namely,-

"FORM 25E

(See rule 154A)

Loan Licence to manufacture for sale Ayurvedic, Siddha or Unani Drugs

1. Number of Licence.....date of issue.....

2 ..... of. ..... is hereby granted a loan licence to manufacture for sale Ayurvedic, Siddha, or Unani drugs, on the premises situated at ..... C/o.....under the direction and supervision of the following expert technical staff:

(a) Expert Technical staff (Names).....
(b) Names of drugs categorized as per Schedule T (each item to be separately specified)

3. The licence shall be in force from .....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ..... Signature .....

Designation .....

****Conditions of Licence**

1. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.".

27. The Form 26 E2-I, shall be substituted, namely,-

"[FORM 26E2-I]

(See rule 158C)

State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines

Name of the State or Union territory.....

Free Sale Certificate

It is certified that M/s. .....(Name of the company).....situated at ..... (Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing License

Number..... and certificate of Good Manufacturing Practices for the

State or Union territory of .....

It is also certified that the manufacturing plant situated at.....(Address).....in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

The firm has been permitted under License Number.....to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosemtics Act, 1940 and the rules thereunder.

(i).....
(ii).....
(iii).....
Date ..... (Seal of issuing Officer) ... ...

(Signature and Name)
State Drug Controller/Licensing Authority
Address.....
Name of State or Union territory.....]".

28. The Form 26E2-II, shall be substituted, namely,-

"[FORM 26E2-II

(See rule 158C)

State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines

Name of the State or Union territory.....

Free Sale Certificate

It is certified that M/s. .....(Name of the company).....situated at ..... (Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Loan License Number..... .....and the valid certificate of Good Manufacturing Practices for the State or Union territory of .....

It is also certified that the manufacturing plant situated at.....(Address).....in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

The firm has been permitted under Loan License Number.....to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder.

(i).....
(ii).....
(iii).....
Date :..... (Seal of issuing Officer) ... ...

(Signature and Name)
State Drug Controller/Licensing Authority
Address.....
Name of State or Union territory..... "

29. The Form 26 E3, shall be substituted, namely,-

"FORM 26 E3
(See rule 158C)
State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines
Name of the State or Union territory.....
Non-Conviction Certificate

It is certified that M/s. .....(Name of the company).....situated at ..... (Registered

Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing License Number..... in Form 25D/25E and certificate of Good Manufacturing Practices/valid Good Manufacturing Practices certificate of principal or original manufacturer for the State or Union territory of .....

As per the records of the State Drug Controller or Licensing Authority, as it may be, and affidavit (Annexure I) given by the company, the firm has not been convicted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder in the State or Union territory of ....., during the last three years of the issuing of this certificate.

This certificate shall be valid only for one year from the date of issue.

Date :..... (Seal of issuing Officer) ... ...

(Signature and Name)
State Drug Controller/Licensing Authority for
Ayurveda, Siddha and Unani Medicines.
Address.....
Name of State or Union territory.....

[ANNEXURE-I]

(Proforma of Affidavit to be executed on appropriate non-judicial stamp paper of minimum value and attested by Notary Public)

I, ...S/O.....age.....working as .....of.....(Name and address of the company).....from .....to.....do hereby solemnly affirm and declare as under:

1. That I, in the capacity of Authorized Signatory of .....(name and address of the company)....,am duly competent to depose and verify the present affidavit.

2. That I apply for Non-conviction Certificate on behalf of M/s. .....

3. That I declare that I am aware of the details of my organization and day to day activities from....to....

4. That I hereby undertake that the Non-Conviction Certificate, if issued, will be utilized for the bona fide purpose only.

5. I declare that the aforesaid firm is not convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the last three years.

6. That it is my true statement.

.....

Signature of Deponent
Verification

Verified at.....(Place and State).....today on this.....day of.....(month)....(Year).....that the contents of the above affidavit are true to my Knowledge and belief and no part of it is false and nothing has been concealedtherefrom.

.....
Signature of Deponent]

Witness with Address
1.
2."

F.No. T-11011/7/2021-DCC(AYUSH)

(Roshan Jaggi)
Joint Secretary to the Government of India

(51)

Annexure – 3

To be published in the Gazette of India,
Extraordinary, Part II, Section 3, Sub-section (i)
Government of India
Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy

NOTIFICATION

New Delhi, dated the April , 2021

G.S.R.—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said section, for the information of all persons likely to be affected thereby; and notice is hereby given that the objections or suggestions of the stakeholders on the said draft rules will be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Any objection or suggestion, which may be received from any person with respect to the said draft rules within the period specified above, will be taken into consideration by the Central Government;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi – 110023 or emailed at dcc-ayush@nic.in.

DRAFT RULES

1. Short title, extent and commencement. ___

(1) These Rules may be called the draft Drugs and Cosmetics (Amendment) Rules, 2021.
(2) They shall come into force from the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to be as the principal Rules) rule 2(dd) shall be substituted namely-
"(dd) Homoeopathic medicines include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative literature of Homoeopathy as mentioned in first and second schedule of the Act and which is prepared according to the techniques of the official Homoeopathic Pharmacopoeia of India and abroad and covers combination of ingredients of such Homocopathic medicines but does not include a medicine which is administered by parenteral route."

3. After rule 2 (ec) the following rule shall be inserted namely-
"(ed) "Registered Ayurvedic or Siddha or Sowa-Rigpa or Unani medical practitioner" means a person -
(i) holding a qualification granted by an authority specified or notified in the Schedules to the Indian Medicine Central Council Act, 1970 (48 of 1970); or
(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practising the Ayurveda or Siddha or Sowa-Rigpa or Unani system of medicine;"

4. After Rule 2 (h) following rules shall be inserted namely-
"(hh) Sowa Rigpa drugs .— Sowa Rigpa drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Sowa Rigpa systems of medicine, specified in the First Schedule of the Drugs and Cosmetic Act, 1940.
(hi) Sowa-Rigpa Proprietary medicine.- In relation to Sowa Rigpa systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Sowa Rigpa systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (hh)."

(52)

5. Under Rule 67A

i. subrule (2) shall be substituted namely.-

" (2) Application for the grant of a licence to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines shall be made in Form19-B to the Licensing Authority and shall be accompanied by a fee of rupees two thousand.

ii. subrule (3) shall be substituted namely.- (3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the sale license of Homoeopathic Medicines.

Provided that this rule shall not be applicable to licence obtained under Form 20C or 20D prior to the date of commencement of this Amendment Rules, 2021. Such licence holders have to deposit a license retention fee of rupees one thousand for perpetuity of existing licence."

6. Rule 67C shall be substituted namely.-

"67C. Forms of licences to sell drugs.-(1) A licence to sell, stock or exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in **Form 20C or 20D** as the case may be.

Form of licence to manufacture Ayurvedic, Siddha or Unani drugs. — (1) Subject to the conditions of rule 67F being fulfilled, a licence to sell, stock or exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in **Form 20C or 20D** as the case may be. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 20C or 20D issued online as per the format provided in the said portal."

7. Rule 67E shall be substituted with the following rule namely.-

"67E **Duration of licences**.(1) A licence issued in Form 20C or 20D shall remain valid perpetually.

Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every five years from the date of issue of license in form 20C or 20D or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within one month of completion of five years from the date of issue of license in Form 20C or 20D or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled."

8. Rule 67EE shall be omitted.

9. Second Proviso under Rule 67F shall be substituted namely.-

"Provided further that registered Homoeopathic medical practitioner who is practising Homoeopathy in the premises licensed under 20C or 20D shall only prescribe medicines to his patients and not take part in the retail sale of Homoeopathic medicines."

10. Subclause 6 of Rule 67G shall be omitted.

Accordingly appropriate changes will be made in the Form 19B, 20C and 20D respectively.

11. Rule 85B shall be substituted with the following rule namely.-

"85B. Application for licence to manufacture Homoeopathic medicines.

(1) An application for the grant of a licence to manufacture for sale of Homoeopathic medicines falling under clause (dd) of Rule 2 shall be made in Form 24C to the licensing authority along with a fee of rupees five thousand.

(3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the license for manufacture for sale of Homoeopathic

medicines.

Provided that this rule shall not be applicable to licence obtained under Form 25C prior to the date of commencement of this Amendment Rules, 2021. Such licence holders having factory premises complying with the requirements and conditions as specified in Schedule M1 have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence."

12. Rule 85D shall be substituted with the following rule namely.-
"**85D. Form of licence to manufacture Homeopathic medicines.** — (1) Subject to the conditions of rule 85E being fulfilled, a licence to manufacture for sale of Homeopathic medicines shall be issued in Form 25-C. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.
(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Homoeopathic Systems of medicine as the case may be, which the State Government may approve in this behalf.
(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 25C issued online as per the format provided in the said portal."

13. In rule 85 E the words "or renewal" and "or renewed" shall be omitted.

14. The proviso to rule 85E namely "Provided that in case potentised preparations are made in a Pharmacy holding licence in Form 20-C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label" shall be omitted.

15. Rule 85EA shall be substituted with following rule namely.-
"**85EA. Inspection for grant of license and verification of compliance.**-(1) Before a GMP certificate for License under Form 25C is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more inspectors appointed by the State Government under this Act, with or without an expert in the field concerned. The inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs.
(2) The establishment licensed under sub-rule (1) shall be inspected by the drug inspectors appointed by the State Government under this Act to verify the self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules not less than once in three years or as needed as per risk based approach.
(3) Provided the drug inspectors are allotted the inspection duty in a randomized manner ensuring same drug inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than three years duration."

16. Rule 85EB shall be substituted with following rule namely.-
"**85EB. Report by Inspector.**– (1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and the Requirements of Plant and Equipments as laid down in Schedule M1.
(2) The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the sub- rule (1), to the Licensing Authority.

17. Rule 85EC shall be substituted with following rule namely.-

"85EC.-Procedure of Licensing Authority.-(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the licence and the Rules under the Act shall be observed, he shall issue a licence under this Part.

(2) If the Licensing Authority is not satisfied, he shall issue a memorandum of shortcoming, and the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.

(3) Such memorandum of shortcomings as under sub-rule (2) is to be replied back by the applicant within two months of issue of such memorandum.

(4) On non submission of requirements in sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.

(5) For this purpose, the licensing authority shall intimate the applicant and process the application through portal e-AUSHADHI (www.e-aushadhi.gov.in).

18. Rule 85ED shall be substituted with following rule namely.-

"85ED.- Further application after rejection. -If within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices as the case may be, the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees one thousand the Licensing Authority may after causing a further inspection to be made, he is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part."

19. Rule 85F shall be substituted with following rule namely.-

"**85F.- 156. Duration of licence**—(1) A licence issued in Form 25C shall remain valid perpetually.

Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every three years from the date of issue of license in form 25 C or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within one month of completion of three years from the date of issue of license in form 25 C or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled."

20. Rule 85G shall be omitted.

Accordingly appropriate changes will be made in the Form 24C and 25C, respectively.

21. In rule 157

(i) In sub clause (1A), for the words "as per Schedule T" the words "as per Schedule T, Level (a) for a micro enterprise, where the investment in Plant and Machinery or Equipment does not exceed one crore rupees and turnover does not exceed five crore rupees and a small enterprise, where the investment in Plant and Machinery or Equipment does not exceed ten crore rupees and turnover does not exceed fifty crore rupees; Level (b) for enterprise, where the investment in Plant and Machinery or Equipment exceeds ten crore rupees and turnover exceeds fifty crore rupees." shall be substituted.

(ii) sub clause (2)(b) shall be omitted.

(iii) sub clause (2)(c) shall be substituted namely-"(b) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government with experience of at least three years in manufacturing of Ayurveda, Sidhha, Unani drugs in a licensed manufacturing unit or MD Ras-shastra/Bhaishajya Kalpana/ Dravyaguna/Saidala/Gunapadam.

(iv) sub clause (2)(d) shall be omitted.

(v) sub clause (2)(e) shall be omitted.

22. Rule 158 (B)

i. in subrule I (A) for the words "Ayurvedic, Siddha and Unani Tibb system of medicine as specified in the First Schedule;" following words "First Schedule either by using the traditional methods of manufacturing or by using the modern equipment / machinery. The methods of technology transfer may be provided as the proof of no deviation from the original texts in the form of a note at the time of new license application or at the time of perpetuity of existing license;

In subrule I(A) following clause may be inserted namely.-

"(ii.) The ingredients of ASU Drugs mentioned in the authoritative books of First Schedule are of two categories viz., crude herbs / raw material; and intermediates / value added product / extracts / volatile oils / fixed oils etc.

a. **Raw Material** - Raw material is the plant, mineral/metal or animal material which is harvested or collected and used in the formulation without subjecting them to processes other than washing, cleaning, powdering etc.

b. **Intermediates / Value Added Products / Extracts / Volatile oils / Fixed oils** – are the semi processed raw material or processed raw material which is physically not identified with the raw material. The following are the examples –

   i.) Amla pishti, kwatha, and prakshepa churna are three different intermediates which will go into Chyawanprash with sugar as the base. Asavarishtas and Ghrita-taila formats also have similar intermediates in 2-3 stages.

   ii.) Camphor, Kattha, Kanyasar, Lavang tel, Chandan tel, Sesame oil, Chaulmoghra oil etc are examples of VAPs, Volatile oils & Fixed oils.

(iii.) Wherever, the Aushadh Ghana / Rasakriya or Kshirapaka or Taila-Ghrita are used in the traditional method, the same may be recognized as traditional water extract or traditional milk extract or traditional emulsion extract respectively. These will be separately considered as intermediates / value added products / semi-processed finished goods."

ii. subrule I (B) shall be substituted namely-

I (B) Patent and Proprietary Ayurvedic, Siddha, Unani medicines as defined under section 3(h)(i) and also of following subtypes-

(i) **Raw Material** – Any plant material which is harvested and used in the formulation without subjecting them to processes other than washing, cleaning, powdering etc.

(ii) **Intermediates/Value Added Products/Extracts / Volatile oils / Fixed oils** – Semi processed raw material or processed raw material which is physically not identified with the raw material. They may be extracts made using solvents or super-critical extraction or any other new method as may be developed through research.

(iii) **Aushadh Ghana (Medicinal plant extracts - dry/wet)** extract obtained either from plant(s) mentioned in books of First Schedule of the Act or from the herb(s) approved by PCIM&H and/or ASUDTAB.

Provided that in case of preparations of Intermediates / Value Added Products / Extracts / Volatile oils / Fixed oils for a Pharmacy holding a valid GMP certificate issued under Form 26 E-1, the license under Form 25D or 25E shall not be required. Such manufacturers shall ensure voluntary registration with the Licensing Authority.

iii. In Table under subrule II.(A) column 2 row 4 after the words "as referred in" the words "Section 3(a)" shall be inserted.

iv. For the table under subrule II (B) the following shall be substituted namely-

"Sl No.	Category	Ingredient (s)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
1	2	3	4	5	6	
					Published Literature	Proof of Effectiveness
1	(A) Patent or Proprietary medicine as mentioned in rule 158 B and in Section 3(h)(i) of the Act	Ingredients from books of First Schedule of D&C Act 1940)	Textual Rationale for one, two or three ingredient mixtures / combinations	Not Required for one, two or three ingredient mixtures / combinations	Of ingredients for one, two or three ingredient mixtures / combinations	Pre-clinical or Clinical Study as per relevant protocol for Ayurveda, Siddha and Unani drugs (Clinical Research Guidelines issued by MoA on 31.03.2013; or Clinical Research Protocols of Central Council for Research in Ayurvedic Sciences; or OECD guidelines; or Indian Council of Medical Research guidelines; or Schedule Y.
2	(B) Patent or Proprietary medicine, with Ayurveda, Siddha and Unani ingredients of Schedule E(1) of the Drugs and Cosmetics Act, 1940	Ingredients of Schedule E(1) of the Drugs and Cosmetics Act, 1940)	Textual Rationale	Required if published literature is not available (90 to 180 toxicity of the E(1) ingredient is minimum. Special toxicity studies may be provided on the basis of the outcome of acute and/or chronic toxicity studies following the OECD guidelines / Schedule Y.	Required if published literature is not available	Required if published literature is not available. (Clinical Research Guidelines issued by MoA on 31.03.2013; or Clinical Research Protocols of or Clinical Research Protocols of Central Council for Research in Ayurvedic Sciences; or OECD guidelines; or Indian Council of Medical Research guidelines; or Schedule Y.
3	(C) Patent or Proprietary medicine, with Ayurveda, siddha and Unani ingredients from books of	Ingredients from books of First Schedule of D&C Act 1940 or any new ingredient	New Indication	Required if published literature is not available (90 to 180 toxicity of the E(1) ingredient is minimum.	Required if published literature is not available	Required if published literature is not available. (Clinical Research Guidelines issued by MoA on 31.03.2013; or Clinical Research

	First Schedule of D&C Act 1940 with new dosage forms or new ingredients or new indications**	which is accepted by PCIM&H and/or ASUDTAB		Special toxicity studies may be provided on the basis of the outcome of acute and/or chronic toxicity studies following the OECD guidelines /Schedule Y.		Protocols of or Clinical Research Protocols of Central Council for Research in Ayurvedic Sciences; or OECD guidelines; or Indian Council of Medical Research guidelines; or Schedule Y.

Explanation.-**For the purpose of this Rule**

1) **'New dosage form'** means any dosage forms covered under the existing formulary or pharmacopoeia (except parenterals)
2) **'New ingredient'** means any ingredient which is not part of books of First Schedule but being practiced / recommended by the registered practitioners of AYUSH systems which is subsequently vetted by the PCIM&H and/or ASUDTAB.
3) **'New indication'** means any indication which is not mentioned in the books of first schedule either for the single ingredient or for a group of ingredients.

V. For registration with respect to Aushadh Ghana/extract of medicinal plant (dry or wet).

Sl. No.	Category	Ingredient (s)	Indication (s)
1	2	3	4
1	(A) Aqueous	As per text	As per text
2	(A-I)	As per text or New	New indication
3	(B) Hydro-alcoholic	As per text or New	As per text
4	(B-I) Hydro-alcoholic	As specified	New indication
5	(C) Other solvent extract	As specified	As per text
6	(C-I) Other solvent extract	As specified	New indication
7	Supercritical extract etc	As specified	As per text
8	Supercritical extract etc	As specified	New indication"

23. Rule 160A shall be substituted with the following rule namely.-

"**160A Institutions for carrying out tests on Ayurvedic, Siddha and Unani Drugs and Raw materials used in their manufacture on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs.** All such institutions which have facilities as required for Quality Control Section as laid down under Schedule T and accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) for the category of chemical and biological testing for identity, purity, quality and strength of Ayurvedic, Siddha and Unani Drugs and raw materials will be notified as approved drug testing laboratories for the purpose of this rule by the central government.

Provided the rule shall be applicable for approved laboratories under Form 48 from the date of notification of the said rules or from the date of next renewal of Form 48 whichever is earlier."

24. Rule 160 B to J shall be omitted.

25. In subrule (2) of Rule 161B the words "Real time" shall be substituted with "Real time and accelerated".

26. After rule 162A following rules shall be inserted namely.-

"162-AA. Controlling Authority. - (1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.

(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.

(3) For the purposes of these rules an officer appointed by the Central Government under sub- rule (1), or as the case may be, an officer appointed by the State Government under sub-rule (2), shall be a controlling authority.

162.AB: Qualification of a Controlling Authority. -(1) No person shall be qualified to be a Controlling Authority under the Act unless: -

(i) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years or

(ii) MD Ras-shastra/Bhaisajya Kalpana/Dravyaguna/Saidala/Gunapadam with a experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of three years."

27. In table under rule 168, for the words "12%" the words "11.42 %" shall be substituted.

28. The Rule 170 shall be omitted.

SCHEDULE T
(See rule 157)

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

The Good Manufacturing Practices (GMP) are prescribed as follows in Part I and Part II to ensure that:

(i) Raw Materials used in the manufacture of drugs are authentic and of prescribed quality as per pharmacopeia standard and are free from contamination.
(ii) The manufacturing process is as has been prescribed to maintain the standards.
(iii) Adequate quality control measures are adopted.
(iv) The manufactured drug which is released for sale is of acceptable quality.
(v) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection.

PART I
PREMISES AND MATERIALS.

1. GENERAL REQUIREMENTS:-

1.1 Location and Surroundings- The factory building shall be so situated and shall have such construction as to avoid risk of contamination from external environment including open sewerage, drain, public lavatory and any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust, smoke, chemical or biological emissions.

1.2 Building & Premises- The buildings used for factory shall be such as to permit manufacturing of drugs under hygienic conditions and should be free from cobwebs and insects/rodents. It should have adequate provision of light and ventilation. The floor and the walls should not be damp or moist.

The premises used for manufacturing, processing, warehousing, packaging, labelling and testing purposes shall be-

(I) Compatible with other manufacturing operations that may be carried out in the same or adjacent premises.
(II) Machineries and equipment shall be at least 1.5 meter apart to allow orderly and logical placement of equipment, materials and movement of personnel so as to:

(a) avoid the risk of mix-up between different category of drugs or with raw materials, intermediates and in-process material;
(b) avoid the possibilities of contamination and cross-contamination by providing suitable arrangements;

(III) Designed/constructed/ maintained to prevent entry of insects, pests, birds, vermins and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning, painting and disinfection.

(IV) Air-conditioned be equipped, where prescribed to control environmental factors, for the operations and dosage forms under production. The production and dispensing area shall be well lighted, effectively ventilated, and air control facilities (wherever applicable) and may have proper Air handling units (wherever applicable) to maintain conditions including temperature and, humidity (wherever necessary), as defined for the relevant product. These conditions shall be appropriate to the category of drugs and nature of operation. These conditions shall also be suitable to the comforts of the personnel working with protective clothing, products handled, and operations undertaken within them in relation to external environment. These areas shall be regularly monitored for compliance with required specifications;

(V) Provided with proper drainage system in the processing area. The sanitary fittings and electrical fixtures in the manufacturing area shall be proper and of adequate size and so designed as to prevent back flow and/or prevent insects and rodents entering the premises.

(VI) Furnace/Bhatti section could be covered with tin roof with proper ventilation, but sufficient care should be taken to prevent flies and dust.

(VII) Fire safety measures and proper exits should be provided.

(VIII) Drying Space: - Separate space is required for drying of raw material, in process medicine or medicines which require drying before packing. This space shall be protected from flies/insects/dust etc., by proper flooring, wire mash window, glass panels or other material and shall permit easy & effective cleaning and dis-infection.

(IX) Same manufacturing Facility/ Store shall not be used for any purpose other than manufacturing of Ayurveda, Siddha and Unani Drugs.

1.3 Water System- There shall be validated system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by the Bureau of Indian Standards or Local Municipality, as the case may be, so as to produce Purified Water conforming to Pharmacopoeial specification. Purified Water so produced shall only be used for all the operations except washing and cleaning operations where potable water may be used. Water shall be stored in tanks, which do not adversely affect quality of water and ensure freedom from microbiological growth. The tank shall be cleaned periodically and records shall be maintained by the licensee in this behalf.

1.4 Disposal of Waste- From the manufacturing section and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off with the requirements of Environment Pollution Control Board.

2. WAREHOUSING AREA:

2.1 Adequate areas shall be designed to allow sufficient and orderly warehousing of various categories of materials and products like raw materials and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned or recalled, machine and equipment spare parts.

2.2 Warehousing areas shall be designed and adapted to ensure good storage conditions. They shall be clean, dry and maintained with acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity), these shall be provided, monitored and recorded. Storage areas shall have appropriate house-keeping and rodent, pests and vermin control procedures and records maintained. Proper racks, bins and platforms shall be provided for the storage of materials.

2.3 Receiving and dispatch bays shall protect materials and products from adverse weather conditions.

2.4 Where quarantine status is ensured by warehousing in separate earmarked areas in the same warehouse or store, these areas shall be clearly demarcated. Any system replacing the physical quarantine, shall give equivalent assurance of segregation. Access to these areas shall be restricted to authorized persons.

2.5 There shall be separate sampling area in the warehousing area for raw materials and excipients. If sampling of active components is performed in any other area, it shall be conducted in such area to prevent contamination, cross- contamination and mix-up.

2.6 Segregation shall be provided for the storage of rejected, recalled or returned materials or products. Such areas, materials or products shall be suitably marked and secured. Access to these areas and materials shall be restricted.

2.7 Highly hazardous, poisonous and explosive materials such as Poisonous drugs and substances presenting potential risks of abuse, fire or explosion shall be stored in safe and secure areas. Adequate fire protection measures shall be provided in conformity with the rules of the concerned civic authority.

2.8 Printed packaging materials shall be stored in safe, separate and secure area.

2.9 Sampling and dispensing of sterile materials shall be conducted under aseptic conditions, which shall also be performed in a dedicated area within the manufacturing facility.

2.10 Regular checks shall be made to ensure adequate steps are taken against spillage, breakage and leakage of containers.

2.11 Rodent treatments (Pest control) should be done regularly and at least once in a year and record maintained.

2.12 Storage containers for raw material, intermediates and finish goods shall be of food grade/non- reacting material.

3. PRODUCTION AREA:-

3.1 The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations.

3.2 Working and in- process space shall be adequate to permit orderly and logical positioning of equipment **(at least 1.5 meter gap in between)** and materials and movement of personnel to avoid cross- contamination and to minimize risk of omission or wrong application of any manufacturing and control measures.

3.3 The Production area shall be washable and with clean airflow to avoid the risk of cross-contamination.

3.4 Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid [accumulation of dust). Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

4. ANCILLARY AREAS: -

4.1 Rest and refreshment rooms shall be separate from stores & production areas. These areas shall not lead directly to the manufacturing and storage areas.

4.2 Facilities for changing, storing clothes and for washing and toilet purposes shall be easily accessible and adequate for the number of users. Toilets, separate for males and females, shall not be directly connected with production or storage areas. There shall be written instructions for routine cleaning and disinfection of such areas and records maintained.

4.3 Maintenance workshops shall be separate and away from production areas. Whenever spares, changed parts and tools are stored in the production area, these shall be kept in dedicated rooms or lockers. Tools and spare parts for use in sterile areas shall be disinfected before these are carried inside the production areas.

5. QUALITY CONTROL AREA: -

5.1 Quality Control. - Every licensee is required to provide facility for quality control section in his own premises. Quality Control Laboratories shall be independent of the production areas. The test shall be as per the Ayurveda, Siddha and Unani Pharmacopoeial standard including Microbiology, Aflatoxins. Heavy Metals as and where applicable. Where the Pharmacopoeial standards are not available, the test should be performed according to the manufacturers' specification or other information available which shall be duly verified by the state licensing authority. The quality control section shall verify all the raw materials (Identification and analysis), monitor in-process quality checks and control the quality of finished prod-

uct being released to finished goods store/warehouse. The quality control section shall have the following facilities: -

(1) There should be at least 100 sq. feet area for quality control section.

(II) There should be at least facility for physico-chemical analysis.

(III) There should be provided facility for microbiology and other parameters through sophisticated instruments analysis etc in own premises or through Government approved public testing laboratory.

(IV) The design of the laboratory shall take into account the suitability of construction materials and ventilation. Separate air handling units and other requirements shall be provided for microbiological and sophisticated instruments testing areas. The laboratory shall be provided with regular supply of water of appropriate quality for cleaning and testing purposes.

(V) Quality control laboratory shall be divided into separate sections i.e. for physico-chemical, microbiology and sophisticated instruments analysis. This shall have adequate area for basic installation and for ancillary purpose. The microbiology section shall have arrangements such as airlock and laminar air flow work station, whenever considered necessary.

(VI) For identification of raw drugs, reference books and reference samples should be maintained.

(VII) To verify the finished products, At least three sample of each pack size as controlled samples of finished products of each batch will be kept till the expiry date of product.

(VIII) To supervise and monitor adequacy of conditions under which raw materials, semi-finished products and finished products are stored.

(IX) Keep record for establishing shelf life and storage requirements of the drugs.

(X) Manufacturers who are manufacturing patent and proprietary Ayurveda, Siddha, and Unani medicines shall provide their own specification and control references in respect of such formulated drugs which shall be duly verified by state licensing authority.

(XI) The standards for identity, purity and strength as given in respective pharmacopoeias of Ayurveda, Siddha and Unani systems of medicines published by Government of India shall be complied with.

(XII) Quality control section will have a minimum whole time employee of: -
(a) Expert in Ayurveda or Siddha or Unani medicine who possesses a degree qualification recognized under Schedule II of Indian Medicine Central Council Act 1970 or Pharmacy (Ayurveda/Unani), awarded by a recognized University,

(b) Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda or Siddha/Unani), awarded by a recognized University; and

(c) Botanist/ Pharmacognosist, who shall possess at least Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) or Diploma in Unani Pharmacy/Diploma in Pharmacy (Ayurveda) (with at least one year experience) awarded by a recognized University.]

(XIII) The manufacturing unit shall have a quality control section. Alternatively, these quality control provisions will be met by getting testing from a recognised laboratory for Ayurveda, Siddha and Unani drugs; under Rule 160-A of the Drugs and Cosmetics Act for certain parameters. The manufacturing company will maintain all the record of various tests got done from outside recognised laboratory. Quality control facility for physicochemical parameters and some basic test is mandatory required.

(XIV) List of equipment recommended for in-house quality control section alternatively, unit can get testing of certain parameters done from the Government approved laboratory).

(A)	CHEMISTRY SECTION	(B)	PHARMACOGNOSY SECTION
1.	Alcohol Determination Apparatus(complete set)	1.	Microscope Binocular.
2.	Volatile Oil Determination Apparatus.	2.	Dissecting Microscope.
3.	Boiling Point Determination Apparatus.	3.	Research Electronic Microscope attached with system
4.	Melting Point Determination Apparatus.	4.	Microtome.
5.	Refractometer.	5.	Stage Micrometer
6.	Polarimeter.	6.	Physical Balance.
7.	Viscometer.	7.	Camera Lucida (Prism and Mirror Type)
8.	Tablet Disintegration Apparatus.	8.	Chemicals, Dies & Reagents etc.
9.	Moisture Meter.	9.	Slides & Glassware
10.	Muffle Fumace.	10.	Tray Dryer
11.	Electronic Balance.	11.	Aluminium Slide Trays.
12.	Magnetic Stirrer.	12.	Grinder Machine
13.	Hot Air Oven.	13.	Jucer Machine
14.	Refrigerator,	14.	Clevenger Apparatus
15.	Glass/Steel Distillation Apparatus,	15.	Soxhlet Apparatus
16.	LPG Gas Cylinders with Burners.	16.	Supercritical Fluid Extraction Unit
17.	Water Bath (Temperature controlled.)	17.	Percolator
18.	Heating Mantles/Hot Plates.	18.	Magnifying Lens Glass 10x

19.	TLC Apparatus with all accessories(Manual)	**19.**	Dissection Box
20.	Paper Chromatography apparatus with accessories.		
21.	Sieve size 10 to 120 with Sieve shaker.		
22.	Centrifuge Machine.		
23.	Dehumidifier.		
24.	pH Meter.(Digital)		
25.	Limit Test Apparatus.(Arsenic)		
26.	Homogenizer		
27.	Dissolution Apparatus		
28.	Thermometer		
29.	Stop watch		
30.	Physical Balance		
31.	Digital Weighing Balance (Weight in mg)		
32.	Micronizer		
33.	Pastel & Mortar		

6. QUALITY CONTROL SYSTEM:- Quality control shall be concerned with sampling, specifications, testing, documentation, release procedures which ensure that the necessary and relevant tests are actually carried and that the materials are not released for use, nor products released for sale or supply until their quality has been judged to be satisfactory. It is not confined to laboratory operations but shall be involved in all decisions concerning the quality of the product. It shall be ensured that all quality control arrangements are effectively and reliably carried out. The department as a whole shall have other duties such as to establish, evaluate, validate and implement all Quality Control Procedures and methods.

6.1 Every manufacturing establishment shall establish its own quality control laboratory (at least for physico-chemical analysis) managed by qualified and experience staff.

6.2 The area of the quality control laboratory may be divided into Physico-Chemical, Instrumentation and Microbiological.

6.3 Adequate area having the required storage conditions shall be provided for keeping reference samples. The quality control department shall evaluate, maintain and store reference samples.

6.4 Standard operating procedures shall be available for sampling, inspecting and testing of raw materials. intermediate bulk finished products and packing materials and, wherever necessary, for monitoring environmental conditions.

6.5 There shall be authorized and dated specifications for all materials, products, reagents and solvents including test of identity, content, purity and quality. These shall include specifications for water, solvents and reagents used in analysis.

6.6 No batch of the product shall be released for sale or supply until it has been certified by the authorized person(s) that it is in accordance with the requirements of the standards laid down.

6.7 Reference/retained samples from each batch of the products manufactured shall be maintained in quantity which is at least twice the quantity of the drug required to conduct all the tests, except sterility and pyrogen/ Bacterial Endotoxin. The retained product shall be kept in its final pack or simulated pack for a period of three months after the date of expiry.

6.8 Assessment of records pertaining to finished products shall include all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack. Assessment records should be signed by the incharge of production and countersigned by the authorised quality control personnel before a product is released for sale or distribution.

6.9 Quality control personnel shall have access to production areas for sampling and investigation, as appropriate.

6.10 The quality control department shall conduct stability studies of the products as per Rule 161-B to ensure and assign their shell life at the prescribed conditions of storage. All records of such studies shall be maintained.

6.11 The in-charge of Quality Assurance shall investigate all product complaints and records thereof shall be maintained.

6.12 Each specification for raw materials, intermediates, final products, and packing materials shall be approved and maintained by the Quality Control Department. Periodic revisions of the specifications shall be carried out wherever changes are necessary.

6.13 Pharmacopoeia, Standard testing procedures (STP), reference standards, reference materials and authoritative & technical books, as required, shall be available in the Quality Control Laboratory of the licensee.

7. PERSONNEL: -

7.1. The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience.

7.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.

7.3. Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.

7.4 Written duties of technical and Quality Control personnel shall be laid and followed strictly.

7.5 Number of personnel employed shall be adequate and in direct proportion to the workload. 7.6 The licensee shall ensure in accordance with a written instruction that all personnel in production area or into Quality Control Laboratories shall receive training appropriate to the duties and responsibility assigned to them. They shall be provided with regular in-service training.

8. HEALTH, CLOTHING AND SANITATION OF WORKERS: -

8.1 Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof. The licensee shall provide the services of a qualified physician for assessing the health status of personnel involved in different activities.

8.2 All persons prior to and during employment shall be trained in practices which ensure personnel hygiene. A high level of personal hygiene shall be observed by all those engaged in the manufacturing processes. Instructions to this effect shall be displayed in change- rooms and other strategic locations.

8.3 No person showing, at any time, apparent illness or open lesions which may adversely affect the quality of products, shall be allowed to handle starting materials, packaging materials, in-process materials, and drug products until his condition is no longer judged to be a risk.

8.4 All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.

8.5 Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.

8.6 All personnel shall wear clean body coverings appropriate to their duties. Before entry into the manufacturing area, there shall be change rooms separate for each sex with adequate facilities for personal cleanliness such as wash basin with running water, clean towels or hand

dryers, soaps, disinfectants, etc. The change rooms shall be provided with cabinets for the storage of personal belongings of the personnel.

8.7 Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicines shall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.

9. MANUFACTURING OPERATIONS AND CONTROLS: -

9.1 All manufacturing operations shall be carried out under the supervision of technical staff approved by the concerned state Licensing Authority. Each critical step in the process relating to the selection, weighing and measuring of raw material addition during various stages shall be performed by trained personnel under the direct personal supervision of approved technical staff.

The contents of all vessels and containers used in manufacture and storage during the various manufacturing stages shall be conspicuously labelled with the name of theproduct, batch number, batch size and stage of manufacture. Each label should beinitialled and dated by the authorised technical staff.

9.2 Precautions against mix-up and cross-contamination:

9.2.1 The licensee shall prevent mix-up and cross-contamination of drug material and drug product (from environmental dust) by proper arrangements, status labelling and cleaning. Proper records and Standard Operating Procedures there of shall be maintained.

9.2.2 To prevent mix-ups during production stages, material under process shall be conspicuously labelled to demonstrate their status. All equipment used for production shall be labelled with their current status.

9.2.3 Packaging lines shall be independent and adequately segregated. It shall be ensured that all left-overs of the previous packaging operations, including labels, cartons and caps are cleared before the closing hour.

9.2.4 Before packaging operations are begun, steps shall be taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials and spillages. The line clearance shall be performed according to an approximate check list and recorded.

9.2.5 The correct details of any printing (for example of batch numbers or expiry dates) done separately or in the course of the packaging shall be rechecked at regular intervals. All printing and overprinting shall be authorized in writing.

9.2.6 The manufacturing environment shall be maintained at the required levels of temperature, humidity and cleanliness.

9.2.7 Authorised persons shall ensure change-over into specific uniforms before undertaking any manufacturing operations including packaging.

9.2.8 There shall be segregated secured areas for recalled or rejected material and for such material which are to be reprocessed or recovered.

10. SANITATION IN THE MANUFACTURING PREMISES: -

10.1 The manufacturing premises shall be cleaned and maintained in an orderly manner, so that it is free from accumulated waste, dust, debris and other similar material. A validated cleaning procedure shall be maintained.

10.2 The manufacturing areas shall not be used for storage of materials, except for the material being processed. It shall not be used as a general thoroughfare.

10.3 A routine sanitation program shall be drawn up and observed, which shall be properly recorded and which shall indicate-

(a) specific areas to be cleaned and cleaning intervals;

(b) cleaning procedure to be followed, including equipment and materials to be used for cleaning; and

(c) personnel assigned to and responsible for the cleaning operation.

10.4 The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of mix-up between different pharmaceutical products or their components to avoid cross contamination, and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.

10.5 Production areas shall be well lit, particularly where visual on-line controls are carried out.

11. RAW MATERIALS:

11.1 The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records.

11.2 All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored under appropriate conditions and in an orderly fashion to permit batch segregation and stock rotation by a 'first in/first-out' principle. All incoming materials shall be checked to ensure that the consignment corresponds to the order placed.

11.3 All incoming materials shall be purchased under valid purchase vouchers. Wherever possible, raw materials should be purchased directly from the producers/farmers.

11.4 Authorized staff appointed by the licensee in this behalf, which may include personnel from the Quality Control Department, shall examine each consignment on receipt and shall check each container for integrity of package and seal. Damaged containers shall be identified, recorded and segregated.

11.5 If a single delivery of material is made up of different batches, each batch shall be considered as a separate batch for sampling, testing and release.

11.6 Raw materials in the storage area shall be appropriately labelled. Labels shall be clearly marked with the following information:

(1) designated name of the product and the internal code reference, (where applicable), and analytical reference number;

(II) manufacturer's / Supplier's name, address and batch number;

(III) the status of the contents (e.g. quarantine, under test, released, approved, rejected); and

(IV) the manufacturing date, expiry date and re-test date.

11.7 There shall be adequate separate areas for materials "under test", "approved" and "rejected" with different standard colour label and arrangements and equipment to allow dry, clean and orderly placement of stored materials and products, wherever necessary, under controlled temperature and humidity.

11.8 Containers from which samples have been drawn shall be identified.

11.9 It shall be ensured that all the containers of raw materials are placed on the raised platforms/racks and not placed directly on the floor, care may be taken to handle the following different categories of raw materials: -

(I). Raw material of metallic origin.

(II). Raw material of mineral origin.

(III). Raw material from animal source.

(IV). Fresh herbs.

(V). Dry herbs or plant parts

(VI). Excipients etc.

(VII). Volatile oils/perfumes and flavours

(VIII). Plant concentrates/extracts and exudates/resins.

12. EQUIPMENT:-

12.1 Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products. Each equipment shall be provided with a logbook, wherever necessary.

12.2 Balances and other measuring equipment of an appropriate range, accuracy and precision shall be available in the raw material stores, production and in-process control operations and these shall be calibrated and checked on a scheduled basis in accordance with Standard Operating Procedures and records maintained.

12.3 The parts of the production equipment that come into contact with the product shall not be reactive, additive or adsorptive to an extent that would affect the quality of the product.

12.4 To avoid accidental contamination, wherever possible, non-toxic/edible grade lubricants shall be used and the equipment shall be maintained in a way that lubricants do not contaminate the products being manufactured.

12.5 Defective equipment shall be removed from production and Quality Control areas and appropriately labelled.

13. DOCUMENTATION AND RECORDS: -

13.1 Documents designed, prepared, reviewed and controlled, wherever applicable, shall comply with these rules.

13.2 Documents shall be approved, signed and dated by appropriate and authorized persons.

13.3 Documents shall specify the title, nature and purpose. They shall be laid out in an orderly fashion and be easy to check. Reproduced documents shall be clear and legible. Docu-

ments shall be regularly reviewed and kept up to date. Any alteration made in the entry of a document shall be signed and dated.

13.4 The records shall be made or completed at the time of each operation in such a way that all significant activities concerning the manufacture of pharmaceutical products are traceable. Records and associated Standard Operating Procedures (SOP) shall be retained for at least one year after the expiry date of the finished product.

13.5 Data may be recorded by electronic data processing systems or other reliable means, but Master Formulae and detailed operating procedures relating to the system in use shall also be available in a hard copy to facilitate checking of the accuracy of the records. Wherever documentation is handled by electronic data processing methods, authorized persons shall enter modify data in the computer. There shall be record of changed and deletions. Access shall be restricted by passwords or other means and the result of entry of critical data shall be independently checked. Batch records electronically stored shall be protected by a suitable back-up. During the period of retention, all relevant data shall be readily available.

14. LABELS AND OTHER PRINTED MATERIALS: -

The Printing shall be done in bright colours and in a legible manner. The label shall carry all the prescribed details about the product.

14.1 All containers and equipment shall bear appropriate labels. Different colour coded labels shall be used to indicate the status of a product (for example under test, approved, rejected).

14.2 To avoid chance mix-up of printed packaging materials, product leaflets, relating to different products, shall be stored separately.

13.3 Prior to release, all labels for containers, cartons and boxes and all circulars, inserts and leaflets shall be examined by the Quality Control Department of the licensee.

13.4 Prior to packaging and labelling of a given batch of a drug, it shall be ensured by the licensee that samples are drawn from the batch and duly tested, and approved by the quality control personnel. The contents on label shall conform to Rule 161 and Rule 161-B and Rule 170 of the Drugs & Cosmetics 1945, The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 & Rule, 1955 and other legal requirements.

14.5 Records of receipt of all labelling and packaging materials shall be maintained for each shipment received indicating receipt, control reference numbers and whether accepted or rejected. Unused coded and damaged labels and packaging materials shall be destroyed and recorded.

14.6 All labels on finished Goods must mention customer help line number/contact to brief complaint or adverse reaction from the product.

15. QUALITY ASSURANCE: -

15.1 The system of quality assurance appropriate to the manufacture of ASU products shall ensure that: -

(I) the products are designed, developed and manufactured in a way that takes account of the requirements of Good Manufacturing Practices (hereinafter referred as GMP).

(II) adequate controls on raw materials, intermediate products and bulk products and other in-process controls, calibrations, and validations are carried out.

(III) the finished product is correctly processed and checked in accordance with established procedures;

(IV) the pharmaceutical products are not released for sale or supplied before authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the label claim and any other provisions relevant to production, control and release of pharmaceutical products.

16. SELF INSPECTION AND QUALITY AUDIT: - Firm shall constitute a self-inspection team supplemented with a quality audit procedure for assessment of all or part of a system with the specific purpose of improving it.

16.1 To evaluate the manufacturer's compliance with GMP in all aspects of production and quality control, concept of self-inspection shall be followed. The manufacturer shall constitute a team of independent, experienced, qualified persons from within or outside the company, who can audit objectively the implementation of methodology and procedures evolved. The procedure for self-inspection shall be documented indicating self-inspection results, evaluation, conclusions and recommended corrective actions with effective follow up program. The recommendations for corrective action shall be adopted.

16.2 The program shall be designed to detect shortcomings in the implementation of Good Manufacturing Practice and to recommend the necessary corrective actions. Self- inspections shall be performed routinely and on specific occasions, like when product recalls or repeated rejections occur or when an inspection by the licensing authorities is announced. The team responsible for self-inspection shall consist of personnel who can evaluate the implementation of Good Manufacturing Practice objectively; all recommendations for corrective action shall be implemented.

16.3 Written instructions for self-inspection shall be drawn up which shall include the following: -

(a) Personnel.

(b) Premises including personnel facilities.

(c) Maintenance of buildings and equipment

(d) Storage of starting materials and finished products.

(e) Equipment.

(f) Production and in-process controls.

(g) Quality control.

(h) Documentation.

(i) Sanitation and hygiene.

(j) Validation and revalidation programmes.

(k) Calibration of instruments or measurement systems.

(1) Recall procedures.

(m) Complaints management.

(n) Labels control.

(0) Results of previous self-inspections and any corrective steps taken.

17.SPECIFICATION:

17.1 For raw materials and packaging materials. -

They shall include-

a) the designated name;

b) reference, if any, to a pharmacopoeial monograph;

c) qualitative and quantitative requirements with acceptance limits;

d) name and address of manufacturer or supplier

e) specimen of printed material;

1) directions for sampling and testing or reference to procedures;

g) storage conditions; and

h) maximum period of storage before re-testing.

17.2 For finished products. Appropriate specifications for finished products shall include: -

a) the designated name of the product;

b) the formula or a reference to the formula and the pharmacopoeial reference;

c) directions for sampling and testing or a reference to procedures;

d) a description of the dosage form and package details;

f) the storage conditions and precautions, where applicable, and

g) the shelf-life.

18. MASTER FORMULA RECORDS: -

There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff i.e. head of production and quality control. The master Formula shall include: -

(a) the name of the product relating to its specifications;

(b) the patent or proprietary/ Classical name of the product, a description of the dosage form, composition of the product and batch size;

(c) name, quantity, and reference number of all the raw materials to be used.

(g) detailed stepwise processing instructions and the time taken for each step;

(h) the instructions for in-process control with their limits;

(i) the requirements for storage conditions of the products, including the container, labelling and special storage conditions where applicable;

(g) any special precautions to be observed; and

(h) packing details and specimen labels.

19. PACKAGING RECORDS: -

There shall be authorised packaging instructions for each product, pack size and type. These shall include or have a reference to the following:-

(a) name of the product;

(b) description of the dosage form, strength and composition;

(c) the pack size expressed in terms of the number of doses, weight or volume of the product in the final container;

(d) complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types with the code of reference number relating to the specifications of each packaging material.

(e) reproduction of the relevant printed packaging materials and specimens indicating where batch number and expiry date of the product have been applied;

(g) description of the packaging operation, including any significant subsidiary operations and equipment to be used;

(h) details of in-process controls with instructions for sampling and acceptance; and

(i) upon completion of the packing and labelling operation, a reconciliation shall be made between number of labelling and packaging units issued, number of units labelled, packed and excess returned or destroyed. Any significant or unusual discrepancy in the numbers shall be carefully investigated before releasing the final batch.

20. BATCH PACKAGING RECORDS:-

20.1 A batch packaging record shall be kept for each batch or part batch processed. It shall be based on the relevant parts of the packaging instructions, and the method of preparation of such records shall be designed to avoid transcription errors.

20.2 Before any packaging operation begins, check shall be made and recorded that the equipment and the work stations are clear of the previous products, documents or materials not required for the planned packaging operations, and that the equipment is clean and suitable for use.

21. BATCH PROCESSING RECORDS:-

21.1 There shall be Batch Processing Record for each product. It shall be based on the relevant parts of the currently approved Master Formula.

21.2 Before any processing begins, check shall be performed and recorded to ensure that the equipment and work station are clear of previous products, documents or materials not required for the planned process are removed and the equipment is clean and suitable for use.

21.3 During processing, the following information shall be recorded at the time each action is taken and the record shall be dated and signed by the person responsible for the processing operations: -

(a) the name of the product
(b) the number of the batch being manufactured,
(c) dates and time of commencement, of significant intermediate stages and of completion of production, (d) initials of the operator of different significant steps of production and where appropriate, of the person who checked each of these operations,
(e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed,
(f) any relevant processing operation or event and major equipment used,
(g) a record of the in-process controls and the initials of the person
(s) carrying them out, and the results obtained,
(h) the amount of product obtained after different and critical stages of manufacture (yield),

22. STANDARD OPERATING PROCEDURES (SOPs) AND RECORDS, REGARDING: -

22.1 Receipt of materials:

22.1.1 there shall be written Standard Operating Procedures and records for the receipt of each delivery of all raw materials, primary and printed packaging material.

22.1.2 the records of the receipts shall include;

(a) the name of the material on the delivery note and the number of containers;
(b) the date of receipt;
(c) the manufacturers and/or suppliers name;
(d) the manufacturers batch or reference number;
(e) the total quantity, and number of containers, quantity in each container received;
(f) the control reference number assigned after receipt;
(g) any other relevant comment or information.

22.1.3 There shall be written standard operating procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.

22.1.4 There shall be Standard Operating Procedures available for each instrument and equipment and these shall be placed in close proximity to the related instrument and equipment.

22.2 Sampling: -

22.2.1 There shall be written Standard Operating Procedures for sampling which include the person(s) authorized to take the samples.

22.2.2 The sampling instruction shall include:

(a) The method of sampling and the sampling plan,
(b) any precautions to be observed to avoid contamination of the material or any deterioration in its quality,
(c) The quantity of samples to be taken,
(d) The types of sample containers to be used,
(e) any specific precautions to be observed.

22.3. Batch Numbering. -

22.3.1 There shall be Standard Operating Procedures describing the details of the batch (lot) numbering set up with the objective of ensuring that each batch of intermediate, bulk or finished product is identified with a specific batch number.

22.4. Testing:

22.4.1 There shall be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed shall be recorded.

22.5 Records of Analysis. -

22.5.1 The records shall include the following data:

(a) name of the raw material or product and the dosage form
(b) batch number and, where appropriate the manufacturer and/or supplier,
(c) reference to the relevant specifications and testing procedures,
(d) test results, including observations and calculations, and reference to any specifications (limits).
(e) dates of testing.
(f) initials of the persons who performed the testing,
(g) initials of the persons who verified the testing and the detailed calculations,
(h) A statement of release or rejection, and
(i) signature and date of the designated responsible person.

22.5.2 There shall be written standard operating procedures and the associated records of actions taken for:

(a) equipment assembly and validation
(b) analytical apparatus and calibration,
(c) maintenance, cleaning and sanitation;
(d) personnel matters including qualification, training, clothing, hygiene
(e) environmental monitoring;
(f) pest control;
(g) complaints;
(h) recalls made; and
(i) returns received.

23.REFERENCE SAMPLES:-

23.1 Test Report of every raw material, shall be retained for a period of 3 months after the date of expiry of the last batch produced from that raw material.

23.2. Reference Samples of finished formulations shall be stored in the same or simulated containers in which the drug has been actually marketed, till the end of shelf life

23A Validation and process validation: [NOT FEASIBLE. BEING UNABLE TO ANALYSE QUANTITATIVELY/

1. Validation studies shall be an essential part of Good Manufacturing Practices and shall be conducted as per the pre-defined protocols. These shall include validation of processing, testing and cleaning procedures.
2. A written report summarizing recorded results and conclusions shall be prepared, documented and maintained.
3. Processes and procedures shall be established on the basis of validation study and undergo periodic revalidation to ensure that they remain capable of achieving the intended results. Critical processes shall be validated. prospectively or retrospectively.
4. When any new Master Formula or method of preparation is adopted, steps shall be taken to demonstrate its suitability for routine processing. The defined process, using the materials and equipment specified shall be demonstrated to yield a product consistently of the required quality.
5. Significant changes to the manufacturing process, including any change in equipment or materials that may affect product quality and/or the reproducibility of the process, shall be validated.

24. DISTRIBUTION RECORDS:-

24.1. Prior to distribution or dispatch of given batch of a drug, it shall be ensuring that the batch has duly tested, approved and released by the quality control personnel. Pre-dispatch inspection shall be performed on each consignment on a random basis to ensure that only the correct goods are dispatched. Periodic audits of warehousing practices followed at distribution centres shall be carried out and records thereof shall be maintained. Standard Operating Procedures shall be developed for warehousing of products.

24.2. Records for distribution shall be maintained in a manner such that finished batch of a drug can be traced to the retail level to facilitate prompt and complete recall of the batch, if and when necessary.

25.PRODUCT RECALLS: -

25.1 A prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockists, wholesalers, suppliers, upto the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard.

25.2. There shall be an established written procedure in the form of Standard Operating Procedure for effective recall of products distributed by the licensee. Recall operations shall be capable of being initiated promptly so as to effectively reach at the level of each distribution channel.

25.3 The distribution records shall be readily made available to the persons designated for recalls.

25.4 The designated person shall record a final report issued, including reconciliation between the delivered and the recovered quantities of the products.

25.5 The effectiveness of the arrangements for recalls shall be evaluated from time to time.

25.6 The recalled products shall be stored separately in a secured segregated area pending final decision on them.

26. COMPLAINTS AND ADVERSE REACTIONS: -

26.1. Record of Market Complaints - Manufacturers shall maintain a register to record all reports of market complaints received regarding the products sold in the market.

26.2. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the li-

censing authority. The Register shall also be available for inspection during any inspection of the premises.

26.3 Reports of any adverse reaction resulting from the use of manufactured Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or itis a new observation and documents shall be forthwith reported to the concerned licensing authority

26.4. There shall be written procedure describing the action to be taken, recall to be made of the defective product.

26.5 Site Master File.- The licensee shall prepare a succinct document in the form of Site Master File' containing specific and factual Good Manufacturing Practices about the production and/or control of pharmaceutical manufacturing preparations carried out at the licensed premises. It shall contain the information on various areas likes General information, Personnel, Premises, Equipment, Sanitation, Documentation, Production, Quality Control, Loan licence manufacture and licensee, Distribution, complaints and product recall, Self inspection, Export of drugs etc.

27. Specific Requirements For Manufacture Of Rasaushadhies Or Rasamarunthukal And Kushtajat (Herbomineral-Metallic Compounds) Of Ayurveda, Siddha And Unani Medicines: In addition to general requirements, following Specific Requirements shall also be followed, namely: -

27.1 Bhatti or Heating Device Section for Bhasma and Rasaushadhies:- for heating, buming, putta and any heat related work with proper ventilation, exhaust and chimney. This could be tin shed also.

27.2 Grinding, Drying and Processing Section for Kushta, Bhasma and Rasaushadhies (Manual or Mechanical, oven etc.). Drying shall be done in a space which is covered by glass or other transparent material to allow entry of sunrays on the material to keep for the purpose. If drying is being done in oven the temperature of the same may be selected specific temperature.

27.3 The manufacturing area should be designed with special attention to process the products that help evacuate the generated toxic fumes like SO2, arsenic and mercury vapour, etc. When heating and boiling of the materials is necessary, suitable ventilation and air exhaust flow mechanism should be provided to prevent accumulation of unintended fumes and vapours. Such areas may be provided with properly designed chimneys or ducts fitted with exhaust system and suitable scrubbing system to remove fumes and smoke, so that safety of personnel and environment is taken care of.

27.4 Records shall be maintained specially for temperatures attained during the entire process of Bhasmikaran, while employing different kinds of classical puta, furnaces using oil, gas or electricity. Appropriate temperature measuring instrument should be employed such as pyrometer and, pyrograph for manual reading or recording by heat sensors, connected to computer as the case may be. In order to handle large quantities, appropriate technology like use of hand operated extruders for making chakrikas or pellets may be adopted. However, such equipments made of aluminum or its alloys should not be used.

27.5 Product Quality Control:-The specifications for finished Rasaushadhi are primarily intended to define the quality rather than to establish full characterization, and should focus on those characteristics found to be useful in ensuring the quality. Consistent quality for Rasaushadhi can only be assured if the starting material-metals and minerals are used of Pharmacopoeial standards. In some cases more detailed information may be needed on aspects of their process. The manufacturer will ensure in-house standards for the uniform quality of product. Special care is required to assure that the eliminated air from Rasaushadhi air is not contaminating other production area, particularly in closed or centrally air conditioned premises.

27.6 Standard Operating Procedures (SOP) should be included for storage of recalled Rasaushadhies in a secure segregated area, complying with the requirements specified for storage till their final disposal.

27.7. Medical examination of the employees: Employees engaged in manufacturing should be medially examined at the time of employment and then periodically at least once a year for any adverse effect of the drug during manufacturing process for which necessary investigations Shall be carried out for ensuring that there is no effect of material on the vital organs of the employees. Annual examination reports of the employees shall be made available to statutory inspectors during Good Manufacturing Practices inspections.

27.8. Dosage form of Rasaushadhi/Kushtajat:- The Rasaushadhies may be made into an acceptable dosage forms such as churna, vati, guti, tablet or capsules etc. after adding suitable permissible fillers or binding agents as permissible under the Ayurvedic Pharmacopoeia of India or Indian pharmacopoeia as updated from time to time. In such cases the label must indicate the quantity of Ayurveda, Siddha and Unani medicines in one Tablet or Pill or Capsule in addition to the filler. The crystalline product may be grinded before packing in the individual dispensing size. All the Rasaushadhi or Rasamaruthukal or Kushtajat shall be packed in a dosage form which is ready for use for the consumer. Grinding and weighing of individual dose of potentially poisonous products will not be permissible in patient consumer pack. This arrangement may reduce the Adverse Drug Reaction of Rasaushadhi which takes place due to dose variation. However, for hospital bulk pack, it will not be applicable and label will clearly indicate the "Hospital pack".

SPECIFIC REQUIREMENTS FOR MANUFACTURE OF STERILE PRODUCTS

1.2. Requirement for Sterile Product:-

(A) Manufacturing Areas: For the manufacture of sterile Ayurvedic, Unani and Siddha drugs, separate enclosed areas specifically designed for the purpose shall be provided. These areas shall be provided with air locks for entry and shall be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas. The filters shall be checked for performance on installation and periodically thereafter the record of checks shall be maintained. All the surfaces in sterile manufacturing areas shall be designed to facilitate cleaning and disinfection. For sterile manufacturing routine microbial counts of all Ayurvedic, Siddha and Unani drug manufacturing areas shall be carried out during operations. Results of such count shall be checked against established in-house standards and record maintained.

Access to manufacturing areas shall be restricted to minimum number of authorized personnel. Special procedure to be followed for entering and leaving the manufacturing areas shall be written down and displayed.

For the manufacturing of Ayurvedic, Siddha and Unani drug that can be sterilized in their final containers, the design of the areas shall preclude the possibility of the products intended for sterilization being mixed with or taken to be products already sterilized. In case of terminally sterilized products, the design of the areas shall preclude the possibility of mix-up between non-sterile products.

(B) Precautions against contamination and mix:

(a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated enclosure within the building,
(b) Using appropriate pressure differential in the process area.
(c) Providing a suitable exhaust system.
(d) Designing laminar flow sterile air system for sterile products.
(e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.
(f) Individual containers of liquids and ophthalmic solutions shall be examined against black-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.

(g) Expert technical staff approved by the Licensing Authority shall check and compare actual yield against theoretical yield before final distribution of the batch.

All process controls as required under master formula including room temperature, relative humidity, volume filled, leakage and clarity shall be checked and recorded.

PARTICLE SIZE OR PARTICULATE MATTER OF SOLUTION IS TO BE MENTIONED

PART II

A. LIST OF MACHINERY, EQUIPMENT AND MINIMUM AREA REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF AYURVEDIC, SIDDHA & UNANI SYSTEM OF MEDICINES

One machine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. Similarly some of the manufacturing areas like powdering, furnace, packing of liquids and Avaleha, Paks, Majoon etc could also be shared for these items.

S.No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
1.	Itrifal Tiryaq/Majoon Laooq/ Jawarish/Khamiras Pak/Avaleh/Khand/Modak/Lakayam/Murabba	100 sq. feet	Grinder/ Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Furnace/Bhatti and other accessories, plant mixer for Khamiras, Mortar and Pestle/Kharal, Aluminium Vessels, S. S. Storage Container
2.	Arq/Timit/Ark	100 sq. feet	Distillation Plant (garembic) S.S. storage tank, Boiling Vessel, Gravity filter, Bottle filling machine, Bottle washing machine, Bottle drier, Cap sealing machine
3.	Chuma/Sufoof (Powder)	100 sq feet	Grinder/ Pulveriser, disintegrator, Powder mixer, sieves, shifter.
4.	Habb(Pills)/Vati/Gutika/Matirai/tablets/Qurs (Tab.)	100 sq. feet	Ball Mill, Grinder/Pulveriser, Sieves, Mass mixer/powder mixer, Granulator, drier, tablet compressing machine, Die punches Trays, O.T. Apparatus, pill/Vati cutting machine, stainless steel trays/container for storage and sugar coating, polishing pan in case of sugar-coated tablets, mechanised chattoo (for mixing guggulu) where required, Balance with weights, Scoops, Heater, Counter & packing Machineries
5.	Roughan (nils) Tails (Crushing	100 sq. feet	Oil Expeller, S.S. Patilas, Oil

	and boiling Ghrit		Filter bottle, Filling & sealing machine, Bottle drier, Bhani, Kadahi/S 5 Patila, S.S.Storage Containers, Filtration equipment, filling tank with tap/Liquid filling machine.
6.	Kupipaka-va/Ksara/Parpati/Lavana/Bhasma/ Kushta/Satva/ Sindura/Karpu/Uppu/Param	100 sq. feet	Bhatti, Karahi/Stainless steel Vessels/Patila, Flask, Earthen container, Gaj Put Bhatti, Muffle furnace (Electrically operated) End/ Edge Runner, Wooden/S.S.Spatula.
7.	Kajal, Shiyaf, Surma, Anjana/Pisti	100 sq. feet	Mortar and Pestle /Kharal, Shifter. Earthen lamps for collection of Kajal, Triple Roller Mill, End Runner, Sieves, mixing S.S. Vessel, S.S. Patila,
8.	Capsules	100 sq. feet	Air Conditioner, Dehumidifier, hygrometer, thermometer, Capsule filling machine and chemical balance. Pulveriser, Powder mixer (where needed), Balance with weights, storage containers, glass, counter and packing machinery.
9.	Ointment/Marham Pasal, Marham, Zimad (Ointment)/Soap/Aerosol	100 sq. feet	Tube filling machine, Crimping Machine/Ointment Mixer, End Runner/Mill (Where required) S.S.Storage Container, S.S. Patila, Mortar and Pestle /Kharal, Bhatti, End runner, Grinder, Pulveriser, Triple Roller Mill (if required), Aerosol filling machine.
10.	Panak/Syrup/Pravahi Kwath/ Manapaku/Sharbat and Joshanda	100 sq. feet	Tincture press, Mortar and Pestle /Bhatti section, filter press/Gravity filter, liquid filling machine P.P. Capping Machine. Liquid filling tank with tap/liquid filling machine, hot air oven electrically heated with thermostatic control, kettle.
11.	Asava/Arishta/Sura	100 sq. feet	Fermentation tanks, containers and distillation plant where necessary, Filter Press. Distillation plant and Transfer pump (additionally required for Su-

			ra)
12.	Aschyotan/Netra Malham/Panir/Karn Bindu/Nasabindu/ Qutoor-e-Chashm and Marham (Eye drops, eye ointment)	100 sq. feet	Hot air oven electrically heated with thermostatic control, kettle gas or electrically heated with suitable mixing arrangements, collation mill, or ointment mill, tube filling equipment, mixing and storage tanks of stainless steel or of other suitable material sintered glass funnel, seitz filter or filter candle, liquid filling equipment, autoclave.
13.	Dry extract/wet extract	200 sq. ft.	
14.	Any other category except parenteral	100 sq. ft.	
15.	Raw material store	100 sq. ft.	
16.	Packing material storage	100 sq. ft.	
17.	Finished goods storage	100 sq. ft.	
18.	Quarantine Area for Finished Goods	100 sq. ft.	
19.	Quality Control Section including storage of control sample	150 sq. ft.	
20.	Stability Chamber Room	200 sq. ft	
21.	Retain sample room	80 sq. ft	
22.	Rejected goods store	Adequate	
23.	Changing Room (Male/Female)	50 sq. ft.	
24.	Office cum record room	Adequate	
25.	Drying area	80 sq. ft.	
26.	Grinding/pulverising area	80 sq. ft.	
27.	Shifting and mixing area	80 sq. ft.	
28.	Granulation area	80 sq. ft.	

Part III
CHECKLIST OF GMP INSPECTION

S. No	**GMP Clause**	**Areas/Activities to be Audited**	**Observations**	
1.		**GENERAL**	**Document Review**	**Remark**
		Name and address of Unit MFG. Lic. No. Telephone Fax: Email: Names and designation of the inspection team:		
2.		**PERSONAL**		

		Name of In charge a) production b) quality control		
		Number of Production Supervisors/Asstt. Mfg./Chemist		
		Number of Analysts		
		Have all personal received GMP Training?		
		Is Training Documented?		
		What is the periodicity of the training?		
3.		**FACTORY PREMISES**		
		Does manufacturing unit have adequate space for Receiving and storing raw material. Manufacturing process areas. Quality control section. Finished goods store. Office Rejected goods/drugs store.		
4.	1.1 (A)	**LOCATION AND SURROUNDINGS**		
		Is the establishment located away from environmentally polluted areas?		
		Is the establishment located away from areas adjacent to open sewerage, drain/public lavatory or any factory which produces excessive, disagreeable odour.		
		Are sewage, trash and other effluent disposal provided?		
5.	1.1 (B)	**BUILDINGS**		
		Do the internal design and layout of establishment permit good hygiene practices including protection from cross- contamination?		
		Are surfaces of walls, partitions and floors made of impervious materials and capable of being kept clean?		
		Do walls and partitions have smooth surface?		
		Are floors constructed to allow adequate cleaning and drainage?		
		Are doors, windows, ceiling and overhead fixtures constructed and finished to minimize buildup of dirt, condensation and shedding of particles and easy to clean?		
		Are working surfaces that come into direct contact with drugs of sound condition, durable and easy to clean, maintain and disinfect?		
		Any open drain blocked sewer or public lavatory nearby?		
		Are any products other than drugs manufac-		

		tured in the same building?		
		Is there adequate space for equipment, material and movement of personal and materials?		
		Is there any programme/system to check of birds, rodents and insects?		
		Are lightening and ventilation adequate?		
		Are facilities for changing street clothes, footwear, washing and toilets adequately and satisfactorily maintained?		
		Is the space for drying of raw materials satisfactory?		
6.	1.1 (C)	**WATER SUPPLY**		
		Is there adequate supply of potable water?		
		Does the potable water meet the specifications published API specifications?		
		Is only potable water Used in ASU medicines?		
7.	1.1 (D)	**DISPOSAL OF WASTE**		
		Are drainage and water disposal systems designed, constructed and maintained in such a way as to avoid contamination of ASU products?		
		Are the waste water and residues disposed of after suitable treatment as per guidelines of pollution control authorities?		
		Are the arrangements for the following adequate?		
		Disposal of solid/semi solid waste		
		Disposal of sewage		
		Disposal of Liquid laboratory waste?		
		Disposal of Management of gaseous pollutants?		
		Is efficient treatment plant in existence / if yes, give comment on it?		
		Are fume hoods of adequate design in existence and used wherever necessary?		
8.	1.1(E)	**CLEANING OF CONTAINERS**		
		Is there proper arrangement for washing, cleaning and drying of containers? Is this area separated from manufacturing area?		
9.	**1.1(F)**	**STORES**		
		Is there independent adequate space for storage of different types of materials such as raw material, packaging material and finished products?		
		Are ASU medicine storage facilities designed		

		and constructed to Permit adequate maintenance and cleaning? Avoid pest ace and harbourage? Enable drugs to be effectively protected from contamination? Provided the necessary environment to prevent spoilage?		
		Are storage facilities deigned, constructed and maintained to ensure that malicious or accidental contamination of ASU medicines with harmful materials is prevented?		
10.	1.1(F)(A)	**RAW MATERIALS STORES**		
		Are raw materials or ingredients checked for parasites, undesirable microorganisms, pesticide or decomposed or extraneous substances		
		Are raw materials or ingredients inspected and tested before processing?		
		Are raw materials or ingredients subjected to effective stock rotation?		
		Are the ventilation and lighting of stores adequate?		
		Is the Raw Material store segregated for different types of Raw Material? Raw materials of metallic origin Raw materials of mineral origin Raw materials of animal source Fresh herbs Dry herbs or plant parts Excipients etc. Volatile oils/perfumes and flavours Plant extracts and exudates/resins Others		
		Is special area with special condition provided for special Raw Materials?		
		Are there labels for material of different status i.e. quarantine, tested and releases for use and rejected?		
		Are these labels of different colours?		
		Are labels on containers of RM to be used in		

		manufacture checked with regard to identity, quantity and QA approval? If not give details/		
		Is there the following information on the labels? Name of material Batch number Analysis number Date of release/rejection? Date of testing? Date of expiry?		
		Is the sampling performed by quality control personal?		
		Are there sampling procedures?		
		Are the containers provided for storage of raw material suitable to preserve the quality?		
		Is exterior storage available for: Solvent storage area? Inflammable material storage area? Whether safety measures provided have been assessed by regulatory agency if any? Is SOP's available for handling of these materials? Are SOP's for cleaning of containers and closures available before packing of products?		
		Is the weighing area segregated?		
		Are lighting and ventilation adequate?		
		Is the area clean?		
		Do the personal wear appropriate clothing?		
		Is there danger of cross contamination during weighing?		
		Are the scales and balance calibrated regularly and records maintained?		
		Are the containers of the raw materials to be weighed, cleaned before opening?		
		After weighing, are these containers sealed?		
		Are the raw materials for each batch, after weighing properly identified and checked? Are adequately clean and dried equipment		

		used for dispensing materials from the containers?		
		Is FIFO principle adopted?		
11.	1.1 (F)(B)	PACKING MATERIALS		
		Is the area adequate with reference to packing material?		
		Are the containers and closures adequately cleared and checked?		
12.	1.1 (F)(C)	FINISHED GOODS STORES		
		Is the area adequate with reference to materials stored?		
		Are lighting and ventilation adequate?		
		Are there inventory records to show:		
		Quantities		
		Batch number		
		Date of receipt		
		Have the distribution records been maintained?		
		Do distribution records provide sufficient information for drug recall purpose?		
		Is there segregation area for retrieved good?		
		Are records available for the retrieved goods?		
		Is there any marked quarantine area?		
		Is there space for special storage conditions (environmental condition), if required?		
13.	1.1 (G)	**WORKING SPACE**		
		Is space adequate as per manufacturing operations?		
		Is machinery alongwith working manual orderly placed with adequate space?		
		Are there adequate precautions to check cross contamination?		
14.	1.1 (H)	**HEALTH, CLOTHING, SANITATION AND HYGIENE OF WORKERS**		
		Are workers free from contagious disease?		
		Are workers properly uniformed?		
		Are there separate lavatories for men and women?		
		Is there provision for changing their cloth and to keep personal belongings?		
		Are adequate facilities like wash-basin with running water hand drier & clean towels, etc., available for personal hygiene before entering into production area?		
		Are personnel instructed to observe personal hygiene?		
		Are hygiene instructions displayed in change		

		rooms and strategic locations?		
		Is the sanitation system monitored for effectiveness?		
		Is the sanitation system periodically verified by inspections? Is microbiological sampling of environment and ASU drugs contact surfaces carried out ?		
		Is the sanitation system regularly reviewed and adapted to reflect changed circumstances?		
15.	1.1(1)	**MEDICAL SERVICES**		
		Is medical file of each worker maintained separately?		
		Is recruitment of an employee preceded by medical examinations?		
		What is the periodicity of subsequent medical examinations?		
		Is an employee whose state of health is doubtful immediately removed from work site until he is fully recovered?		
16.	1.1 (J)	**MACHINERY AND EQUIPMENT**		
		Is manually operated or semioperated or automatic machines are used for Crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labelling and packing?		
		Are equipment and containers coming into contact with ASU drugs designed such that they can be adequately cleaned, disinfected and maintained?		
		Are equipment made of nontoxic materials?		
		Are equipment used to cook, heat, treat, cool, store designed to achieve the required temperature as rapidly as necessary?		
		Are equipments used to cook, heat, treat, cool, store designed to monitor and control the required temperature?		
		Are containers for waste suitably identified?		
		Are containers for waste closable to prevent malicious or accidental contamination of ASU Medicines?		
		Is the equipment adequate for intended use?		
		Is it constructed in such a way that lubricants, coolant, etc. cannot contaminate the drug product?		
		Does the equipment permit cleaning and maintenance?		
		Does the equipment show its status i.e. clean, dirty, batch contents?		
		Do all apparatus/equipment bear appropriate		

		labels to identify the product for which the equipment is used, its batch no., date of manufacturing etc.		
		Are SOPS available for cleaning maintenance and sanitation of major equipment?		
		Are log books maintained for cleaning maintenance and sanitation of major equipment?		
		Are SOP's readily available to operators		
		If automatic electronic or mechanical equipment is used, are there: Written programs for calibration/inspection Checks to ensure that may changes are made only by authorized persons/ Are suitable closures or lids available to protect the changes in properties of material exposed to outside atmosphere?		
17.	1.1(K)	**BATCH MANUFACTURING RECORDS**		
		Are appropriate records of processing, production and distribution kept?		
		Are SOP's available for the following Receipt of raw material and other components? Quarantine and storage? Quality control system and approval/rejection Release of production In process testing and control Finished product? Storage of finished product? Distribution Returned goods Recalls and complaints Cleaning and maintenance? Quality control of water For reworking of non-conforming batches in existence? If yes, check)		
		Are there additional documents like log books, notebooks or other similar records available to show execution of various functions?		
		Are there records of receipts of materials and do these have following information? (goods receipt Note-GRN) Receiving GRN documents number? Date of receipt? Supplier? Manufacturer?		

		Manufacture's batch number? Type and size of containers? Number of containers and conditions?		
		Are specifications available for all materials?		
		Are they dated authorized?		
		Are test methods validated?		
		Are periodic reviews of specification carried out to ensure compliance with new/revised National/international pharmacopoeia?		
		Are these records of stock and issue of raw materials and do these have following information: Opening balance? Date of receipt? Quantity received? Name and batch number assigned by the manufacturer? Invoice number, date name and address of supplier? Analysis receipt no. and date? Date of expiry, if any? Name and batch number of product for manufacture for which issued? Balance? Signature of issuing person?		
		Are there master formulation records for each drug product being produced?		
		Is there a separate master production documents for each dosage form/batch size?		
		Are these master production records signed and dated by competent person?		
		Is a batch production record prepared for every batch produced?		
		Is it reproduction of the appropriate master production documents or it has all critical information about the batch?		
		Are batch records retained for at least one year after expiry date?		
		Has it been checked for accuracy, signed and dated by a responsible person?		
		Are the records maintained by QC for all the tests carried out? Do these records include: The name of the product Number of the batch being manufactured? Issue slip with lab ref. No Job cards? Graphs, chart, spectra, etc? List of major equipment used? In-process testing reports?		

		Calculations of yield? Notes on deviations with signed authorization? Signature of individuals of who performed the tests? Material returns to store slip? Lab report of final product? Review of results for any raw material issued under "positive Recall"? Signature of the designated person responsible for the review of records for accuracy and compliance with established standards?		
		Are other associated records available?		
		Is documentation available readily for examination?		
		Are batch production records capable of giving complete history of the batch right from the raw material stage to the distribution of finished products?		
18.	1.1(L)	**DISTRIBUTION RECORD**		
		Are records of sale and distribution of each batch of ASU drugs maintained? Are records maintained at least up to 5 years of the exhausting of stock?		
19.	1.1 (M)	**RECORD OF MARKET COMPLAINTS**		
		Are the firm maintain a record of complaint received from market?		
		Does the firm have investigated the complaint and has taken any corrective action?		
		Does the firm has intimated such complaint six monthly to the Licensing Authority?		
		Does the firm maintain register of any ADR report received?		
		Are written procedure available for receipt and control of return products?		
		Are returned or salvaged drug products destroyed unless QC determines their reprocessing?		
		Are records of the returned products maintained including their disposition?		
		Is a safety manual available?		
20.	1.1 (N)	**QUALITY CONTROL**		
		Is the QC area more than 150 sq ft?		
		Has Quality Control section minimum of: a) One person with Degree qualification in Ayurveda/ Siddha/Unani; b) One chemist with bachelor in Science or Pharmacy or Pharmacy (Ayurveda) and;		

		c) One Botanist (Pharmacognosist) with bachelor in Science (medical) or Pharmacy or Pharmacy (Ayurveda)?		
		Are master control procedures signed and stated by authorized persons?		
		Do these control procedure include specifications, test procedure or other control procedure for:		
		Raw materials		
		In process materials		
		Packaging and labelling materials?		
		Finished products?		
		Are the procedure in written form and readily available to QC personnel for acceptance of reprocessed material?		
		Are the procedure in written form and readily available for acceptance of reprocessed material?		
		Do these control procedure include specifications test procured or other control procedure for:		
		Raw material		
		In process material		
		Packaging and labelling materials		
		Finished products?		
		Are samples collected by QC personal		
		Is there special room for microbiological and sterility testing?		
		Is the environment of room controlled?		
		Are only materials, containers and appliance necessary for the job in hand stored in the vicinity of the manufacturing areas and are these properly labelled with name of the product, batch no. date etc.?		
		Are all raw materials, containers, closures, label and printed packaging material approved and released by QC for use in manufacture of drugs products		
		Are in-process controls carried out by QC personnel?		
		Are semi-finished products tested for appropriate tests when necessary?		
		Is bulk finished product tested for established specifications before packing?		
		Is every finished product tested for established specifications before release for sale?		
		Does the QC maintain records of all the tests carried out?		
		Does the QC review all production and con-		

		trol records to ensure compliance with established written procedure before a batch of the product is released for sale?		
		Reference standards: Are reference standards (R.S) available? Are these RS or working standards (WS)? Are WS standardised against RS or CRS? Are RS stored properly (at appropriate temperature under dehumidified conditions)? Are records of R.S and their standard maintained?		
		Are samples iil sufficient quantity for testing twice retained of starting materials and finished products for future examination, in case of need?		
		Are quality control procedures validated?		
		Is written programs available for stability including the following:		
		Sample storage condition		
		Room temperature?		
		Sample size and test intervals?		
		Reliable and specific test methods?		
		Testing in the same containers closure system in which it is marketed?		
		Date and expiration date if any?		
		Established of in-house specification?		
		Does the firm provided the equipment as recommended in Part II C?		
21.	1.2	**REQUIREMENT FOR STERILE PRODUCT**		
		Manufacturing areas		
		Is there separate manufacturing area		
		Are their air locks for entry?		
		Is there dust free and ventilated for air supply		
		Precautions against contaminations and mix.		
		Are manufacturing operations being carried out in a separate block of adequately isolated building		
		Is there appropriate pressure differential in the process area.		
		Is suitable exhaust system provided?		
		For asceptic manufacturing proper air supply (filtered through HEPA) provided? Signatures of Inspecting Team Members		

Signatures of Inspecting Team Members

True type Copy

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REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

सी.जी.-डी.एल.-अ.-08072021-228177
CG-DL-E-08072021-228177

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 383] नई दिल्ली, बुधवार, जुलाई 7, 2021/आषाढ़ 16, 1943
No. 383] NEW DELHI, WEDNESDAY, JULY 7, 2021/ASHADHA 16, 1943

आयुष मंत्रालय

अधिसूचना

नई दिल्ली, 2 जुलाई, 2021

सा.क.नि. 473 (अ).—औषधि और प्रसाधन सामग्री नियमावली, 1945 का और संशोधन, जैसा कि केंद्र सरकार का प्रस्ताव है, करने के लिए कतिपय नियमों का निम्नलिखित प्रारूप, जिसे औषधि और प्रसाधन सामग्री अधिनियम, 1940 (के 23 1940) की धारा 33-ढ द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए और आयुर्वेद, सिद्ध, यूनानी औषधि तकनीकी सलाहकार बोर्ड के परामर्श के बाद इसके द्वारा प्रभावित होने की संभावना वाले सभी व्यक्तियों की जानकारी के लिए प्रकाशित किया जाता है, जैसा कि उक्त धारा द्वारा अपेक्षित है, और एतदद्वारा सूचना दी जाती है कि उक्त प्रारूप नियमों पर हितधारकों की आपत्तियों अथवा सुझावों पर उस तारीख से तीस दिनों की अवधि समाप्त होने पर या उसके बाद विचार किया जाएगा जिस तारीख को इन प्रारूप नियमों वाले भारत के राजपत्र की प्रतियां जनता को उपलब्ध कराई जाएंगी;

केंद्र सरकार द्वारा उपर्युक्त निर्दिष्ट अवधि के भीतर किसी भी व्यक्ति से उक्त प्रारूप प्राप्त होने वाली आपत्तियों और सुझावों पर विचार किया जाएगा;

आपत्तियां या सुझाव, यदि कोई हों, तो सचिव, आयुष मंत्रालय, आयुष भवन,'बी' ब्लॉक, जीपीओ कॉम्पलेक्स, आईएनए, नई दिल्ली-110023 को अग्रेषित किए जाएं अथवा ई-मेल dcc-ayush@nic.in. पर भेजें।

(99)

प्रारूप नियम

1. लघु शीर्षक, विस्तार और प्रारंभ ___

(1) इन नियमों को औषधि एवं प्रसाधन सामग्री (संशोधन) नियम, 2021 कहा जाएगा।

(2) ये नियम सरकारी राजपत्र में इनके अंतिम प्रकाशन की तारीख से लागू होंगे।

2. औषधि और प्रसाधन सामग्री नियमावली- 1945 (इसके पश्चात इन्हें प्रमुख नियम कहा जाएगा) में नियम 2(घघ) के स्थान पर निम्नलिखित रखा जाएगा, अर्थात-

"(घघ) होम्योपैथी औषधियों में शामिल हैं ऐसी कोई औषधि जो होम्योपैथी प्रमाणों में दर्ज हो अथवा जिसकी उपचारात्मक कारगरता अधिनियम की प्रथम और द्वितीय अनुसूची में यथा उल्लिखित होम्योपैथी में प्राधिकृत साहित्य में यथा दर्जित लम्बे नैदानिक अनुभव के जरिए स्थापित हुई हो और जो भारत के शासकीय होम्यौपैथिक भेषजसंहिता और विदेशी तकनीकों के अनुसार तैयार की जाती हो और जिसमें ऐसी होम्योपैथिक औषधियों के अवयवों का संयोजन शामिल हो किंतु ऐसी औषधि शामिल न हो जो आंत्रेतर मार्ग से दी जाती हो"

3. नियम 2 (ङग) के बाद निम्नलिखित जोड़ा जाएगा, नामत: -

"(ङग) "पंजीकृत आयुर्वेदिक अथवा सिद्ध अथवा सेवा-रिग्पा अथवा यूनानी चिकित्साभ्यासी का अभिप्राय ऐसे व्यक्ति से है जो-

(i) भारतीय चिकित्सा केंद्रीय परिषद अधिनियम, 1970 (1970 का 48) की अनुसूचियों में विनिर्दिष्ट अथवा अधिसूचित किसी प्राधिकारी द्वारा अनुमोदित योग्यता रखता हो; अथवा

(ii) आयुर्वेद अथवा सिद्ध अथवा सोवा-रिग्पा अथवा यूनानी चिकित्सा पद्धति का अभ्यास करने वाले व्यक्तियों के पंजीकरण हेतु किसी राज्य के चिकित्सा रजिस्टर में पंजीकृत हो अथवा पंजीकरण हेतु योग्य हो।"

4. नियम 2(ज) के पश्चात् निम्नलिखित जोड़ा जाएगा, नामत:-

'(जज) सोवा रिग्पा औषधियां—सोवा रिग्पा औषधि के अन्तर्गत वे सब औषधियां हैं जो मनुष्यों या पशुओं में रोग या विकार के निदान, उपचार, शमन या निवारण के लिए अथवा उसमें आन्तरिक या बाह्य उपयोग के लिए आशयित हैं और जो औषधि एवं प्रसाधन सामग्री अधिनियम, 1940 की प्रथम अनुसूची में विनिर्दिष्ट सोवा रिग्पा चिकित्सा पद्धतियों की प्रामाणिक पुस्तकों में वर्णित फार्मूलों के अनुसार अनन्य रूप से विनिर्मित हैं।

(जझ) सोवा रिग्पा सांपत्तिक चिकित्सा—सोवा रिग्पा चिकित्सा पद्धतियों के सम्बन्ध में वे सब यौगिक अभिप्रेत हैं जिनमें केवल ऐसे संघटक अन्तर्विष्ट हैं जो प्रथम अनुसूची में विनिर्दिष्ट सोवा रिग्पा चिकित्सा पद्धतियों की प्रामाणिक पुस्तकों में वर्णित फार्मूलों में उल्लिखित हैं, किन्तु इसके अन्तर्गत ऐसी औषधि नहीं है जो आन्त्रेतर मार्ग से दी जाती है और ऐसा यौगिक भी नहीं है जो खंड (जज) में यथा विनिर्दिष्ट प्रामाणिक पुस्तकों में सम्मिलित है।

5. नियम 67क के अंतर्गत

i. उपनियम 2 के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:-

"(2) होम्योपैथी औषधियों की बिक्री, भंडारण अथवा प्रदर्शनी अथवा विक्रय अथवा वितरण हेतु प्रस्ताव के लिए अनुज्ञप्ति हेतु आवेदन, प्रपत्र-19ख में दो हजार रुपए के शुल्क के साथ अनुज्ञप्ति अधिकारी को किया जाएगा।"

ii. उपनियम (3) के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत: —(3) आवेदन ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से इसमें उपलब्ध कराए गए होम्योपैथी औषधियों की विक्रयार्थ अनुज्ञप्ति से संबंधित प्रपत्र के अनुसार किया जाएगा।

परंतु, यह नियम इस संशोधन नियम, 2021 के प्रारंभ होने की तारीख से पहले प्रपत्र 20ग अथवा 20घ में प्राप्त अनुज्ञप्ति हेतु आवेदन पर लागू नहीं होगा। ऐसे अनुज्ञप्तिधारक को मौजूदा अनुज्ञप्ति को जारी रखने के लिए एक हजार रुपए का अनुज्ञप्ति प्रतिधारण शुल्क जमा कराना होगा।"

6. नियम 67ग के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:—

"67ग. औषधियों की बिक्री हेतु अनुज्ञप्तियों के लिए प्रपत्र—(1) होम्योपैथीऔषधियों की फुटकर अथवा थोक द्वारा बिक्री, भंडारण अथवा प्रदर्शनी अथवा बिक्री अथवा वितरण हेतु प्रस्ताव के लिए अनुज्ञप्ति,**प्रपत्र 20ग अथवा 20घ** में, जैसा भी मामला हो, जारी की जाएगी।

आयुर्वेदिक, सिद्ध अथवा यूनानी औषधियों के विनिर्माण हेतु अनुज्ञप्ति के लिए प्रपत्र**—(1) नियम 67च की शर्तों का पालन करते हुए होम्योपैथी** औषधियों की फुटकर अथवा थोक द्वारा बिक्री, भंडारण अथवा प्रदर्शनी अथवा बिक्री अथवा वितरण हेतु प्रस्ताव के लिए अनुज्ञप्ति,**प्रपत्र 20ग अथवा 20घ** में, जैसा भी मामला हो, जारी की जाएगी। अनुज्ञप्ति आवेदन के प्राप्त होने की तारीख से अथवा अनुज्ञप्ति अधिकारी द्वारा बताई गई कमियों को आवेदक द्वारा पूरा किए जाने की तारीख से, जो भी मामला हो, दो माह की अवधि के भीतर जारी की जाएगी।

(3) आवेदन पर ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से कार्रवाई की जाएगी और उपर्युक्त पोर्टल में दिए गए प्रपत्र के अनुसार इसमें उपलब्ध कराए गए प्रपत्र 20ग अथवा 20घ में अनुज्ञप्ति ऑनलाइन जारी की जाएगी।"

7. नियम 67ड. के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:--

67ड "अनुज्ञप्ति की अवधि—(1) प्रपत्र 20ग अथवा 20घ में जारी अनुज्ञप्ति अनंतकाल तक वैध बनी रहेगी।

परंतु, अनुज्ञप्तिधारी अनुज्ञप्ति की शर्तों और औषधि एवं प्रसाधन सामग्री अधिनियम के उपबंधों और नियमों के अनुपालन की स्वत:घोषणा, प्रपत्र 20ग अथवा 20घ में अनुज्ञप्ति जारी होने की तारीख से अथवा पिछली स्वत:घोषणा की प्रस्तुति की तारीख, जो भी मामला हो, प्रत्येक पांच वर्ष में प्रस्तुत करेगा।

यह भी कि, इस प्रकार की स्वत:घोषणा, प्रपत्र 20ग अथवा 20घ में अनुज्ञप्ति के जारी होने की तारीख से अथवा पिछली स्वत:घोषणा की प्रस्तुति की तारीख से, जो भी मामला हो, पांच वर्ष की समाप्ति के एक माह के भीतर प्रस्तुत की जाएगी, और इस प्रकार की स्वत:घोषणा के प्रस्तुत न किए जाने पर, अनुज्ञप्ति निरस्त समझी जाएगी।"

8. नियम 67ड.ड. विलोपित समझा जाएगा।

9. नियम 67च के अंतर्गत द्वितीय उपबंध के स्थान पर निम्नलिखित उपबंध रखा जाएगा, नामत:,

परंतु यह भी कि ऐसा पंजीकृत होम्योपैथिक चिकित्साभ्यासी जो 20ग अथवा 20घ के तहत अनुज्ञप्ति परिसर में होम्योपैथी का अभ्यास कर रहा है, केवल अपने मरीजों को ही औषधि प्रदान करेगा और होम्योपैथी औषधियों की फुटकर बिक्री में भाग नहीं लेगा।

10. नियम 67छ का उप खंड 6 विलोपित किया जाएगा।

11. नियम 85ख के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:--

85ख "होम्योपैथिक औषधियों के विनिर्माण हेतु अनुज्ञप्ति के लिए आवेदन

(1)नियम 2 के खंड (घघ) के अंतर्गत आने वाली होम्योपैथी औषधियों के विक्रयार्थ विनिर्माण हेतु अनुज्ञप्ति के लिए आवेदन, प्रपत्र-24ग में पांच हजार रुपए के शुल्क के साथ अनुज्ञप्ति अधिकारी को किया जाएगा।

(2)आवेदन ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से इसमें उपलब्ध कराए गए होम्योपैथी औषधियों की विक्रयार्थ विनिर्माण हेतु अनुज्ञप्ति से संबंधित प्रपत्र के अनुसार किया जाएगा।

परंतु, यह नियम इस संशोधन नियम, 2021 के प्रारंभ होने की तारीख से पहले प्रपत्र 24ग में प्राप्त अनुज्ञप्ति हेतु आवेदन पर लागू नहीं होगा। ऐसे अनुज्ञप्तिधारक को, जिसके पास फैक्ट्री परिसर है और जो अनुसूची ड1 में विनिर्दिष्ट आवश्यकताओं और शर्तों को पूरा करता है, मौजूदा अनुज्ञप्ति को जारी रखने के लिए पांच हजार रुपए का अनुज्ञप्ति प्रतिधारण शुल्क जमा कराना होगा।"

12. नियम 85घ के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:–

"85घ. होम्योपैथिक औषधियों के विनिर्माण हेतु अनुज्ञप्ति के लिए प्रपत्र — (1)**नियम 85घ की शर्तों का पालन करते हुए होम्योपैथी** औषधियों के विक्रयार्थ विनिर्माण हेतु अनुज्ञप्ति, प्रपत्र 25ग में जारी की जाएगी। अनुज्ञप्ति आवेदन के प्राप्त होने की तारीख से अथवा अनुज्ञप्ति अधिकारी द्वारा बताई गई कमियों को आवेदक द्वारा पूरा किए जाने की तारीख से, जो भी मामला हो, दो माह की अवधि के भीतर जारी की जाएगी।

(2) इस अधिनियम के अधीन अनुज्ञप्ति, अनुज्ञप्ति अधिकारी द्वारा होम्योपैथी चिकित्सा पद्धतियों, जो भी मामला हो, के ऐसे विशेषज्ञ, जिसका अनुमोदन इस संबंध में राज्य सरकार द्वारा किया जाए, से परामर्श लेने के बाद जारी की जाएगी।

(3) आवेदन पर ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से कार्रवाई की जाएगी और उपर्युक्त पोर्टल में दिए गए प्रपत्र के अनुसार इसमें उपलब्ध कराए गए प्रपत्र 25ग में अनुज्ञप्ति ऑनलाइन जारी की जाएगी।"

13. नियम 85ड. में "अथवा नवीनीकरण" और "अथवा नवीनीकृत" शब्दों को विलोपित किया जाएगा।

14. नियम 85ड. का परंतुक नामत:,"परंतु यदि किसी फार्मेसी में, जो प्रपत्र 20-ग के तहत अनुज्ञप्तिधारक है,प्रभावकारी सम्पाक तैयार किया जाता है तो उस पर शर्त (2) और (3) लागू नहीं होंगी। अनुज्ञप्तिधारक, अनुज्ञप्ति अधिकारी की संतुष्टि के लिए यह सुनिश्चित करेगा कि उसके द्वारा विनिर्मित उत्पाद, लेबल पर किए गए दावे के अनुरूप हैं", को विलोपित किया जाएगा।

15. नियम 85ड.क के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:–

"85ड.क विज्ञप्ति देने और अनुपालन के सत्यापन के लिए निरीक्षण—(1) प्रपत्र 25ग में विज्ञप्ति हेतु जीएमपी प्रमाण पत्र देने से पहले, अनुज्ञप्ति अधिकारी उस प्रतिष्ठान का कारण जानेगा जिसमेंदवाओं का विनिर्माण किया जाना प्रस्तावित है या जिनका निरीक्षण इस अधिनियम के तहत राज्य सरकार द्वारा नियुक्त एक या अधिक निरीक्षक या संबंधित क्षेत्र के विशेषज्ञ के साथ या उसके बिना किया जाना है। एक या अधिक निरीक्षक दवाओं के विनिर्माण के लिए उपयोग किए जाने वाले या उपयोग किए जा रहे प्रतिष्ठान की जांच करेंगे।

(2)उप नियम-(1) के तहत अनुज्ञप्ति की शर्तों और औषधि और प्रसाधन सामग्री अधिनियम के प्रावधानों और नियमों के अनुपालन की स्व:घोषणा का सत्यापन करने के लिए अनुज्ञप्ति प्राप्त प्रतिष्ठान इस अधिनियम के तहत राज्य सरकार द्वारा नियुक्त औषध निरीक्षकों द्वारा तीन साल में कम से कम एक बार या जोखिम आधारित दृष्टिकोण के अनुसार जैसा जरूरी हो, सत्यापन किया जाएगा।

(3) बशर्ते कि औषध निरीक्षकों को निरीक्षण ड्यूटी एक यादृच्छिक तरीके से यह सुनिश्चित करते हुए सौंपी जाती है कि उस औषध निरीक्षक को किसी विशेष स्थापना का निरीक्षण का कार्य कम से कम 3 वर्ष की अवधि में लगातार दो बार से अधिक नहीं सौंपा गया हो।

16. नियम 85ड.ख के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:–

"85ड.ख निरीक्षक द्वारा रिपोर्ट — (1) निरीक्षक अथवा निरीक्षकों द्वारा सभी परिसरों, संयंत्र और उपकरणों के लिए सभी

क्षेत्रों की जांच की जाएगी और विनिर्माण में प्रयुक्त की जाने वाली या प्रयुक्त की जा रही प्रक्रिया का, साथ ही विनिर्माण की जा रही औषधियों के मानकीकरण तथा परीक्षण के लिए प्रयुक्त किए जाने वाले या प्रयुक्त किए जा रहे साधनों का निरीक्षण किया जाएगा और नियोजित किए जाने वाले तकनीकी स्टाफ की व्यावसायिक योग्यताओं की भी जांच की जाएगी। वह आवेदन में दिए गए कथनों की सत्यता, और सक्षम तकनीकी स्टाफ की आवश्यकता को पूरा करने के लिए आवेदक की क्षमता, विनिर्माण संयंत्रों, परीक्षण उपकरणों और उत्तम विनिर्माण पद्धतियों की अपेक्षाओं तथा अनुसूची 'ड1'में निर्धारित संयंत्र और उपकरणों की अपेक्षाओं की जांच और सत्यापन भी करेगा।

(2) निरीक्षक, अनुज्ञप्ति अधिकारी को उप-नियम(1) के अनुसार अपने निरीक्षण को पूरा कर लिए जाने पर अपनी अनुशंसाओं के साथ निरीक्षण के प्रत्येक पहलू पर अपने निष्कर्ष देते हुए विस्तृत विवरणात्मक रिपोर्ट प्रस्तुत करेगा।

17. नियम 85ड.ग के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:--

"85ड.ग अनुज्ञप्ति अधिकारी की प्रक्रिया — (1) यदि अनुज्ञप्ति प्राधिकारी ऐसी किसी और जांच, यदि कोई हो, जैसा भी वह आवश्यक समझे, के पश्चात् संतुष्ट है कि अधिनियम के तहत नियमों का अनुपालन किया गया है और यह भी कि अनुज्ञप्ति की शर्तों तथा अधिनियम के तहत नियमों का पालन किया जाएगा, तो वह इस भाग के तहत एक अनुज्ञप्ति जारी करेगा।

(2) यदि अनुज्ञप्ति प्राधिकारी संतुष्ट नहीं है तो वह कमियों पर एक ज्ञापन जारी करेगा और अनुज्ञप्ति प्रदान करने से पूर्व उन शर्तों को पूरा किया जाना आवश्यक होगा तथा निरीक्षण रिपोर्ट की प्रति आवेदक को भेजेगा।

(3) उप-नियम (2) के तहत कमियों के ऐसे ज्ञापन पर जवाब आवेदक द्वारा ऐसे ज्ञापन के जारी होने के दो माह के भीतर देना अपेक्षित होगा।

(4) उप-नियम (2) में अपेक्षित जवाब प्रस्तुत नहीं करने पर प्राधिकारी द्वारा आवेदन रद्द कर दिया जाएगा और आवेदक को रद्द करने के कारणों के बारे में सूचित किया जाएगा।

(5) इस प्रयोजनार्थ अनुज्ञप्ति प्राधिकारी आवेदक को सूचित करेगा औरई-औषधि (www.e-aushadhi.gov.in) पोर्टल के माध्यम से आवेदन पर कार्रवाई की जाएगी।

18. नियम 85ड.घ के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:--

"85ड.घ —रद्द होने के पश्चात पुन: आवेदन – यदि आवेदक अनुज्ञप्ति अथवा उत्तम विनिर्माण पद्धतियों के लिए प्रमाण-पत्र, जैसा भी मामला हो, के लिए किसी आवेदन के रद्द होने के छ माह की अवधि के भीतर अनुज्ञप्ति प्राधिकारी को सूचित करता है कि निर्धारित शर्तें पूरी कर ली गई हैं और एक हजार रूपए का निरीक्षण शुल्क जमा कर देता है, तब अनुज्ञप्ति प्राधिकारी द्वारा पुन: निरीक्षण कर लिए जाने पर वह इससे संतुष्ट होता है कि अनुज्ञप्ति अथवा प्रमाण पत्र प्रदान करने की शर्तों को पूरा कर लिया गया है तो वह इस भाग के तहत अनुज्ञप्ति अथवा प्रमाणपत्र जारी करेगा।"

19. नियम 85च के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:--

"85च.-अनुज्ञप्ति की अवधि — (1) प्रपत्र 25ग में जारी अनुज्ञप्ति अनंतकाल तक वैध बनी रहेगी।

परंतु, अनुज्ञप्तिधारी अनुज्ञप्ति की शर्तों और औषधि एवं प्रसाधन सामग्री अधिनियम के उपबंधों और नियमों के अनुपालन की स्वत:घोषणा, प्रपत्र 25ग में अनुज्ञप्ति जारी होने की तारीख से अथवा पिछली स्वत:घोषणा की प्रस्तुति की तारीख, जो भी मामला हो, प्रत्येक तीन वर्ष में प्रस्तुत करेगा।

यह भी कि, इस प्रकार की स्वत:घोषणा, प्रपत्र 25ग में अनुज्ञप्ति के जारी होने की तारीख से अथवा पिछली स्वत:घोषणा की प्रस्तुति की तारीख से, जो भी मामला हो, तीन वर्ष की समाप्ति के एक माह के भीतर प्रस्तुत की जाएगी, और इस प्रकार की स्वत:घोषणा के प्रस्तुत न किए जाने पर, अनुज्ञप्ति निरस्त समझी जाएगी।"

20. नियम 85छ विलोपित किया जाएगा।

21. नियम 157 में

(i) उप खंड (1 क) में, "अनुसूची-न के अनुभाग" शब्दों के लिए "अनुसूची-न,के अनुसार,स्तर (क) एक सूक्ष्म उद्यम के लिए, जहां प्लांट और मशीनरी या उपकरण में निवेश एक करोड़ रुपये से अधिक नहीं है और टर्नओवर पांच करोड़ रुपये से अधिक नहीं है और एक छोटे उद्यम के लिए जहां प्लांट और मशीनरी या उपकरण में निवेश दस करोड़ रूपए से अधिक नहीं है और टर्नओवर पचास करोड़ रुपये से अधिक नहीं है; स्तर (ख) ऐसेउद्यम के लिए जहां संयंत्र और मशीनरी या उपकरण में निवेश दस करोड़ रुपये से अधिक है और टर्नओवर पचास करोड़ रुपये से अधिक है",शब्दों को प्रतिस्थापित किया जाएगा।

(ii) उप खंड (2)(ख) विलोपित किया जाएगा।

(iii) उप खंड (2) (ग) निम्निलिखित से प्रतिस्थापित किया जाएगा, नामत: - "(ख) केंद्र सरकार द्वारा मान्यता प्राप्त विश्वविद्यालय के फार्मेसी (आयुर्वेद या सिद्ध या यूनानी) या फार्मास्युटिकल रसायन विज्ञान में स्नातक और एक अनुज्ञप्तिप्राप्त विनिर्माण इकाई या एमडी रस-शास्त्र/भैषज्य कल्पना/औषधीय पादप/द्रव्यगुण/सईदला/गुणपदम में आयुर्वेद, सिद्ध, यूनानी दवाओं के निर्माण में कम से कम तीन वर्षों का अनुभव।

(iv) उप खंड (2)(घ) विलोपित किया जाएगा।

(v) उप खंड (2)(ङ) विलोपित किया जाएगा।

22. नियम 157क में

i. "आयुर्वेद, सिद्ध और यूनानी औषधि के राज्य अनुज्ञप्ति अधिकारी को और" शब्दों को विलोपित किया जाएगा।

ii. प्रथम परंतुक के पश्चात निम्नलिखित परंतुक अंतर्स्थापित किया जाएगा, अर्थात:-

"(ii) विनिर्माताओं/किसान जो खेती की उपज को पृथक रूप से घोषित करना चाहते हैं वे निम्नलिखित दो प्रतिक्रियाओं में से एक को अपना सकते हैं:

(क) वे राष्ट्रीय औषधीय पादप बोर्ड द्वारा समय-समय पर प्रकाशित कृषि तकनीकों के आधार पर खेती के क्षेत्र और अनुमानित उपज के अनुसार www.echarak.inपोर्टल पर विशेष औषधीय पादपों की खेती (कच्ची सामग्री की कटाई हेतु) पूर्व पंजीकरण करा सकते हैं। ऐसे आवेदनों के मामलों में राष्ट्रीय औषधीय पादप बोर्ड अपने मूल्यांकन दल के माध्यम से ई-चरक पोर्टल द्वारा ऑनलाइन आवेदन के आधार पर किसानों/किसान उत्पादक संगठनों/समूहों/ गैर-सरकारी संगठनों/स्व-सहायता समूहों/शीघ्र चालित उपभोक्ता वस्तुओं के विनिर्माताओं को एक प्रमाण पत्र जारी करेगा।

(ख) जो लोग खेती शुरू करने से पूर्व राष्ट्रीय औषधीय पादप बोर्ड अथवा राज्य औषधीय पादप बोर्ड या क्षेत्रीय सह सुविधा केंद्र में प्रमाणीकरण हेतु पंजीकृत नहीं हैं वे फसल कटाई से पूर्व संलग्नक में टीए प्रपत्र के लिए खेती/मूल उत्पादन हेतु प्रमाण पत्र के लिए आवेदन करें।

उपरोक्त शर्तों में से किसी एक का भी अनुपालन करने में विफल रहने पर किसी भी सामग्री को निकाली गई कच्ची सामग्री के रूप में माना जा सकता है और उसमें जैविक विविधता अधिनियम, 2002 के प्रावधानों के अनुसार लाभ सहभाजन में भागीदारी का मामला बन सकता है।

खेती/मूल उत्पादन का प्रमाणपत्र उन अधिकारियों द्वारा जारी किया जाएगा जो राष्ट्रीय औषधीय पादप बोर्ड अथवा क्षेत्रीय सह सुविधा केंद्र या राष्ट्रीय औषधीय पादप बोर्ड द्वारा समय-समय पर निर्णित किसी मनोनीत अधिकारी द्वारा नामित किए गए हों।

23. नियम 158 (ख)

i. उप नियम 1(क) में "पहली अनुसूची में निर्दिष्ट आयुर्वेदिक, सिद्ध और यूनानी चिकित्सा पद्धति", शब्दों के लिए निम्नलिखित शब्द रखे जाएंगे - "पहली अनुसूची विनिर्माण के पारंपरिक तरीकों का उपयोग करके या आधुनिक उपकरण/मशीनरी का उपयोग करके। प्रौद्योगिकी हस्तांतरण की विधियाँ नए अनुज्ञप्ति आवेदन के समय या मौजूदा अनुज्ञप्ति की अवधि के जारी रखने के समय टिप्पणी के रूप में मूल ग्रंथों से कोई विचलन न होने के प्रमाण स्वरूप प्रदान की जाएं;

उप नियम 1 (क) में निम्नलिखित खंड अत:स्थापित किया जाए नामत:-

"(i.) प्रथम अनुसूची की प्रामाणिक पुस्तकों में उल्लिखित आयुर्वेद, सिद्ध एवं यूनानी (एएसयू) औषधियों के अवयवों की दो श्रेणियां है अर्थात, कच्ची जड़ी बूटियां/कच्ची सामग्री; और मध्यस्थ/मूल्य वर्धित उत्पाद/अर्क/ वाष्पशील तेल/निश्चित तेल आदि।

क. कच्चा माल - कच्चा माल वह पादप, खनिज/धातु या पशु सामग्री है, जिसे काटकर अथवा एकत्र कर धुलाई, सफाई करने, चूर्ण बनाने की प्रक्रियाओं को छोड़कर अन्य प्रक्रियाओं के बगैर नुस्खे में प्रयोग किया जाता है।

ख. मध्यस्थ/मूल्य वर्धित उत्पाद/अर्क/वाष्पशील तेल/फिक्स्ड तेल - अर्ध संसाधित कच्ची सामग्री या संसाधित कच्ची सामग्री होती हैं जिन्हें भौतिक रूप से कच्ची सामग्री से पहचाना नहीं जाता है। निम्नलिखित उदाहरण हैं –

(i) आंवला पिट्टी, क्वाथ और प्रक्षेपा चूर्ण तीन अलग-अलग मध्यस्थ हैं जो आधार के रूप में शर्करा के साथ च्यवनप्राश में जाएंगे। आसवरिष्ट और घृत-तैल प्रारूप में भी 2-3 चरणों में समान मध्यस्थ होते हैं।

(ii) कपूर, कत्था, कन्यासार, लवंग तैल, चंदन तैल, तिल का तैल, चुलमोगरा तैल आदि वीएपी, वाष्पशील तेल और स्थिर तेलों के उदाहरण हैं।

(iii) जहाँ भी, पारंपरिक विधि में औषध घन/रसक्रिया या क्षीरपाक या तैल-घृत का उपयोग किया जाता है, उन्हें पारंपरिक जल अर्क या पारंपरिक दुग्ध-अर्क या पारंपरिक पायस अर्क के रूप में पहचाना जा सकता है। इन्हें अलग से मध्यस्थ/मूल्य वर्धित उत्पाद/अर्ध-संसाधित तैयार माल के रूप में माना जाएगा।"

ii. उप नियम 1(ख) के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत:-

"(ख)पेटेंट और सांपत्तिक आयुर्वेद, सिद्ध, यूनानी औषधियां जो धारा 3 (ज) (i) के तहत परिभाषित हैं और निम्नलिखित उपप्रकारों में भी-

i.) **कच्ची सामग्री** - कोई भी पादप सामग्री जिसकी कटाई की जाती है और धुलाई, सफाई करने और चूर्णआदि बनाने को छोड़करअन्य प्रक्रियाओं के बगैर नुस्खे में उपयोग की जाती है।

ii.) **मध्यस्थ/मूल्य वर्धित उत्पाद/अर्क/वाष्पशील तेल/निश्चित तेल** - अर्ध संसाधित कच्ची सामग्री या संसाधित कच्ची सामग्री जो भौतिक रूप से कच्ची सामग्री से पहचानी नहीं जाती है। ये विलायक या सुपर-क्रिटिकल निष्कर्षण या अनुसंधान के माध्यम से यथा विकसित किसी अन्य नई विधि का उपयोग करके बनाए गए अर्क हो सकते हैं।

iii.) **औषध घन (औषधीय पादप अर्क- सूखा/गीला)** अर्क या तो पादप से प्राप्त किया जाता है जिसका उल्लेख अधिनियम की पहली अनुसूची की पुस्तकों में किया गया है या पीसीआईएम और या एएसयूडीटीएबी द्वारा अनुमोदित जड़ी बूटी से प्राप्त किया जाता है।

किंतु प्रपत्र 26ङ -1 के तहत जारी वैध जीएमपी प्रमाणपत्रधारी फार्मेसी के लिए मध्यस्थ/मूल्यवर्धित उत्पाद/अर्क/वाष्पशील तेल/निश्चित तैल की तैयारी के मामले में, प्रपत्र 25 घ या 25 ङ के तहत अनुज्ञप्ति की

आवश्यकता नहीं होगी। ऐसे निर्माता अनुज्ञप्ति प्राधिकरण में स्वैच्छिक पंजीकरण सुनिश्चित करेंगे।"

iii. उप नियम ।। (क) के तहत तालिका में कॉलम 2 पंक्ति 4 में,"में उल्लिखित" शब्दों के बाद "धारा शब्दों को अंत:स्थापित किया जाएगा।

iii. उपनियम ।। (ख) के तहत तालिका के लिए निम्नलिखित को प्रतिस्थापित किया जाएगा-

"क्र.सं.	श्रेणी	अवयव	संकेत	सुरक्षा अध्ययन	प्रभावशीलता का अनुभव/साक्ष्य
1	2	3	4	5	6
					प्रभावशीलता या प्रमाण
1	(क) नियम 158 ख और अधिनियम की धारा 3 (ज) (झ) में उल्लिखित पेटेंट या साम्पत्तिक औषधि	अधिनियम की पहली अनुसूची की पुस्तकों से अवयवों	एक, दो या तीन अवयव मिश्रण/संयोजन के लिए पाठीय मूलाधार	एक, दो या तीन अवयव मिश्रण/संयोजन के लिए आवश्यक नहीं	एक, दो या तीन अवयव मिश्रण/संयोजन	(आयुष मंत्रालय द्वारा जारी दिशानिर्देश; या ओईसीडी दिशानिर्देशोंके अनुसार पूर्व-नैदानिक या नैदानिक अध्ययन)
2	(ख) अधिनियम, की अनुसूची ङ (1) की आयुर्वेद, सिद्ध और यूनानी अवयवों के साथ पेटेंट या साम्पत्तिक औषधि	अधिनियम, की अनुसूची ङ(1) अवयव	पाठीय मूलाधार	प्रकाशित साहित्य उपलब्ध न होने पर अपेक्षित अनुसूची ङ (1) अवयवों की 90 से 180 विषाक्तता न्यूनतम है। ओईसीडी दिशानिर्देशों का अनुपालन करते हुए तीव्र और/या पुरानी विषाक्तता अध्ययनों के परिणाम के आधार पर विशेष	प्रकाशित साहित्य उपलब्ध न होने पर आवश्यक	प्रकाशित साहित्य उपलब्ध न होने पर अपेक्षित। (आयुष मंत्रालय द्वारा जारी दिशानिर्देश; या ओईसीडी दिशानिर्देश के अनुसार नैदानिक अध्ययन;)

				विषाक्तता अध्ययन उपलब्ध किए जा सकते हैं।		
3	(ग) पेटेंट या साम्पत्तिक औषधि, नए खुराक रूपों या नए अवयवों या नए संकेतों के साथ, अधिनियम की प्रथम अनुसूची की पुस्तकों से आयुर्वेद, सिद्ध और यूनानी अवयवों के साथ **	अधिनियम की प्रथम अनुसूची की पुस्तकों से अवयव कोई भी नया अवयव जो पीसीआईएम और एच और/या एएसयूडीटीएवी द्वारा स्वीकार किया जाता है।	नया संकेत	प्रकाशित साहित्य उपलब्ध न होने पर अपेक्षित ङ-(1) अवयवों की 90 से 180 विषाक्तता न्यूनतम है। ओईसीडी दिशानिर्देशों का अनुपालन करते हुए तीव्र और/या पुरानी विषाक्तता अध्ययनों के परिणाम के आधार पर विशेष विषाक्तता अध्ययन उपलब्ध किए जा सकते हैं।	प्रकाशित साहित्य उपलब्ध न होने पर आवश्यक	प्रकाशित साहित्य उपलब्ध न होने पर अपेक्षित। (आयुष मंत्रालय द्वारा जारी दिशानिर्देश; या ओईसीडी दिशानिर्देश; के अनुसार नैदानिक अनुसंधान।

स्पष्टीकरण-इस नियम के प्रयोजनार्थ

1) **'नया खुराक रूप'**,मौजूदा फॉर्मुलरी या फार्माकोपिया (पैरेंटेलर्स को छोड़कर) के तहत शामिल किए गए किसी भी खुराक रूपसेअभिप्रेत है।

2) **'नया अवयव'**, ऐसे किसी भी अवयव से अभिप्रेत है जो प्रथम अनुसूची की पुस्तकों का हिस्सा नहीं है, किंतु आयुष पद्धतियों के पंजीकृत चिकित्साभ्यासियों द्वारा अभ्यास/अनुशंसित किया जा रहा है जिसकी बाद में पीसीआईएम और एच और/या एएसयूडीटीएबी द्वारा पुनरीक्षा की जाती है।

3) **'नया संकेत'**,किसी भी ऐसे संकेत से अभिप्रेत है जिसका उल्लेख प्रथम अनुसूची की पुस्तकों में या तो एकल अवयव के लिए या अवयवों के समूह के लिए नहीं किया गया है।

V. आयुष घन/औषधीय पादप अर्क (सूखा अथवा गीला) के संबंध में पंजीकरण हेतु।

क्र.सं.	श्रेणी	अवयव	संकेत
1	2	3	4
1	(ए) जलीय	ग्रंथ के अनुसार	ग्रंथ के अनुसार
2	(ए-आई)	ग्रंथ के अनुसार नया	नया संकेत
3	(बी) हाइड्रो-एल्कोहॉलिक	ग्रंथ के अनुसार नया	ग्रंथ के अनुसार
4	(बी- I) हाइड्रो- एल्कोहॉलिक	यथा विनिर्दिष्ट	नया संकेत
5	(सी) अन्य विलायक अर्क	यथा विनिर्दिष्ट	ग्रंथ के अनुसार
6	(ग-I) अन्य विलायक अर्क	यथा विनिर्दिष्ट	नया संकेत
7	सुपरक्रिटिकल अर्क आदि	यथा विनिर्दिष्ट	ग्रंथ के अनुसार
8	सुपरक्रिटिकल अर्क आदि	यथा विनिर्दिष्ट	नया संकेत "

24. नियम 160क के स्थान पर निम्नलिखित नियम रखा जाएगा, नामत: -

"160क आयुर्वेदिक, सिद्ध और यूनानी दवाओं की बिक्री के लिए विनिर्माण हेतु विज्ञप्तिधारियों की ओर से उनके विनिर्माण में उपयोग की जाने वाली आयुर्वेदिक, सिद्ध और यूनानी औषधियों और कच्चे माल पर परीक्षण करने के लिए संस्थाएं। ऐसे सभी संस्थानों, जिनके पास गुणवत्ता नियंत्रण अनुभाग हेतु आवश्यक सुविधाएं हैं, जैसा कि अनुसूची-न के तहत यथानिर्धारित हैं और जो आयुर्वेद, सिद्ध और यूनानी औषधियों तथा कच्ची सामग्री की शक्ति की पहचान, शुद्धता, गुणवत्ता हेतु रासायनिक और जैविक परीक्षण की श्रेणी के लिए राष्ट्रीय परीक्षण और अंशांकन प्रयोगशाला प्रत्यायन बोर्ड (एनएबीएल) द्वारा मान्यता प्राप्त हैं,को केंद्र सरकार द्वारा इस नियम के प्रयोजनार्थ अनुमोदित औषधि परीक्षण प्रयोगशालाओं के रूप में अधिसूचित किया जाएगा।

किंतु यह नियम प्रपत्र 48 के तहत अनुमोदित प्रयोगशालाओं के लिए उक्त नियमों की अधिसूचना की तारीख से दो साल के भीतर या प्रपत्र 48 के अगले नवीनीकरण की तारीख से, जो भी पहले हो, लागू होगा।"

25. नियम 160 ख से ञ विलोपित किए जाएंगे।

26. नियम 161 ख के उप नियम (2) में-

(i) "वास्तविक समय" शब्दों के स्थान पर "वास्तविक समय और त्वरित" शब्द रखे जाएंगे।

(ii) निम्नलिखित उपबंध जोड़ जाएगा अर्थात- "अनुज्ञप्तिधारी जो 1-2 साल के शैल्फलाइफ का दावा करना चाहते हैं, वे अनुज्ञप्ति हेतु आवेदन के समय या मौजूदा अनुज्ञप्ति के जारी रखने के समय 3 महीने या 6 महीने के लिए बढ़ाया गया स्वामित्व प्रस्तुत कर सकते हैं।

27. नियम162क के बाद निम्निलखित नियम जोड़े जाएंगे अर्थात-

"162-कक नियंत्रण प्राधिकारी - (1)केंद्र सरकार द्वारा नियुक्त सभी निरीक्षक, केंद्र सरकार द्वारा इस संबंध में नियुक्त एक अधिकारी के नियंत्रण में होंगे।

(2) राज्य सरकार द्वारा नियुक्त सभी निरीक्षक, राज्य सरकार द्वारा इस संबंध में नियुक्त एक अधिकारी के नियंत्रण में होंगे।

(3) इन नियमों के प्रयोजनार्थ उप-नियम (1) के तहत केंद्र सरकार द्वारा नियुक्त एक अधिकारी, या जैसा भी मामला हो, उप-नियम (2) के तहत राज्य सरकार द्वारा नियुक्त एक अधिकारी, नियंत्रण प्राधिकारी होगा।

162.कख:नियंत्रण प्राधिकारी की योग्यता - (1)कोई व्यक्ति अधिनियम के तहत नियंत्रण प्राधिकारी बनने के लिए तभी योग्य होगा जब वह -

(i) केंद्र सरकार द्वारा मान्यता प्राप्त विश्वविद्यालय के फार्मेसी (आयुर्वेद या सिद्ध या यूनानी) या फार्मास्युटिकल केमिस्ट्री में स्नातक होने के साथ औषधि निर्माण या परीक्षण या अधिनियम के प्रावधानों के प्रवर्तन का कम से कम पांच साल का अनुभव रखता हो या

(ii) रस-शास्त्र/भैषज्य कल्पना/द्रव्यगुण/सयदला/गुणपदम/औषधीय पादर्पोमें एमडी होने के साथ औषधि विनिर्माण या परीक्षण में या अधिनियम के प्रवर्तन का कम से कम तीन साल का अनुभव रखता हो"।

28. नियम 168 के तहत तालिका में,"12%" शब्द के स्थान पर "11.40 %" शब्द रखा जाएगा।

29. नियम 170 विलोपित किया जाएगा।

30. प्रपत्र 20ग में, i. परन्तुक 1 में "थोक द्वारा" शब्दों को विलोपित किया जाएगा।

ii. परन्तुक 2 में "को ....." शब्दों को विलोपित किया जाएगा।

iii. अनुज्ञप्ति की शर्त के तहत परन्तुक 3 को विलोपित किया जाएगा।

31. प्रपत्र 20घ में, परन्तु 2 में,"को ....." शब्दों को विलोपित किया जाएगा।

32. प्रपत्र 20ङ को विलोपित किया जाएगा। .

33. प्रपत्र 24ग के स्थान पर निम्नलिखित को रखा जाएगा, अर्थात-

"प्रपत्र 24ग

(नियम 85ख देखें)

होम्योपैथी औषधों की बिक्रयार्थ या वितरणार्थ विनिर्माण हेतु अनुज्ञप्ति प्रदान करने के लिए आवेदन

1.

मैं/हम*.....निवासी.....एतद्वारा..... ..... में स्थित परिसर में निम्नलिखित होम्योपैथी मदर टिंक्चर्स/पेटेंट मिश्रण के विनिर्माण हेतु अनुज्ञप्ति प्रदान करने के लिए आवेदन करता हूँ/करते हैं।

होम्योपैथी मिश्रणों का नाम.....(प्रत्येक मद पृथक रूप से स्पष्ट की जाए)

2. होम्योपैथी औषधों के विनिर्माण और परीक्षण हेतु नियोजित तकनीकी कर्मचारीवृंद के नाम, योग्यताएं और अनुभव .....

3. .....लेखाशीर्ष के तहत.....रू. का शुल्क सरकार के खाते में जमा करा दिया गया है।

दिनांक..... हस्ताक्षर.....

टिप्पण 1. जो हिस्सा लागू न हो उसे काट दें।

2.आवेदन के साथ परिसर के नक्शे की प्रति संलग्न होनी चाहिए"

34. प्रपत्र 25ग के स्थान पर निम्नलिखित रखा जाएगा, अर्थात्-

"प्रपत्र 25ग

(नियम 85घ देखें)

होम्योपैथी औषधों की विक्रयार्थ या वितरणार्थ विनिर्माण हेतु अनुज्ञप्ति प्रदान करने के लिए

अनुज्ञप्ति की संख्या और जारी करने की तारीख.....

1. .....को एतद्वारा निम्नलिखित सक्षम तकनीकी कर्मचारीवृंद के निर्देशन और पर्यवेक्षण में.....स्थित परिसर में निम्नलिखित होम्योपैथी मदर टिंक्चर्स/पेटेंट तथा अन्य मिश्रणों के विनिर्माण हेतु अनुज्ञप्त किया जाता है:-

होम्योपैथी मिश्रणों का नाम.....(प्रत्येक मद पृथक रूप से स्पष्ट की जाए)

तकनीकी कर्मचारीवृंद का नाम.....

2. अनुज्ञप्ति,.....जारी होने की तिथि से प्रभावी होगी।

3. अनुज्ञप्ति, नीचे दी गई शर्तों तथा ऐसी अन्य शर्तों, जो औषधि और प्रसाधन सामग्री अधिनियम, 1940 के तहत फिलहाल लागू नियमों में विनिर्दिष्ट की जाएं, के अधीन है।

दिनांक..... हस्ताक्षर .....

पदनाम .....

विज्ञप्ति की शर्तें

1. विज्ञप्ति में नामित तकनीकी कर्मचारियों में कोई भी परिवर्तन विज्ञप्ति प्राधिकारी को सूचित किया जाएगा।
2. इस विज्ञप्ति को ऐसी अतिरिक्त वस्तुओं तक विस्तारित करने के लिए समझा जाएगा, जैसा कि विज्ञप्तिधारक समय-समय पर विज्ञप्ति प्राधिकारी को सूचित कर सकता है, और जैसा कि विज्ञप्ति प्राधिकारी द्वारा समर्थन किया जा सकता है।
3. विज्ञप्तिधारक विज्ञप्ति के तहत काम कर रही फर्म के गठन में किसी भी बदलाव की स्थिति में लिखित रूप में विज्ञप्ति प्राधिकारी को सूचित करेगा। जहां फर्म के गठन में कोई भी बदलाव होता है, वर्तमान विज्ञप्ति परिवर्तन की तारीख से अधिकतम तीन महीने के लिए वैध मानी जाएगी, जब तक कि इस बीच पुनर्गठन के साथ फर्म के नाम पर विज्ञप्ति प्राधिकारी से नई विज्ञप्ति नहीं ली गई हो।
4. विज्ञप्ति जब तक निलंबित या रद्द नहीं की जाती है, स्थायी रूप से वैध रहेगी। हालाँकि, विज्ञप्ति की शर्तों के अनुपालन और औषधि एवं प्रसाधन सामग्री अधिनियम 1940 (1940 का 23) और औषधि एवं प्रसाधन सामग्री नियमावली, 1945 के प्रावधानों का तीन साल में कम से कम एक बार या जोखिम आधारित दृष्टिकोण के अनुसार आवश्यकतानुसार मूल्यांकन किया जाएगा।
5. औषधि एवं प्रसाधन सामग्री नियमावली, 1945 की अनुसूची-न में यथानिर्धारित होम्योपैथी औषधों के अच्छे विनिर्माण अभ्यासों (जीएमपी) की अपेक्षाओं को पूरा करने के बाद ही विज्ञप्ति जारी की जाती है"।

35. प्रपत्र 25ङ. के स्थान पर निम्नलिखित रखा जाएगा, अर्थात-

36. अनुसूची-न में, i. पैरा 1,"जैसा कि भाग I और भाग II में उल्लिखित है" शब्दों के स्थान पर "जैसा कि स्तर क और स्तर

ख के भाग I और भाग II, जैसा भी मामला हो, में उल्लिखित है" शब्दों को रखा जाएगा।

ii. "भाग I" शब्दों के स्थान पर "भाग I स्तर क" शब्दों को रखा जाएगा।

iii. "भाग II" शब्दों के स्थान पर "भाग II स्तर क" शब्दों को रखा जाएगा।

iv. अनुसूची न की अंतिम टिप्पणी के बाद निम्नलिखित जोड़ा जाएगा, अर्थात्-

"भाग I स्तर ख

परिसर और सामग्री

1. सामान्य अपेक्षाएं:-

1.1स्थान और परिवेश- कारखाने का भवन ऐसे स्थान पर और इस तरह निर्मित होगा कि उसे बाहरी वातावरण से संदूषित होने का खतरा न हो, जिसमें खुला सीवरेज, नाली, सार्वजनिक शौचालय, ऐसा कोई कारखाना जो असहनीय या अप्रिय गंध या धुआं या अत्यधिक कालिख, धूल, धुआं, रासायनिक या जैविक उत्सर्जन करता हो, शामिल हैं।

1.2 भवन और परिसर-कारखाने हेतु प्रयुक्त भवन ऐसा होगा जिसमें स्वच्छ परिस्थितियों में दवाओं का निर्माण हो सके और वह मकड़-जाल और कीड़ों/कृन्तकों से मुक्त हो। इसमें प्रकाश और वेंटिलेशन का पर्याप्त प्रावधान होना चाहिए। फर्श और दीवारों को सीलन/नमी रहित होना चाहिए।

विनिर्माण, प्रसंस्करण, भंडारण, पैकेजिंग, लेबलिंग और परीक्षण परियोजनार्थ इस्तेमाल किए जाने वाला परिसर–

(I) अन्य विनिर्माण परिचालनों के अनुकूल होगा जो उसी या समीपवर्ती परिसर में किए जाएं।

(II) मशीन और उपकरण कम से कम 1.5 मीटर की दूरी पर होने चाहिए, ताकि उपकरण, सामग्री व्यवस्थित और सही ढंग से रखी जा सके और कार्मिकों की आवाजाही बनी रहे,जिससे कि:

(क) विभिन्न श्रेणी की दवाओं या कच्चे माल, मध्यस्थ सामग्री और प्रसंस्करण प्रक्रियाधीन सामग्री के आपस में मिल जाने के जोखिम से बचा जा सके;

(ख) उपयुक्त व्यवस्था कराकर संदूषण और प्रतिसंदूषण की संभावनाओं से बचा जा सके;

(III) परिसर का इस तरह से डिज़ाइन और निर्माण और रख-रखाव किया जाएगा कि उसमें कीड़ों, कीटों, पक्षियों, कीड़े-मकोड़ों और कृन्तकों का प्रवेश न हो सके। आंतरिक सतह (दीवारें, फर्श और छत) चिकनी और दरारों से मुक्त होंगी और उनकी आसानी से सफाई, पेंटिंग हो सके और उन्हें संक्रमणरहित बनाया जा सके।

(IV)संचालन कार्यों और बनाई जा रही विभिन्न खुराकों के लिए, जहां पर्यावरणीय कारकों को नियंत्रित करने के लिए निर्धारित किया गया हो, वहां परिसर वातानुकूलित होगा। उत्पादन और वितरण क्षेत्र भली-भांति प्रकाशयुक्त, हवादार होगाऔर प्रभावी वायु नियंत्रण सुविधाएं (जहां लागू होंगी) और तापमान तथा आद्रता (जहां आवश्यक हो) सहित परिस्थितियों को बनाए रखने के लिए समुचित वायु हैंडलिंग इकाइयां (जहां भी लागू होंगी) होंगी जैसा कि संगत उत्पाद के लिए विनिर्दिष्ट किया गया हो। ये परिस्थितियां दवाओं और औषधियों की श्रेणी और संचालन की प्रकृति के लिए उपयुक्त होनी चाहिए। ये परिस्थितियाँ बाहरी वातावरण के संबंध में सुरक्षात्मक वस्त्रों, उत्पादों को संभालने और उनके बीच काम करने वाले कर्मियों की सुविधा के लिए भी उपयुक्त होनी चाहिए। इन क्षेत्रों की, अपेक्षित विनिर्देशों के अनुपालन के लिए नियमित रूप से निगरानी की जाएगी;

(V) प्रसंस्करण क्षेत्र में उचित जल निकासी प्रणाली की व्यवस्था होगी। विनिर्माण क्षेत्र में सैनिटरी फिटिंग और इलेक्ट्रिकल फिक्सचर्स उचित और पर्याप्त आकार के होंगे और ऐसे डिज़ाइन किए गए होंगे कि परिसर में वापस प्रवाह और/या कीड़ों और कृन्तकों के प्रवेश को रोका जा सके।

(VI)फर्नेस/भट्टी खंड को उचित वातायन के साथ टिन की छत के साथ कवर किया जा सकता है, किंतु मक्खियों और धूल को रोकने का पर्याप्त ध्यान रखा जाना चाहिए।

(VII) अग्नि सुरक्षा उपायों और उचित निकास द्वारों की व्यवस्था होनी चाहिए।

(VIII) सुखाने की जगह:- कच्चे माल को सुखाने के लिए और प्रक्रियाधीन दवाओं, जिन्हें पैकिंग से पहले सुखाने की आवश्यकता होती है, के लिए अलग जगह की जरूरत होती है। इस जगह की उचित फ्लोरिंग की जाएगी, खिड़की पर तार जाली और कांच के पैनल या अन्य सामग्री लगाई जाएगी ताकि मक्खियों/कीड़ों/धूल आदि से बचाव किया जा सके और साथ ही उसकी आसानी और सही ढंग से साफ-सफाई हो सकेगी तथा उसे संक्रमणरहित बनाया जा सकेगा।

(IX)आयुर्वेद, सिद्ध और यूनानी औषधियों के विनिर्माण के अलावा किसी अन्य उद्देश्य के लिए एक ही निर्माण सुविधा/स्टोर का उपयोग नहीं किया जाएगा।

1.3 जल प्रणाली–स्वयं या किसी अन्य स्रोत से प्राप्त पानी के उपचार के लिए मान्य प्रणाली होगी, जिससे पानी को भारतीय मानक ब्यूरो या स्थानीय नगर पालिका, जैसा भी मामला हो, द्वारा विनिर्दिष्ट मानकों के अनुसार पेय योग्य बनाया जा सके और भेषजसंहिता विनिर्देश के अनुरूप शुद्ध जल का उत्पादन किया सके। इस तरह उत्पादित जल का उपयोग, धुलाई और सफाई कार्यों, जिनमें पीने योग्य पानी का उपयोग किया जा सकता है, को छोड़कर सभी कार्यों के लिए उपयोग किया जाएगा। पानी को ऐसी टंकियों में संग्रहित किया जाएगा, जिनसे पानी की गुणवत्ता पर प्रतिकूल प्रभाव न पड़े और सूक्ष्मजीवी न पनप सकें। टंकियों को समय-समय पर साफ किया जाएगा और इस संबंध में अनुज्ञप्तिधारी द्वारा रिकॉर्ड रखा जाएगा।

1.4 अपशिष्ट का निपटान- निर्माण खंड और प्रयोगशालाओं से उत्पन्न अपशिष्ट जल और अवशेष, जिसका श्रमिकों या जन-स्वास्थ्य पर प्रतिकूल असर हो सकता है, कोपर्यावरण प्रदूषण नियंत्रण बोर्ड की अपेक्षाओं के अनुरूप निपटानकिया जाएगा।

2. भण्डारण क्षेत्र:-

2.1पर्याप्त मात्र में क्षेत्रों को इस तरह से डिजाइन किया जाएगा कि विभिन्न श्रेणियों की सामगरी और उत्पादों, जैसे कच्ची सामग्री और पैकेजिंग सामग्री, मध्यस्थ सामग्री, थोक और तैयारशुदा उत्पादों, संगरोध उत्पादों, निर्गत/रद्द, वापस किए गए या वापस मंगाए गए उत्पादों, मशीन और उपकरण स्पेयर पाट्र्स का पर्याप्त और व्यवस्थित ढंग से भंडारण हो सके।

2.2 भण्डारण क्षेत्रों को इस तरह डिजाइन और अनुकूलित किया जाएगा ताकि अच्छी परिस्थितियों में भंडारण सुनिश्चित हो सके। उन्हें तापमान की स्वीकार्य सीमा पर साफ, सूखा और संरक्षित रखा जाएगा। जहां भंडारण के लिए विशेष परिस्थितियों की आवश्यकता होती है (जैसे तापमान, आद्रता), वहांइनकी व्यवस्था की जाएगी और इसके लिए निगरानी और रिकॉर्ड रखा जाएगा। भंडारण क्षेत्रों में उचित रख-रखाव और कृंतक, कीट और कीड़े-मकोड़ों को नियंत्रित करने की व्यवस्था होगी और उसका रिकॉर्ड रखा जाएगा। सामग्री के भंडारण के लिए समुचित रैक, डिब्बे और प्लेटफॉर्म उपलब्ध कराए जाएंगे।

2.3 अभिग्राही और प्रेषण आलों से सामग्री और उत्पादों को मौसम की प्रतिकूल परिस्थितियों से बचाकर रखा जाएगा।

2.4 जहाँ एक ही गोदाम या स्टोर में अलग-अलग निर्धारित क्षेत्रों में भंडारण द्वारा संगरोध स्थिति सुनिश्चित की जाती है, वहां इन क्षेत्रों को स्पष्ट रूप से सीमांकित किया जाएगा। भौतिक संगरोध के स्थान पर किसी भी प्रणाली को उतना ही पृथक रखा जाएगा। इन क्षेत्रों में प्रवेश अधिकृत व्यक्तियों तक ही सीमित रहेगा।

2.5 कच्चे माल और अनुद्रव्यों के लिए भंडारण क्षेत्र में अलग नमूना क्षेत्र होगा यदि सक्रिय घटकों का नमूना कार्य किसी अन्य क्षेत्र में किया जाता है, तो यह ऐसे क्षेत्र में किया जाएगा जहां संदूषण, प्रतिसंदूषण और उत्पादों के आपस में मिलान से बचा जा सके।

2.6 अस्वीकृत, वापस मंगाए गए या लौटाई गई सामग्री या उत्पादों के भंडारण के लिए अलग स्थान प्रदान किया जाएगा। ऐसे क्षेत्रों, सामग्रियों या उत्पादों को उपयुक्त रूप से चिह्नित और सुरक्षित किया जाएगा। इन क्षेत्रों और सामग्रियों तक पहुंच प्रतिबंधित होगी।

2.7 अत्यधिक खतरनाक, जहरीली और विस्फोटक सामग्री जैसे जहरीली दवाओं और पदार्थों, जिनके दुरुपयोग किए जाने, आग या विस्फोट होने के जोखिम की संभावना हो, को सुरक्षित और निरापद क्षेत्रों में संग्रहित किया जाएगा। संबंधित नागरिक प्राधिकरण के नियमों के अनुरूप पर्याप्त अग्नि सुरक्षा के उपाय उपलब्ध कराए जाएंगे।

2.8 मुद्रित पैकेजिंग सामग्री सुरक्षित, अलग और निरापद क्षेत्र में संग्रहित की जाएगी।

2.9 रोगाणुरहित सामग्री का जर्महीन परिस्थितियों में नमूनाकरण और वितरण किया जाएगा और यहनिर्माण सुविधा के भीतर एक समर्पित क्षेत्र में किया जाएगा।

2.10 नियमित जांच की जाएगी ताकि यह सुनिश्चित किया जा सके कि कंटेनर के छलकाव, टूटन और रिसाव के लिए पर्याप्त कदम उठाए गए हैं।

2.11 कृंतक उपचार (कीट नियंत्रण) नियमित रूप से वर्ष में कम से कम एक बार किया जाना चाहिए और इसका रिकॉर्ड रखा जाना चाहिए।

2.12. कच्चे माल, मध्यस्थ सामग्री और तैयारशुदा माल के भंडारण कंटेनर, खाद्य ग्रेड/अभिक्रिया न करने वाली सामग्री के होंगे।

3. उत्पादन क्षेत्र:-

3.1 उत्पादन क्षेत्र इस तरह से डिजाइन किया जाएगा कि एक सार उत्पादन और सिलसिलेवार कार्यों का संचालन हो सके।

3.2 कार्य करने और इन-प्रोसेस की जगह पर्याप्त होनी चाहिए ताकि उपकरणों और सामग्री को व्यवस्थित ढंग से और सही स्थिति में रखा जा सके **(बीच में कम से कम 1.5 मीटर का अंतर)**और कर्मिकों की आवाजाही बनी रहे जिससे प्रति-संदूषण से बचा जा सके और किसी भी विनिर्माण और नियंत्रण उपायों की चूक या गलत अनुप्रयोग के जोखिम से बचा जा सके।

3.3 प्रति-संदूषण के जोखिम से बचने के लिए उत्पादन क्षेत्र धोने योग्य और स्वच्छ वायु प्रवाह के साथ होना चाहिए।

3.4 पाइप वर्क, विद्युत फिटिंग, वेंटिलेशन ओपनिंग और इसी तरह की सर्विस लाइनों को इस तरह डिजाइन स्थिर और निर्मित किया जाना चाहिए ताकि धूल का जमाव न हो सके। सेवा लाइनों को अधिमानतः रंगों से चिह्नित किया जाएगा और आपूर्ति की प्रकृति एवं प्रवाह की दिशा को चिह्नित/निर्दिष्ट किया जाएगा।

4. अनुषंगी क्षेत्र:-

4.1 विश्राम और जलपान कक्ष, स्टोर और उत्पादन क्षेत्रों से अलग होंगे। इन क्षेत्रों से होकर सीधे विनिर्माण और भंडारण क्षेत्रों तक नहीं पहुंचा जा सकेगा।

4.2 उपयोगकर्ताओं की संख्या को देखते हुए कपड़े बदलने, भंडारण करने और धोने और शौचालय के प्रयोजनों के लिए सुविधाएं आसानी से सुलभ और पर्याप्त होनी चाहिए। पुरुषों और महिलाओं के लिए अलग-अलग शौचालय, उत्पादन या भंडारण क्षेत्रों से सीधे नहीं जुड़े होंगे। ऐसे क्षेत्रों की नियमित सफाई और विसंक्रमण के लिए लिखित निर्देश होंगे और इसका रिकॉर्ड रखा जाएगा।

4.3 अनुरक्षण कार्यशालाएं उत्पादन क्षेत्रों से अलग और दूर होंगी। जब भी उत्पादन क्षेत्र में पुर्जे, बदले हुए पुर्जे और औजारों का भंडारण किया जाता है, तो उन्हें समर्पित कमरों या लॉकरों में रखा जाएगा। उपकरणों और स्पेयर पार्टस को रोगाणुरहित क्षेत्रों में उपयोग के लिए उत्पादन क्षेत्रों के अंदर ले जाने से पहले विसंक्रमित किया जाएगा।

5. गुणवत्ता नियंत्रण क्षेत्र:-

5.1 गुणवत्ता नियंत्रण - प्रत्येक विज्ञप्तिधारी को अपने परिसर में गुणवत्ता नियंत्रण अनुभाग के लिए सुविधा प्रदान करना आवश्यक है। गुणवत्ता नियंत्रण प्रयोगशालाएँ उत्पादन क्षेत्रों से स्वतंत्र होंगी। परीक्षण आयुर्वेद, सिद्ध और यूनानी फार्माकोपियल मानक के अनुसार होगा जिसमें माइक्रोबायोलॉजी, एफ्लाटॉक्सिन, हेवी मेटल्स, जैसा और जहां लागू हो, शामिल हैं। जहां फार्माकोपियल मानक उपलब्ध नहीं हैं, वहां परीक्षण निर्माताओं के विनिर्देश या उपलब्ध अन्य जानकारी के अनुसार किया जाना चाहिए, जिसे राज्य अनुज्ञप्ति प्राधिकारी द्वारा विधिवत सत्यापित किया जाएगा। गुणवत्ता नियंत्रण अनुभाग सभी कच्चे माल (पहचान और विश्लेषण) को सत्यापित करेगा, प्रक्रिया में गुणवत्ता जांच की निगरानी करेगा और तैयार माल की दुकान/गोदाम को जारी किए जाने वाले तैयार उत्पाद की गुणवत्ता को नियंत्रित करेगा। गुणवत्ता नियंत्रण अनुभाग में निम्नलिखित सुविधाएं होंगी: -

(I) गुणवत्ता नियंत्रण अनुभाग के लिए कम से कम 100 वर्ग फुट क्षेत्र होना चाहिए।

(II) कम से कम भौतिक-रासायनिक विश्लेषण के लिए तो सुविधा होनी चाहिए।

(III) सूक्ष्म जीव विज्ञान और अन्य मापदंडों के लिए परिष्कृत उपकरणों के विश्लेषण आदि के माध्यम से स्वयं के परिसर में या सरकार द्वारा अनुमोदित सार्वजनिक परीक्षण प्रयोगशाला के माध्यम से सुविधा प्रदान की जानी चाहिए।

(IV) प्रयोगशाला के डिजाइन में निर्माण सामग्री और वेंटिलेशन की उपयुक्तता को ध्यान में रखा जाएगा।माइक्रोबायोलॉजिकल और परिष्कृत उपकरणों के परीक्षण क्षेत्रों के लिए अलग एयर हैंडलिंग यूनिट और अन्य जरूरतें प्रदान की जाएंगी। प्रयोगशाला को सफाई और परीक्षण प्रयोजनों के लिए उपयुक्त गुणवत्ता के पानी की नियमित आपूर्ति की जाएगी।

(V) गुणवत्ता नियंत्रण प्रयोगशाला को अलग-अलग वर्गों में विभाजित किया जाएगा अर्थात भौतिक-रासायनिक, सूक्ष्म जीव विज्ञान और परिष्कृत उपकरणों के विश्लेषण के लिए। इसमें बुनियादी स्थापना और सहायक प्रयोजन के लिए पर्याप्त क्षेत्र होगा। सूक्ष्म जीव विज्ञान अनुभाग में जब भी आवश्यक समझा जाए, एयरलॉक और लैमिनर वायु प्रवाह कार्य केंद्र जैसी व्यवस्थाएं होंगी।

(VI) कच्ची दवाओं की पहचान के लिए संदर्भ पुस्तकें और संदर्भ नमूने रखे जाने चाहिए।

(VII) तैयार उत्पादों को सत्यापित करने के लिए, प्रत्येक पैक आकार के कम से कम तीन नमूनों को प्रत्येक बैच के तैयार उत्पादों के नियंत्रित नमूनों के रूप में उत्पाद की समाप्ति तिथि तक रखा जाएगा।

(VIII)) कच्चे माल, अर्ध-तैयार उत्पादों और तैयार उत्पादों को संग्रहीत करने वाली परिस्थितियों की पर्याप्तता की देख-रेख और निगरानी करना।

(IX) दवाओं की शेल्फ लाइफ और भंडारण जरूरतें स्थापित करने के लिए रिकॉर्ड रखा जाएगा।

(X) निर्माता जो पेटेंट और स्वामित्व आयुर्वेद, सिद्ध और यूनानी दवाओं का निर्माण कर रहे हैं, उन्हें ऐसी तैयार की गई दवाओं के संबंध में अपने स्वयं के विनिर्देश और नियंत्रण संदर्भ उपलब्ध करने होंगे, जिन्हें राज्य अनुज्ञप्ति प्राधिकारी द्वारा विधिवत सत्यापित किया जाएगा।

(XI) भारत सरकार द्वारा प्रकाशित आयुर्वेद, सिद्ध और यूनानी चिकित्सा पद्धतियों की संबंधित भेषजसंहिताओं में दिए गए पहचान, शुद्धता और ताकत के मानकों का अनुपालन किया जाएगा।

(XII) गुणवत्ता नियंत्रण अनुभाग में कम से कम पूर्णकालिक कर्मचारी होगा जो:-

(क) आयुर्वेद या सिद्ध या यूनानी चिकित्सा में विशेषज्ञ हो, जिसके पास भारतीय चिकित्सा केंद्रीय परिषद अधिनियम 1970 की अनुसूची II के तहत मान्यता प्राप्त डिग्री योग्यता है या किसी मान्यता प्राप्त विश्वविद्यालय द्वारा प्रदत्त फार्मेसी (आयुर्वेद/यूनानी) है;

(ख) केमिस्ट, जिसके पास किसी मान्यता प्राप्त विश्वविद्यालय द्वारा सम्मानित विज्ञान या फार्मेसी या फार्मेसी (आयुर्वेद या सिद्ध/यूनानी) में कम से कम स्नातक की डिग्री हो; तथा

(ग) वनस्पतिशास्त्री/भेषजज्ञ, जिसके पास कम से कम विज्ञान (चिकित्सा) या फार्मेसी या फार्मेसी (आयुर्वेद) में स्नातक की डिग्री या यूनानी फार्मेसी में डिप्लोमा/फार्मेसी में डिप्लोमा (आयुर्वेद) (कम से कम एक वर्ष के अनुभव के साथ) किसी मान्यता प्राप्त विश्वविद्यालय द्वारा प्रदान किया गया हो।]

(XIII) निर्माण इकाई में एक गुणवत्ता नियंत्रण अनुभाग होगा। वैकल्पिक रूप से, इन गुणवत्ता नियंत्रण प्रावधानों को आयुर्वेद, सिद्ध और यूनानी दवाओं के लिए किसी मान्यता प्राप्त प्रयोगशाला से, कुछ मानकों के लिए औषधि और प्रसाधन सामग्री अधिनियम के नियम 160-ए के तहत परीक्षण करवाकर, पूरा किया जाएगा। विनिर्माण कंपनी बाहरी मान्यता प्राप्त प्रयोगशाला से किए गए विभिन्न परीक्षणों के सभी रिकॉर्ड रखेगी। भौतिक रासायनिक मानकों के लिए गुणवत्ता नियंत्रण सुविधा और कुछ बुनियादी परीक्षण अनिवार्य हैं।

(XIV) वैकल्पिक रूप से, इन-हाउस गुणवत्ता नियंत्रण अनुभाग के लिए अनुशंसित उपकरणों की सूची,यूनिट सरकार द्वारा अनुमोदित प्रयोगशाला से कुछ मापदंडों का परीक्षण करवा सकती है।

(क)	रसायन शास्त्र अनुभाग	(ख)	फार्मेसी अनुभाग
1.	मद्य निर्धारण उपकरण (पूरा सेट)	1.	सूक्ष्मदर्शी दूरबीन
2.	वाष्पशील तेल निर्धारण उपकरण	2.	विच्छेदन सूक्ष्मदर्शी
3.	क्वथनांक निर्धारण प्रणाली	3.	प्रणाली से जुड़ा अनुसंधान इलेक्ट्रॉनिक माइक्रोस्कोप
4.	गलनांक बिंदु निर्धारण उपकरण	4.	माइक्रोटोम
5.	रेफ्रेक्टोमीटर	5.	स्टेज माइक्रोमीटर
6.	पॉलरीमीटर	6.	फिजिकल बैलेंस
7.	विस्कोमीटर	7.	कैमरा लुसिडा (प्रिज्म एंड मिरर टाइप)
8.	टेबलेट डिसइंटीग्रेशन अप्रेटस	8.	रसायन, डाई और रिजेंट्स आदि
9.	नमी मीटर	9.	स्लाइड्स और ग्लासवेयर
10.	मफल फर्नेस	10.	ट्रे ड्रायर
11.	इलेक्ट्रॉनिक संतुलन	11.	एल्यूमीनियम स्लाइड ट्रे
12.	मॅग्नेटिक स्टीरर	12.	ग्राइंडर मशीन
13.	हॉट एयर ओवन	13.	जूसर मशीन
14.	रेफ्रिजरेटर	14.	क्लीवेंजर अप्रेटस
15.	ग्लास/स्टील आसवन उपकरण	15.	सोक्शलेट अप्रेटस
16.	बर्नर के साथ एलपीजी गैस सिलेंडर	16.	सुपरक्रिटिकल फ्लुइड एक्सट्रैक्शन यूनिट
17	जल स्नान (तापमान नियंत्रित)	17.	परकोलेटर
18	हीटिंग मेंटल/हॉट प्लेट्स	18.	आवर्धक लेंस ग्लास 10x
19.	सभी एक्सेसरीज़ (मैनुअल) के साथ टीएलसी उपकरण	19.	विच्छेदन बॉक्स
20	एक्सेसरीज़ के साथ पेपर क्रोमैटोग्राफी उपकरण		
21.	सीव शेकर सहित 10 से 120 आकार की छलनी		

22.	सेंट्रीफ्यूज मशीन		
23.	डीह्यूमिडिफ़ायर		
24.	पीएच मीटर (डिजिटल)		
25.	लिमिट टेस्ट उपकरण (आर्सेनिक)		
26.	होमिजिनाइजर		
27.	डिसॉल्यूशन उपकरण		
28.	थर्मामीटर		
29.	स्टॉप वॉच		
30.	फिजिकल बैलेंस		
31.	डिजिटल वेइंग बैलेंस (मिलीग्राम में वजन)		
32.	माइक्रोनाइज़र		
33.	पेस्टल और मोर्टार		

6. गुणवत्ता नियंत्रण प्रणाली:- गुणवत्ता नियंत्रण नमूनाकरण, विनिर्देशों, परीक्षण, प्रलेखन, रिलीज प्रक्रियाओं से संबंधित होगा जो सुनिश्चित करता है कि आवश्यक और प्रासंगिक परीक्षण वास्तव में किए गए हैं और न तो सामग्री उपयोग के लिए जारी की जाती है, न ही उत्पाद बिक्री अथवा आपूर्ति के लिए तब तक जारी किए जाते हैं जब तक कि उनकी गुणवत्ता संतोषजनक न हो। यह प्रयोगशाला संचालन तक ही सीमित नहीं है बल्कि उत्पाद की गुणवत्ता से संबंधित सभी निर्णयों में शामिल होगा। यह सुनिश्चित किया जाएगा कि सभी गुणवत्ता नियंत्रण व्यवस्था प्रभावी ढंग से और विश्वसनीय रूप से की जाती है। समग्र रूप से विभाग के पास अन्य कर्तव्य होंगे जैसे कि सभी गुणवत्ता नियंत्रण प्रक्रियाओं और विधियों को स्थापित करना, मूल्यांकन करना, मान्य करना और लागू करना।

6.1 प्रत्येक विनिर्माण प्रतिष्ठान योग्य और अनुभवी कर्मचारियों द्वारा प्रबंधित अपनी गुणवत्ता नियंत्रण प्रयोगशाला (कम से कम भौतिक-रासायनिक विश्लेषण के लिए) स्थापित करेगा।

6.2 गुणवत्ता नियंत्रण प्रयोगशाला के क्षेत्र को भौतिक-रासायनिक, इंस्ट्रुमेंटेशन और माइक्रोबायोलॉजिकल में विभाजित किया जा सकता है।

6.3 संदर्भ नमूने रखने के लिए ऐसे पर्याप्त क्षेत्र उपलब्ध कराए जाएंगे जिनमें भंडारण की अपेक्षित परिस्थितियां हों। गुणवत्ता नियंत्रण अनुभाग संदर्भ नमूनों का मूल्यांकन, रखरखाव और भंडारण करेगा।

6.4 मानक संचालन प्रक्रियाएं कच्चे माल, मध्यवर्ती थोक तैयार उत्पादों और पैकिंग सामग्री के नमूने, निरीक्षण और परीक्षण के लिए उपलब्ध होंगी और, जहां भी आवश्यक हो, पर्यावरणीय परिस्थितियों की निगरानी के लिए उपलब्ध होंगी।

6.5 पहचान, सामग्री, शुद्धता और गुणवत्ता के परीक्षण सहित सभी सामग्रियों, उत्पादों, अभिकर्मकों और विलायकों के लिए अधिकृत और दिनांकित विनिर्देश होंगे। इनमें विश्लेषण में उपयोग किए जाने वाले पानी, विलायकोंऔर अभिकर्मकों के लिए विनिर्देश शामिल होंगे।

6.6 उत्पाद का कोई भी बैच बिक्री या आपूर्ति के लिए तब तक जारी नहीं किया जाएगा जब तक कि यह अधिकृत व्यक्ति (व्यक्तियों) द्वारा प्रमाणित नहीं कर दिया जाता है कि यह निर्धारित मानकों की अपेक्षाओं के अनुसार है।

6.7 निर्मित उत्पादों के प्रत्येक बैच से संदर्भ/प्रतिरक्षित नमूनों को मात्रा के हिसाब से रखा जाएगा जो रोगाणुरहित और पायरोजेन/बैक्टीरियल एंडोटाक्सीन को छोड़कर, सभी परीक्षणों को करने के लिए आवश्यक दवा की मात्रा से कम से कम

दोगुना है। प्रतिधारित उत्पाद को उसकी समाप्ति की तारीख के बाद तीन महीने की अवधि के लिए इसके अंतिम पैक या अनुरूपक पैक में रखा जाएगा।

6.8 तैयार उत्पादों से संबंधित अभिलेखों के मूल्यांकन में सभी प्रासंगिक कारक शामिल होंगे, जिसमें उत्पादन की परिस्थितियां, इन-प्रोसेस परीक्षण के परिणाम, विनिर्माण (पैकेजिंग सहित) प्रलेखनतैयार उत्पाद के लिए विनिर्देश का अनुपालन और तैयार पैक की जांच शामिल है। किसी उत्पाद को बिक्री या वितरण के लिए जारी करने से पहले मूल्यांकन अभिलेखों पर उत्पादन प्रभारी द्वारा हस्ताक्षर किए जाने चाहिए और अधिकृत गुणवत्ता नियंत्रण कर्मियों द्वारा प्रतिहस्ताक्षर किए जाने चाहिए।

6.9 गुणवत्ता नियंत्रण कर्मियों के पास नमूनाकरण और जांच के लिए उत्पादन क्षेत्रों तक पहुंच होगी, जैसा उपयुक्त हो।

6.10 गुणवत्ता नियंत्रण अनुभाग नियम 161-ख के अनुसार उत्पादों की स्थिरता का अध्ययन करेगा ताकि भंडारण की विहितपरिस्थितियों में उनकीशेल्फ लाइफ सुनिश्चित और निर्धारित की जा सके। इस तरह के अध्ययनों के सभी रिकॉर्ड रखे जाएंगे।

6.11 गुणवत्ता आश्वासन प्रभारी उत्पाद की सभी शिकायतों की जांच करेंगे और उनका रिकॉर्ड रखा जाएगा।

6.12 कच्चे माल, मध्यवर्ती, अंतिम उत्पादों और पैकिंग सामग्री के लिए प्रत्येक विनिर्देश गुणवत्ता नियंत्रण विभाग द्वारा अनुमोदित और अनुरक्षित किए जाएंगे। विनिर्देशों का आवधिक संशोधन जहां भी आवश्यक हो, किया जाएगा।

6.13 भेषजसंहिता, मानक परीक्षण पद्धतियां (एसटीपी), संदर्भ मानक, संदर्भ सामग्री और प्राधिकृत तथा तकनीकी पुस्तकें, जैसा अपेक्षित हो,अनुज्ञप्तिधारी की गुणवत्ता नियंत्रण प्रयोगशाला में उपलब्ध होंगी।

7. कार्मिक:-

7.1विनिर्माण, निर्धारित योग्यता और व्यावहारिक अनुभव रखने वाले सक्षम तकनीकी कर्मचारियों के प्रत्यक्ष पर्यवेक्षण के तहत किया जाएगा।

7.2 गुणवत्ता नियंत्रण प्रयोगशाला का प्रमुख विनिर्माण इकाई से स्वतंत्र होना चाहिए। परीक्षण सक्षम तकनीकी स्टॉफ, जो लाइसेंसधारक के पूर्णकालिक कर्मचारी होने चाहिए, के प्रत्यक्ष पर्यवेक्षण में संचालित किया जाना चाहिए।

7.3.गुणवत्ताआश्वासनऔर गुणवत्ता नियंत्रण प्रक्रियाओं केकार्मिक आश्वासनयोग्यताप्राप्त और अनुभवी होने चाहिए।

7.4तकनीकी और गुणवत्ता नियंत्रण कार्मिकों के कार्य लिखित रूप में होने चाहिए और उनका कड़ाई से अनुपालन होना चाहिए।

7.5कार्यरत कार्मिकों की संख्यापर्याप्त और कार्यभार के सीधे अनुपात में होनी चाहिए।

7.6लाइसेंसधारक एक लिखित अनुदेश के अनुसण में यह सुनिश्चित करेगा कि उत्पाद क्षेत्र अथवा गुणवत्ता नियंत्रण प्रयोगशालाओं में सभी कार्मिक उन्हें सौंपे गए कार्यों और जिम्मेदारियों के लिए उचित प्रशिक्षण प्राप्त करेंगे उन्हें नियमित सेवाकालीन प्रशिक्षण दिया जाएगा।

8.कर्मियों कास्वास्थ्य,परिधान और सफाई:–

8.1रोजगार से पूर्व सभी कार्मिकों की आंखों की जांच सहित चिकित्सा जांच होगी और वे क्षयरोग, चर्म तथा अन्य संचारी अथवा संक्रामक रोगों से मुक्त होने चाहिए।तत्पश्चात उनकी आवधिक रूप से वर्ष में कम से कम एक बार चिकित्सीय जांच की जाएगी। इसका रिकॉर्ड अनुरक्षित किया जाएगा। विभिन्न क्रियाकलापों में लगे कार्मिकों की स्वास्थ्य स्थिति का आकलन करने के लिए लाइसेंसधारक योग्यताप्राप्तचिकित्सक की सेवाएं उपलब्ध कराएगा।

8.2 सभी व्यक्तियों को रोजगार से पूर्व और उसके दौरान ऐसा प्रशिक्षण दिया जाएगा जिससे व्यक्तिगतस्वच्छतासुनिश्चित होगी। विनिर्माण प्रक्रियाओं में लगे सभी कर्मचारियों द्वारा उच्च स्तर की व्यक्तिगतस्वच्छता अपनाई जाएगी। इस संबंध में अनुदेश चेंजरूम और अन्यमहत्वपूर्ण स्थानों में प्रदर्शित किए जाएंगे।

8.3 किसी भी समय,स्पष्ट बीमारी या खुले घाव, जो उत्पादों की गुणवत्ता पर प्रतिकूल प्रभाव डाल सकते हैं, दर्शाने वाले किसी भी व्यक्ति को तब तक आरंभिक सामग्री, पैकेजिंग सामग्री,प्रक्रियाधीन सामग्री और औषधउत्पादों को संभालने की अनुमति नहीं दी जाएगी जब तक कि उसकी स्थिति जोखिम मुक्त नहीं मानी जाती।

8.4सभी कर्मचारियों को उनकी बीमारी या असामान्यस्वास्थ्य स्थिति के बारे में अपने तत्कालपर्यवेक्षक को रिपोर्ट करने का अनुदेश दिया जाएगा ताकि उचित कार्रवाई की जा सके।

8.5 कर्मियों के असुरक्षित हाथों और कच्चे माल, मध्यवर्ती या तैयार, पैक नहीं किए गएउत्पादों के बीच सीधे सम्पर्क से बचा जाएगा।

8.6 सभी कर्मी अपने कार्यों के अनुकूल शरीर को स्वच्छवस्त्र से ढकेंगे। विनिर्माण क्षेत्र में प्रवेश करने से पहले व्यक्तिगतस्वच्छताजैसे कि चलते पानी के साथ वॉश-बेसिन, साफ तौलिए अथ्वाहैंड ड्रायर, साबुन, कीटाणुनाशक आदि सहित पर्याप्त सुविधाओं केसाथ महिलाओं और पुरुषों के लिए अलग–अलग चेंज रूम होंगे। कर्मियों के व्यक्तिगत सामान को रखने के लिएचेंज रूम में अलमारियां प्रदान की जाएंगी।

8.7 धूम्रपान, खाना, पीना, चबाना अथवा पौधे, भोजन, पेड़ और व्यक्तिगत औषधियों को उत्पादन, प्रयोगशाला, भंडारण औरअन्यक्षेत्रों, जहां ये उत्पाद की गुणवत्ता पर प्रतिकूल प्रभाव डाल सकते हैं, में रखने की अनुमति नहीं दी जाएगी।

9. विनिर्माण संचालन और नियंत्रण:–

9.1विनिर्माण संबंधी सभी संचालनराज्यलाइसेंसिंग प्राधिकरण द्वारा अनुमोदित तकनीकी कर्मचारियों की देखरेख में किए जाएंगे। विभिन्न चरणों के दौरान कच्ची सामग्री को चुनने, तौलने और मापने से संबंधित प्रक्रिया में प्रत्येकमहत्वपूर्ण क्रिया, अनुमोदित तकनीकी कर्मचारियों के प्रत्यक्षव्यक्तिगत पर्यवेक्षण के तहत प्रशिक्षित कर्मियों द्वारा की जाएगी।

विभिन्न विनिर्माण चरणों के दौरान विनिर्माण और भंडारण में उपयोग किए जाने वाले सभी बर्तनों और कंटेनरों की सामग्री को उत्पाद के नाम, बैच संख्या, बैच आकार और निर्माण के चरण के साथ विशिष्ट रूप से लेबल किया जाएगा। प्रत्येक लेबल को प्राधिकृत तकनीकी कर्मचारी द्वारा आद्याक्षरित और दिनांकित किया जाना चाहिए।

9.2मिश्रण और पार-संदूषण रोकने के लिए सावधानियां:

9.2.1लाइसेंसधारक उचित व्यवस्था, वस्तुस्थिति लेबलिंग और सफाई द्वारा औषध सामग्री तथा औषध उत्पाद (पर्यावरणीय धूल से) कोमिश्रित और पार-संदूषण से रोकेगा। इस संबंध में उचित रिकॉर्ड रखे जाएंगे और मानक प्रचालन प्रक्रिया अपनाई जाएगी।

9.2.2उत्पादन के चरणों के दौरान मिश्रण को रोकने के लिए प्रक्रियाधीन सामग्री की तिथि प्रदर्शित करने के लिए उसे विशिष्ट रूप से लेबल किया जाएगा। उत्पादन के लिए उपयोग किए जाने वाले सभी उपकरणों को उनकी वर्तमान वस्तुस्थिति के साथ लेबल किया जाएगा।

9.2.3पैकेजिंग लाइनेंस्वतंत्र और अलग होंगी। यह सुनिश्चित किया जाएगा कि पिछले पैकेजिंग संचालन का सारा सामान जिसमें लेबल, डिब्बों और ढक्कन शामिल हैं, समय समाप्त होने से पहले साफ हो जाएं।

9.2.4 पैकेजिंग संचालन शुरू होने से पहले यह सुनिश्चित करने के लिए कदम उठाए जाएंगे कि कार्यक्षेत्र, पैकेजिंग लाइनें, प्रिंटिंग मशीनें और अन्य उपकरण किसी भी उत्पाद, सामग्री और छलकाव से साफ और मुक्त हैं। लाइन क्लीरियंस एक अनुमाति चेक लिस्ट के अनुसार किया जाएगा और इसे रिकॉर्ड किया जाएगा।

9.2.5 अलग से या पैकेजिंग के दौरान किसी भी मुद्रण के सही विवरण (उदाहरण के लिए बैच संख्याओं अथवा समापन तिथियों) की नियमित अंतराल पर पुन: जांच की जाएगी। सभी मुद्रण और अधिमुद्रण को लिखित रूप में अधिकृत किया जाएगा।

9.2.6विनिर्माण वातावरण को तापमान, आद्रता और स्वच्छता के अपेक्षित स्तरों पर बनाए रखा जाएगा।

9.2.7प्राधिकृत व्यक्ति सुनिश्चित करेंगे कि पैकेजिंग सहित किसी भी विनिर्माण प्रक्रिया के आरंभ होने से पहले विशिष्ट वर्दी

पहनी जाएगी।

9.2.8 वापस बुलाई गई या अस्वीकृत सामग्री और ऐसी सामग्री जिसे पुन: संसाधित अथवा पुन: प्राप्त किया जाना है, के लिए अलग-अलग सुरक्षित क्षेत्र होंगे।

10. विनिर्माण परिसर में स्वच्छता:–

10.1 विनिर्माण परिसर को साफ और व्यवस्थित तरीके से बनाए रखा जाएगा ताकि वह संचित अपशिष्ट, धूल, मलबे और ऐसी अन्य सामग्री से मुक्त हो।एक विधिमान्यकृत सफाई प्रक्रिया को बनाए रखा जाएगा।

10.2 विनिर्माण क्षेत्रों का उपयोग संसाधित की जा रही सामग्री को छोड़कर, सामग्री के भंडारण के लिए नहीं किया जाएगा। इसे सामान्य रास्ते के रूप में प्रयोग नहीं किया जाएगा।

10.3 एक नियमित स्वच्छता कार्यक्रम तैयार किया जाएगा और उसका अनुपालन किया जाएगा जिसे सही प्रकार से दर्ज किया जाएगा और जो निम्नलिखित इंगित करेगा-

(क) साफ किए जाने वाले विशिष्ट क्षेत्र और सफाई के बीच अंतराल;

(ख) सफाई प्रक्रिया जिसका अनुपालन किया जाना चाहिए जिसमें सफाई के लिए उपयोग किए जाने वाले उपकरण और समाग्री शामिल हैं; तथा

(ग) सफाई के लिए जिम्मेदारकर्मी और जिसे यह कार्य सौंपा गया है।

10.4 कार्यशील और प्रक्रियाधीनभंडारण स्थानकी पर्याप्तता के अनुसार, उपकरण और सामग्रियों की क्रमबद्ध और तार्किक अवस्थिति अनुमत होगी ताकि पार-संदूषण से बचने के लिए विभिन्न औषध उत्पादों या उनके घटकों के बीच मिश्रण के जोखिम को कम किया जा सके और विनिर्माण या नियंत्रण के चरणों में किसी चूक या गलत अनुप्रयोग के जोखिम को कम किया जा सके।

10.5 उत्पादन क्षेत्रों में पर्याप्त रोशनी होनी चाहिए, विशेषरूप से जहां दृश्य ऑनलाइन नियंत्रण होते हैं।

11. कच्ची सामग्री:

11.1 लाइसेंसधारक औषधों के विनिर्माण के किसी भी चरण में उपयोग की जाने वाली सारी कच्ची सामग्री की एक सूची रखेगा और रिकॉर्ड अनुरक्षित करेगा।

11.2 आने वाली सभी सामग्रियों को प्राप्ति अथवा प्रसंस्करण के तुरंत बाद अलग किया जाएगा। बैच-वार अलग करने और 'पहले आया/पहले गया' सिद्धांत द्वारा स्टॉक के आवर्तन के लिए सभी सामग्रियों का उचित परिस्थितियों और एक क्रमबद्ध तरीके से भंडारण किया जाएगा। आने वाली सभी सामग्रियों की जांच यह सुनिश्चित करने के लिए की जाएगी कि प्राप्त खेप दिए गए ऑर्डर से मेल खाती है।

11.3 आने वाली सभी सामग्रियों को वैध खरीद बाउचर के तहत खरीदा जाएगा। जहां भी संभव हो,कच्ची सामग्री सीधे उत्पादकों/किसानों से खरीदी जानी चाहिए।

11.4 इस संबंध में लाइसेंसधारक द्वारा नियुक्त प्राधिकृत कर्मचारी, जिसमें गुणवत्ता नियंत्रण विभाग के कार्मिक शामिल हो सकते हैं, प्राप्ति पर प्रत्येक खेप की जांच करेंगे और पैकेज तथा सील की प्रामाणिकता के लिए प्रत्येक कंटेनर की जांच करेंगे। क्षतिग्रस्त कंटेनरों की पहचान की जाएगी और रिकॉर्ड करके अलग किया जाएगा।

11.5 यदि सामग्री की एक ही खेप में विभिन्न बैच हैं, तो प्रत्येक बैच को नमूने, परीक्षण और निर्मुक्ति के लिए एक अलग बैच माना जाएगा।

11.6 भंडारण क्षेत्र में कच्ची सामग्री को उचित रूप से लेबल किया जाएगा। लेबल को निम्नलिखित जानकारी के साथ स्पष्ट रूप से चिन्हित किया जाना चाहिए:

(I) उत्पाद का नाम और आंतरिक कोड संदर्भ (जहां लागू हो) और विश्लेषणात्मक संदर्भ संख्या;

(II) निर्माता/आपूर्तिकर्ता का नाम, पता और बैच संख्या;

(III) सामग्री की स्थिति (जैसे कि अलग किया गया, परीक्षण के अधीन, निर्मुक्त, अनुमोदित, अस्वीकृत); तथा

(IV) विनिर्माण तिथि, समापन तिथि और पुन: परीक्षण की तारीख।

11.7 अलग मानक रंग के लेबल और व्यवस्था तथा उपकरण सहित"परीक्षण के तहत,"अनुमोदित" और "अस्वीकृत"सामग्री के लिए पर्याप्त अलग-अलग क्षेत्र होंगे ताकि नियंत्रित तापमान और आद्रता में,जहां कहीं भी आवश्यक हो, संग्रहित सामग्री और उत्पादों को शुष्क, स्वच्छ और व्यवस्थित रूप से रखना संभव हो।

11.8 कंटेनर जिनसे नमूने लिए गए हैं, उनकी पहचान की जाएगी।

11.9 यह सुनिश्चित किया जाएगा कि कच्ची सामग्री के सभी कंटेनरों को प्लेटफॉर्म/रैकों पर रखा जाए और सीधे फर्श पर ना रखा जाए, कच्ची सामग्री की विभिन्न श्रेणियों की देखरेख का ध्यान रखा जा सकता है:–

(I) धातु मूल की कच्ची सामग्री।

(II) खनिज मूल की कच्ची सामग्री।

(III) पशु स्रोत की कच्ची सामग्री।

(IV) ताजा जड़ी-बूटी।

(V) सूखी जड़ी-बूटियाँ या पौधे के हिस्से

(VI) अनुद्रव्यआदि।

(VII) वाष्पशील तेल/इत्र और महक

(VIII) पौधे का सार/अर्क और रिसाव/रॉल।

12. उपकरण:-

12.1उपकरणों को संचालन प्रक्रिया के अनुरूप अवस्थित, डिजाइन, निर्मित, अनुकूलित और अनुरक्षित किया जाएगा। उपकरण का खाका और डिजाइन त्रुटियों के जोखिम को कम करने और पार-संदूषण, धूल या गंदगी से बचने और सामान्य रूप से उत्पादों की गुणवत्ता पर कोई प्रतिकूल प्रभाव पड़ने से रोकने के लिए प्रभावशाली सफाई और रखरखाव के लक्ष्य वाला होगा। जहां आवश्यक हो,प्रत्येक उपकरण के लिए एक लॉग-बुक प्रदान किया जाएगा।

12.2 तौल और आश्वासन रेंज, सटीकता और परिशुद्धता के अन्य माप उपकरण,कच्ची सामग्री के स्टोर, उत्पादन और प्रक्रिया नियंत्रण संचालन में उपलब्ध होंगे और इन्हें मानक संचालन प्रक्रियाओं के अनुसार निर्धारित समय के आधार पर जांचा और परखा जाएगा तथा रिकॉर्ड रखा जाएगा।

12.3उत्पाद के सम्पर्क में आने वाले उत्पादन उपकरण का हिस्सा प्रतिक्रियाशील,जोड़ या सोखने वाला नहीं होना चाहिए जो उत्पाद की गुणवत्ता को प्रभावित करे।

12.4 आकस्मिक संदूषण से बचने के लिए, जहां भी संभव हो, गैर-विषैले/खाद्य ग्रेड के स्नेहक का उपयोग किया जाएगा और उपकरण इस प्रकार रखा जाएगा कि स्नेहक निर्मित हो रहे उत्पादों को दूषित न करें।

12.5 खराब उपकरणों को उत्पादन और गुणवत्ता नियंत्रण के क्षेत्रों से हटा लिया जाएगा और उचित रूप से लेबल किया जाएगा।

13. प्रलेखन और रिकॉर्ड:-

13.1 निरूपित, तैयार, समीक्षित और नियंत्रित दस्तावेज, जहां भी लागू हो, इन नियमों का अनुपालन करेंगे।

13.2 उचित और प्राधिकृत व्यक्तियों द्वारा दस्तावेज मंजूर, हस्ताक्षरित और दिनांकित किए जाएंगे।

13.3दस्तावेज शीर्षक, व्यक्ति और उद्देश्यको निर्दिष्ट करेंगे। उन्हें एक क्रमबद्ध तरीके से रखा जाएगा और जांच करना आसान होगा। पुन: प्रस्तुतदस्तावेज स्पष्ट और सुपाठ्य होंगे। दस्तावेजों की नियमित समीक्षा की जाएगी और उन्हें अद्यतन रखा जाएगा। दस्तावेज की प्रविष्टि में किए गए किसी भी परिवर्तन पर हस्ताक्षर और दिनांक होगी।

13.4 रिकॉर्ड, प्रत्येकसंचालन के समय इस तरह से बनाया या पूरा किया जाएगा कि भेषजीय उत्पादों के विनिर्माण से संबंधित सभी महत्वपूर्ण क्रियाकलापों का बाद में पता लगाया जा सके। तैयार उत्पाद की समापन तारीख से कम से कम एक वर्ष के बाद तक रिकॉर्ड और प्रस्तुत मानक प्रचालन प्रक्रिया (एसओपी) को बनाए रखा जाएगा।

13.5 डॉटा, इलैक्ट्रॉनिक डॉटा प्रोसेसिंग सिस्टम या अन्यविश्वसनीय साधनों द्वारा दर्ज किया जा सकता है लेकिन मास्टर फार्मूलों और प्रयुक्तसिस्टम से संबंधित विस्तृत प्रचालन प्रक्रिया एक हॉर्ड-कॉपी में उपलब्ध होगी ताकि रिकॉर्ड की सटीकता की जांच की जा सके। जहां भी प्रलेखन इलैक्ट्रॉनिक डॉटा प्रोसेसिंग विधियों द्वारा नियंत्रित किया जाएगा, प्राधिकृत व्यक्तिकम्प्यूटर में संशोधित डॉटा दर्ज करेंगे। परिवर्तन और हटाए जाने का रिकॉर्ड रखा जाएगा। प्रवेश,पासवर्ड या अन्य माध्यमों से प्रतिबंधित किया जाएगा और महत्वपूर्ण डॉटा की प्रविष्टि का परिणाम स्वतंत्ररूप से जांचा जाएगा। इलैक्ट्रॉनिक रूप से संग्रहित बैच रिकॉर्ड को एक आश्वासन बैकअप द्वारा संरक्षित किया जाएगा। अवधारण की अवधि के दौरान सभी प्रासंगिक डॉटा आसानी से उपलब्ध होंगे।

14. लेबल और अन्य मुद्रित सामग्री:–

मुद्रण चमकीले रंगों में और सुपाठ्य तरीके से किया जाएगा। लेबल पर उत्पाद से संबंधित सभी निर्धारित विवरण होंगे।

14.1 सभी कंटेनरों और उपकरणों पर आश्वासन लेबल होंगे। विभिन्न रंग के कोडित लेबल का उपयोग किसी उत्पाद की स्थिति को दर्शाने के लिए किया जाएगा (उदाहरण के लिए परीक्षण के अधीन, अनुमोदित, अस्वीकृत)।

14.2 मुद्रित पैकेजिंग सामग्री के मिश्रण से बचने के लिए अलग-अलग उत्पादों से संबंधित उत्पाद पत्रक अलग से संग्रहित किए जाएंगे।

14.3 जारी करने से पहले कंटेनर, डिब्बों और बक्सों के सभी लेबलों और सभी परिपत्र, आवेषण और पत्रक की जांच लाइसेंसधारी के गुणवत्ता नियंत्रण विभाग द्वारा की जाएगी।

14.4 औषध के किसी बैच की पैकेजिंग और लेबलिंग से पूर्व, लाइसेंसधारक द्वारा यह सुनिश्चित किया जाएगा कि नमूने बैच से लिए गए हैं और गुणवत्ता नियंत्रण कर्मियों द्वारा विधिवत परीक्षित तथा अनुमोदित हैं। लेबल पर औषधि एवं प्रसाधन सामग्री अधिनियम, 1945 के नियम 161 और नियम 161-ख औषधि एवं चमत्कारी उपाय (आपत्तिजनक विज्ञापन) अधिनियम, 1954 और नियम, 1955 तथा अन्य कानूनी आवश्यकताओं के अनुरूप होंगे।

14.5 प्राप्तप्रत्येक लदान के लिए सभी लेबलिंग और पैकेजिंग सामग्रियों की प्राप्ति का रिकॉर्ड रखा जाएगा जिसमें रसीद, नियंत्रण संदर्भ संख्या और स्वीकार या अस्वीकार किए जाने का संकेत होगा। अप्रयुक्त कोडित और क्षतिग्रस्त लेबल तथा पैकेजिंग सामग्री को नष्ट और दर्ज किया जाएगा।

14.6 तैयार माल के सभी लेबलों पर ग्राहक हेल्पलाइन नम्बर/सम्पर्क से लेकर उत्पाद से शिकायत या प्रतिकूल प्रतिक्रिया का उल्लेख होना चाहिए।

15. गुणवत्ता आश्वासन:–

एएसयू उत्पादों के विनिर्माण के लिए आश्वासनगुणवत्ताआश्वासन की प्रणाली यह सुनिश्चित करेगी कि:–

(I) उत्पादों को इस प्रकार से निरूपित, विकसित और निर्मित किया जाता है जो उत्तम विनिर्माण पद्धतियों (यहां तत्पश्चात जीएमपी के रूप में संदर्भित) की आवश्कताओं को ध्यान में रखते हैं।

(II) कच्चे माल, मध्यवर्तीउत्पादों और थोक उत्पादों तथा अन्य प्रक्रिया नियंत्रण, अंशाकन और सत्यापन पर पर्याप्त नियंत्रण किया जाता है।

(III) तैयार उत्पाद को स्थापित प्रक्रियाओं के अनुसार सही ढंग से संसाधित और जांचा जाता है।

(IV) जब तक प्राधिकृत व्यक्तियों द्वारा यह प्रमाणित नहीं किया जाता कि प्रत्येकउत्पादन बैच को लेबल दावे की आवश्यताओं और औषध उत्पादों के उत्पादन, नियंत्रण और निर्मुक्ति से संबंधित किसी अन्य प्रावधान के अनुरूप उत्पादित और नियंत्रित किया गया है, तब तक औषध उत्पादों को बिक्री या आपूर्ति के लिये निर्मुक्त नहीं किया जाता है।

16. स्व-निरीक्षण और गुणवत्ता लेखा परीक्षा:–कंपनी पूरी प्रणाली अथवा उसके एक भाग का आकलन करने के लिए गुणवत्ता लेखा परीक्षा प्रक्रिया के साथ स्वत: निरीक्षण दल का गठन करेगी जिसका विशिष्टउद्देश्य सुधार करना होगा।

16.1 उत्पादन और गुणवत्ता नियंत्रण के सभी पहलुओं में विनिर्माता द्वारा जीएमपी के अनुपालन का मूल्यांकन करने के लिए स्व-निरीक्षण की अवधारणा का पालन किया जाएगा। विनिर्माता, कंपनी के भीतर या बाहर से स्वतंत्र, अनुभवी, योग्य व्यक्तियों की एक टीम का गठन करेगा जो निष्पक्ष रूप से कार्य प्रणाली और प्रक्रियाओं के कार्यान्वयन का लेखा परीक्षा कर सकती है। स्व-निरीक्षण प्रक्रिया को प्रलेखित किया जाएगा जिसमें स्व-निरीक्षण परिणाम, मूल्यांकन, निष्कर्ष और प्रभावी अनुवर्ती कार्यक्रम के साथ अनुशंसित सुधारात्मक कार्रवाई का उल्लेख होगा। सुधारात्मक कार्रवाई की सिफारिशों को अपनाया जाएगा।

16.2 कार्यक्रम का निरूपण उत्तम विनिर्माण पद्धतियों के कार्यान्वयन में कमियों का पता लगाने और आवश्यक सुधारात्मक कार्रवाई की सिफारिश करने के लिए किया जाएगा। स्व-निरीक्षण नियमित रूप से और विशिष्ट अवसरों पर किया जाएगा जैसे उत्पाद वापसी या बार-बार अस्वीकार होना या जब लाइसेंसिंग अधिकारियों द्वारा निरीक्षण की घोषणा की जाती है। स्व-निरीक्षण के लिए जिम्मेदार टीम में ऐसे कर्मी शामिल होंगे जो निष्पक्ष रूप से उत्तम विनिर्माण पद्धतियों के कार्यान्वयन का मूल्यांकन कर सकते हैं; सुधारात्मक कार्रवाई के लिए सभी सिफारिशों को लागू किया जाएगा।

16.3 स्व-निरीक्षण के लिखित अनुदेशतैयार किए जाएंगे जिनमें निम्नलिखित शामिल होंगे:–

(क) कार्मिक

(ख) कार्मिक सुविधाओं सहित परिसर

(ग) इमारतों और उपकरणों का रखरखाव

(घ) प्रारंभिक सामग्री और तैयार उत्पादों का भंडारण

(ङ) उपकरण

(च) उत्पादन और प्रक्रियाधीन नियंत्रण

(छ) गुणवत्ता नियंत्रण

(ज) प्रलेखन

(झ) सफाई और स्वच्छता

(ञ) मान्यकरण और पुनर्मूल्यांकन कार्यक्रम

(ट) यंत्र या माप प्रणाली की जांच

(ठ) प्रक्रियाओं को वापस लेना

(ड) शिकायत प्रबंधन

(ढ) लेबल नियंत्रण

(ण) पिछले स्व-निरीक्षण और उठाए गए किसी सुधारात्मक कदम के परिणाम

17.विनिर्देश:

17.1 कच्ची सामग्री और पैकेजिंग सामग्री के लिए –

निम्नलिखित शामिल होंगे-

क) विनिर्दिष्टनाम;

ख) किसी भेषजसंहितागत मोनोग्राफ के लिए संदर्भ,यदि कोई हो;

ग) स्वीकृति सीमा के साथ गुणात्मक और मात्रात्मक आवश्यकताएं;

घ) विनिर्माता या आपूर्तिकर्ता का नाम और पता;

ङ) मुद्रित सामग्री का नमूना;

च) नमूना लेने और परीक्षण या प्रक्रियाओं के संदर्भ के लिए निर्देश;

छ) भंडारण परिस्थिति; तथा

ज) पुनः परीक्षण से पहले भंडारण की अधिकतम अवधि।

17.2 तैयार उत्पादों के लिए -तैयार उत्पादों के लिए उचित विनिर्देशों मेंनिम्नलिखित शामिल होंगे:–

क) उत्पाद का विनिर्दिष्ट नाम;

ख) सूत्र या सूत्र का संदर्भ और भेषजसंहितागत संदर्भ;

ग) नमूने और परीक्षण या प्रक्रियाओं के संदर्भ के लिए निर्देश;

घ) खुराक के रूप और पैकेज का विवरण;

ङ) भंडारण की परिस्थिति और सावधानियां,जहां लागू हों,और

च) सेवन अवधि।

18. मास्टर फार्मूला रिकॉर्ड:–

विनिर्मित होने वाले प्रत्येकउत्पाद और बैच आकार के लिए सभी विनिर्माण प्रक्रियाओं से संबंधित मास्टर फार्मूला रिकॉर्ड होंगे। ये सक्षम तकनीकी कर्मचारियों अर्थात उत्पादन और गुणवत्ता नियंत्रण के प्रमुख द्वारा तैयार और समर्थित किए जाएंगे। मास्टर फार्मूला में निम्नलिखित शामिल होंगे :–

(क) इसके विनिर्देशों से संबंधित उत्पाद का नाम;

(ख) उत्पाद का पेटेंट या स्वामित्व/शास्त्रीय नाम,खुराक के रूप का विवरण,उत्पाद की संरचना और बैच आकार;

(ग) उपयोग की जाने वाली सभी कच्ची सामग्री का नाम,मात्रा और संदर्भ संख्या;

(घ) विस्तृत चरण-वार प्रसंस्करण निर्देश और प्रत्येक चरण के लिए लिया गया समय;

(ङ) प्रक्रियाधीन नियंत्रण सहित उनकी सीमाओं के लिए निर्देश;

(च) उत्पादों की भंडारण स्थिति के लिए आवश्यकताएं जिसमें कंटेनर,लेबलिंग और जहां लागू हो, विशेष भंडारण शर्तें शामिल हैं;

(छ) अपनाई जाने वाली कोई विशेष सावधानी;तथा

(ज) पैकेजिंग विवरण और नमूनों के लेबल।

19. पैकेजिंग रिकॉर्ड:–

प्रत्येकउत्पाद,पैक के आकार और प्रकार के लिए प्राधिकृत पैकेजिंग निर्देश होंगे। इनमें निम्नलिखित शामिल होंगे या इनका संदर्भ शामिल होगा:–

(क) उत्पाद का नाम;

(ख) खुराक के रूप,ताकत और संरचना का विवरण;

(ग) खुराककी संख्याके संदर्भ में पैक आकार, कंटेनर में उत्पाद का वजन या मात्रा;

(घ) मानक बैच आकार के लिए आवश्यक सभी पैकेजिंग सामग्रियों की पूरी सूचीजिसमें प्रत्येक पैकेजिंग सामग्री के विनिर्देशों से संबंधित संदर्भ संख्या के कोड के साथ मात्रा,आकार और प्रकार शामिल हैं;

(ङ) प्रासंगिक मुद्रित पैकेजिंग सामग्री और नमूनों को पुन: प्रस्तुत करना जिसमें उत्पाद की बैच संख्या और समापन तिथि कहां लागू की गई है, दर्शाया गया हो;

(च) पैकेजिंग संचालन का वर्णन जिसमें उपयोग किए जाने वाले कोई महत्वपूर्ण सहायक संचालन और उपकरण शामिल हैं;

(छ) नमूनाकरण और स्वीकृति के निर्देशों के साथ प्रक्रियाधीन नियंत्रण का विवरण;तथा

(ज) पैकिंग और लेबलिंग प्रक्रिया के पूरा होने पर,जारी किए गए लेबलिंग और पैकेजिंग यूनिटों की संख्या,लेबल किए गए, पैक किए गए और अधिक होने पर वापस या नष्ट किए गए यूनिटों की संख्या के बीच एक सामंजस्य बनाया जाएगा। संख्या में कोई महत्वपूर्ण या असामान्य विसंगति की अंतिम बैच जारी करने से पहले सावधानीपूर्वक जांच की जाएगी।

20. बैच पैकेजिंग रिकॉर्ड:-

20.1 संसाधित प्रत्येक बैच या बैच के एक भाग के लिए एक बैच पैकेजिंग रिकॉर्ड रखा जाएगा। यह पैकेजिंग निर्देशों के प्रासंगिक भागों पर आधारित होगा और प्रतिलेखन त्रुटियों से बचने के लिए इस तरह के रिकॉर्ड तैयार करने की विधि बनाई जाएगी।

20.2किसी भी पैकेजिंग प्रक्रिया के शुरू होने से पहले जांच की जाएगी और रिकॉर्ड रखा जाएगा, कि उपकरण और कार्य स्टेशन पर पिछले उत्पाद, नियोजित पैकेजिंग संचालन के लिए आवश्यकदस्तावेज या सामग्री नहीं है और यह कि उपकरण साफ और उपयोग के लिए आश्वासन हैं।

21. बैच प्रसंस्करण रिकॉर्ड:-

21.1प्रत्येकउत्पाद के लिए बैच प्रसंस्करण रिकार्ड होगा। यह वर्तमान में अनुमोदित मास्टर फार्मूला के प्रासंगिक भागों पर आधारित होगा।

21.2कोई भी प्रसंस्करण शुरू होने से पहले यह सुनिश्चित करने के लिए कि उपकरण और कार्य स्टेशन पर पिछले उत्पाद, नियोजित प्रक्रिया के लिए आवश्यकदस्तावेज या सामग्री को हटा दिया गया है और उपकरण साफ तथा उपयोग के लिए आश्वासन हैं, जांच की जाएगी और रिकॉर्ड रखा जाएगा।

21.3प्रसंस्करण के दौरान,प्रत्येक कार्रवाई होने पर निम्नलिखित जानकारी दर्ज की जाएगी और रिकार्ड को प्रसंस्करण कार्यों के लिए जिममेदार व्यक्ति द्वारा दिनांकित और हस्ताक्षरित किया जाएगा:–

(क) उत्पाद का नाम,

(ख) निर्मित बैच की संख्या,

(ग) महत्वपूर्ण मध्यवर्ती चरणों और उत्पादन के पूरा होने की तारीखों और प्रारंभ का समय,

(घ) उत्पादन के विभिन्न महत्वपूर्ण चरणों के संचालक और जहां आश्वासन हो, प्रत्येक ऑपरेशन की जाँच करने वाले व्यक्ति, के आद्याक्षर,

(ङ) बैच संख्या और/या विश्लेषणात्मक नियंत्रण संख्या के साथ-साथ प्रत्येक प्रारंभिक सामग्री के वास्तविक भार की

मात्रा,

(च) कोई प्रासंगिक प्रसंस्करण संचालन या घटना और प्रयोग किए गए प्रमुख उपकरण,

(छ) प्रक्रियाधीन नियंत्रण का रिकॉर्ड और व्यक्ति के आद्याक्षर,

(ज) उन्हें संचालित करना और परिणामप्राप्त,

(झ) विनिर्माण (मात्रा) के विभिन्न और महत्वपूर्ण चरणों के बाद प्राप्त उत्पाद की मात्रा,

22.मानक प्रचालन प्रक्रियाएं (एसओपी) और रिकॉर्डके संबंध में:–

22.1 सामग्रियों की प्राप्ति:

22.1.1 सभी कच्ची सामग्री, प्राथमिक और मुद्रित पैकेजिंग सामग्री की प्रत्येक डिलीवरी की प्राप्ति के लिए मानक संचालन प्रक्रिया और रिकॉर्ड लिखित रूप में होगा।

22.1.2 प्राप्तियों के रिकॉर्ड में शामिल होंगे;

(क) वितरण नोट पर सामग्री का नाम और कंटेनरों की संख्या;

(ख) प्राप्ति की तारीख;

(ग) विनिर्माताओं और/अथवा आपूर्तिकर्ताओं का नाम;

(घ) विनिर्माता बैच या संदर्भ संख्या;

(ङ) कुल मात्रा, कंटेनर की संख्या और प्रत्येक कंटेनर में कुल मात्रा;

(च) रसीद के बाद नियत किया गया नियंत्रण संदर्भ संख्या;

(छ) कोई अन्य प्रासंगिक टिप्पणी या जानकारी।

22.1.3आंतरिक लेबलिंग, क्वारंटीन और प्रारंभिक सामग्री, पैकेजिंग सामग्री और अन्य सामग्री के भंडारण के लिए मानक संचालन प्रक्रियाओं को आश्वासन रूप में लिखा जाएगा।

22.1.4प्रत्येक यंत्र और उपकरण के लिए मानक संचालन प्रक्रियाएं उपलब्ध होंगी और इन्हें संबंधित यंत्र तथा उपकरण के निकट रखा जाएगा।

22.2 नमूनाकरण:–

22.2.1 नमूना लेने के लिए मानक संचालन प्रक्रियाएं लिखी जाएंगी जिसमें नमूना लेने के लिए प्राधिकृत व्यक्ति शामिल होंगे।

22.2.2 नमूना अनुदेश में शामिल होंगे:

(क) नमूना लेने की विधि और नमूना योजना,

(ख) सामग्री के संदूषण या इसकी गुणवत्ता में किसी तरह की गिरावट से बचने के लिए बरती जाने वाली कोई भी सावधानी,

(ग) लिए जाने वाले नमूनों की मात्रा,

(घ) प्रयोग किए जाने वाले नमूना कंटेनरों के प्रकार,

(ङ) बरती जाने वाली कोई विशिष्ट सावधानी।

22.3. बैच संख्या डालना–बैच (खेप) संख्याके विवरण का वर्णन करते हुए मानक परिचालन प्रक्रिया होगी जो यह सुनिश्चित करने के उद्देश्य के साथ तैयार की जाएगी कि मध्यवर्ती बैच, थोक अथवा तैयार उत्पाद के प्रत्येकबैच को एक

विशिष्टबैच संख्या के साथ पहचाना जा सके।

22.4. परीक्षण-निर्माण के विभिन्न चरणों में सामग्री और उत्पादों के परीक्षण के लिए लिखित कार्य प्रणाली होगी जिसमें प्रयोग किए जाने वाले तरीकों और उपकरणों का विवरण होगा। किए गए परीक्षण दर्ज किए जाएंगे।

22.5 विश्लेषण के रिकॉर्ड–

22.5.1 रिकॉर्ड में निम्नलिखित सूचना शामिल होगी:

(क) कच्ची सामग्री या उत्पाद का नाम और खुराक का रूप,

(ख) बैच संख्या औरजहां उपयुक्त हो विनिर्माता और/या आपूर्तिकर्ता,

(ग) प्रासंगिक विनिर्देशों और परीक्षण कार्यप्रणाली का संदर्भ,

(घ) टिप्पणियों और गणना सहित परीक्षण परिणाम तथा किसी विनिर्देश (सीमाए)का संदर्भ,

(ङ) परीक्षण की तारीखें,

(च) परीक्षण करने वाले व्यक्तियों के आद्याक्षर,

(छ) परीक्षण और विस्तृत गणनाओं का सत्यापन करने वाले व्यक्तियों के आद्याक्षर,

(ज) निर्मुक्त या अस्वीकृति का विवरण, और

(झ) नामित जिम्मेदार व्यक्ति के हस्ताक्षर और तारीख।

22.5.2 निम्नांकित के लिए लिखित मानक संचालन प्रकियाएं होंगी और की गई कार्रवाई के संबद्ध रिकॉर्ड होंगे:

(क) उपकरण का एकत्रण और सत्यापन,

(ख) विश्लेषणात्मक यंत्र और अंशांकन,

(ग) रखरखाव, सफाई और स्वच्छता;

(घ) योग्यता, प्रशिक्षण, वस्त्र, स्वच्छता सहित कार्मिक मामले

(ङ) पर्यावरण निगरानी;

(च) कीट - नियंत्रण;

(छ) शिकायतें;

(ज) वापस मंगाया गया; तथा

(झ) वापस किया गया।

23.संदर्भ नमूने:-

23.1 प्रत्येक कच्ची सामग्री की टेस्ट रिपोर्ट, उस कच्ची सामग्री मे उत्पादित अंतिम बैच केप्रयोग की तारीख के बाद 3महीने की अवधि के लिए रखी जाएगी।

23.2. तैयार औषधयोगों के संदर्भ नमूने उसी या नकली कंटेनरों में सेवन अवधि के अंत तक संग्रहीत किए जाएंगे जिनमें दवा वास्तव में विपणन की गई है।

24 विधिमान्यकरण और प्रक्रिया विधिमान्यकरण:

24.1 विधिमान्यकरण अध्ययन अच्छी विनिर्माण पद्धतियों का एक अनिवार्य हिस्सा होगा और पूर्व-निर्धारित प्रोटोकॉल के अनुसार आयोजित किया जाएगा। इनमें प्रसंस्करण, परीक्षण और सफाई प्रक्रियाओं का विधिमान्यकरण शामिल होगा।

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24.2 रिकॉर्ड किए गए परिणामों और निष्कर्षों को संक्षेप में लिखित रिपोर्ट तैयार, प्रलेखित और उसका रखरखाव किया जाएगा।

24.3 प्रक्रियाओं और क्रियाविधियों को विधिमान्यकरण अध्ययन के आधार पर स्थापित किया जाएगा और यह सुनिश्चित करने के लिए कि वे इच्छित परिणाम प्राप्त करने में सक्षम हैं; उनको आवधिक रूप से पुन: विधिमान्यकृत किया जाएगा। महत्वपूर्ण प्रक्रियाओं को भावी या पूर्वव्यापी रूप से विधिमान्यकृत किया जाएगा।

24.4 जब कोई नया मास्टर फॉर्मूला या संपाक का तरीका अपनाया जाता है, तो नियमित प्रसंस्करण के लिए इसकी उपयुक्तता प्रदर्शित करने के लिए कदम उठाए जाएंगेकि निर्दिष्ट सामग्री और उपकरणों का उपयोग करके निर्धारित प्रक्रिया, लगातार आवश्यक गुणवत्ता के उत्पाद को प्राप्त करने के लिए प्रदर्शित की जाएगी।

24.5 विनिर्माण प्रक्रिया में महत्वपूर्ण परिवर्तन, जिसमें उपकरण या सामग्री में किसी भी तरह का बदलाव, जो उत्पाद की गुणवत्ता और/या प्रक्रिया कोपुन: प्रस्तुत करने की योग्यता को प्रभावित कर सकता है, को विधिमान्यकृत किया जाएगा।

25.वितरण रिकॉर्ड.:-

25.1. किसी औषध के दिए गए बैच के वितरण या प्रेषण से पहले, यह सुनिश्चित करना होगा कि बैच को गुणवत्ता नियंत्रण कर्मियों द्वारा विधिवत परीक्षित, अनुमोदित और जारी किया गया है। यादृच्छिक आधार पर प्रत्येक खेप का प्रेषण पूर्व निरीक्षण किया जाएगा ताकि यह सुनिश्चित किया जा सके कि केवल सही माल भेजा गया है। वितरण केंद्रों पर पालन किए जाने वाली भण्डारण प्रथाओं के आवधिक ऑडिट किए जाएंगे और उसके रिकॉर्ड रखे जाएंगे। उत्पादों के भंडारण के लिए मानक प्रचालन प्रक्रिया विकसित की जाएगी।

25.2. वितरण के रिकॉर्ड को इस तरह से रखा जाएगा कि किसी औषध के तैयार बैच का खुदरा स्तर तक पता लगाया जा सके, ताकि यदि आवश्यक हो, तो तुरंत और पूरी तरह से बैच को वापस बुलाने की सुविधा मिल सके।

26.उत्पाद वापस लेना:-

26.1 संबंधित स्टॉकिस्टों, थोक विक्रेताओं, आपूर्तिकर्ताओं, खुदरा स्तर तक को समय से जानकारी देने के लिए खराब उत्पादों की एक त्वरित और प्रभावी उत्पाद रिकॉल प्रणाली को कम से कम अवधि के भीतर तैयार किया जाएगा। लाइसेंसधारक इस संबंध में प्रिंट और इलेक्ट्रॉनिक मीडिया दोनों का उपयोग कर सकता है।

26.2लाइसेंसधारी द्वारा वितरित उत्पादों को प्रभावी रूप से वापस बुलाने के लिए मानक प्रचालन प्रक्रिया के रूप में एक लिखित प्रक्रिया स्थापित करनीहोगी। वापस बुलाने की प्रक्रिया तुरंत शुरू किए जाने में सक्षम होगी ताकि प्रत्येक वितरण चैनल के स्तर पर प्रभावी रूप से पहुंचा सके।

26.3 वापस बुलाने के लिए नामित व्यक्तियों को वितरण रिकॉर्ड आसानी सेउपलब्ध कराया जाएगा।

26.4 निर्दिष्ट व्यक्ति, जारी की गई अंतिम रिपोर्ट को रिकॉर्ड करेगा, जिसमें उत्पादों की वितरित और वापस ली गई मात्राओं के बीच मेल शामिल है।

26.5 वापस लेने की व्यवस्था की प्रभावशीलता का समय-समय पर मूल्यांकन किया जाएगा।

26.6 वापस लिए गए उत्पादों को अलग से सुरक्षित क्षेत्र में संग्रहीत किया जाएगा जिन पर अंतिम निर्णय लंबित होगा।

27. शिकायतें और विपरीत प्रक्रियाएं:-

27.1बाजार की शिकायतों का रिकॉर्ड - विनिर्माता बाजार में बेचे गए उत्पादों के संबंध में प्राप्त बाजार शिकायतों की सभी रिपोर्टों को रिकार्ड करने के लिए एक रजिस्टर बनाएंगे।

27.2विनिर्माता ऐसी बाजार शिकायतों,विनिर्माताओं द्वारा शिकायत के संबंध में की गई जांच पर प्राप्त सभी डेटा दर्ज करेगा और साथ ही ऐसी बाजार शिकायतों की पुनरावृत्ति को रोकने के लिए की गई कोई सुधारात्मक कार्रवाई भी दर्ज की जाएगी। एक बार छह महीने की अवधि में विनिर्माता ऐसी शिकायतों के रिकॉर्ड को लाइसेंसिंग प्राधिकरण को प्रस्तुत

करेगा। परिसर के किसी भी निरीक्षण के दौरान निरीक्षण के लिए रजिस्टर भी उपलब्ध होगा।

27.3 विनिर्मित आयुर्वेदिक, सिद्ध और यूनानी औषधों के उपयोग से उत्पन्न किसी भी विपरीत प्रतिक्रिया की रिपोर्ट भी प्रत्येक विनिर्माता द्वारा एक अलग रजिस्टर में रखी जाएगी। विनिर्माता किसी भी विपरीत प्रतिक्रिया की जांच यह जानने के लिए करेगा कि क्या उत्पाद में किसी दोष के कारण ऐसा हुआ है और क्या ऐसी प्रतिक्रियाएं पहले से ही साहित्य में दी गई हैं या यह एक नया अवलोकन है और दस्तावेज़ संबंधित लाइसेंस प्राधिकारी को दिए जाएंगे।

27.4खराब उत्पाद वापस लेने के लिए की जाने वाली कार्रवाई का वर्णन करते हुए लिखित प्रक्रियाविधि होनी चाहिए।

28. साइट मास्टर फ़ाइल–लाइसेंसधारी, साइट मास्टर फाइल के रूप में एक संक्षिप्त दस्तावेज तैयार करेगा, जिसमें लाइसेंस प्राप्त परिसर में किए गए फार्मास्यूटिकल विनिर्माण संपाकों के उत्पादन और/या नियंत्रण के बारे में विशिष्ट और तथ्यात्मक अच्छी विनिर्माण पद्धतियां शामिल होंगी। इसमें विभिन्न क्षेत्रों की जानकारी शामिल होगी, जैसे सामान्य जानकारी, कार्मिक, परिसर,उपकरण, स्वच्छता, प्रलेखन, उत्पादन, गुणवत्ता नियंत्रण, ऋण लाइसेंस निर्माण और लाइसेंसधारी, वितरण, शिकायतें और उत्पाद वापस लेना, स्व निरीक्षण, औषधों का निर्यात आदि।

29. <u>आयुर्वेद, सिद्ध और यूनानी औषधियों की रसौशाधियों या रसामरुथुकल और कुष्टजत (जड़ीबूटीय खनिज-धातु सम्मिश्रणों) के विनिर्माण के लिए विशिष्ट अपेक्षाएं</u>: सामान्य अपेक्षाओं के अलावा,निम्नलिखितविशिष्ट अपेक्षाओं का पालन भी किया जाएगाअर्थात्:-

29.1भस्म और रसौषधि के लिए भट्टी या ताप उपकरण खंड: - उचित वायु संचार,निकास और चिमनी के साथ गरम करने, जलने, पुट्ट और गर्मी से संबंधितकिसी भी कार्य के लिए। यह टिन शेड भी हो सकता है।

29.2 कुशता, भस्म और रसौषधि (हस्त चालित या मशीनी, ओवन आदि) के लिए पीसने, सुखाने और प्रसंस्करण खंड। उस स्थान पर सुखाने की प्रक्रिया होगी जो शीशे या अन्य पारदर्शी सामग्री द्वारा कवर किया गया है ताकि सुखाने के उद्देश्य से रखी गई सामग्री पर सूर्य का प्रकाश पड़ सके। यदि ओवन में सुखाया जा रहा है तो तापमान को विशिष्ट तापमान पर चुना जा सकता है।

29.3 विनिर्माण क्षेत्रइस प्रकार डिज़ाइन किया जाना चाहिए कि एसओ 2, आर्सेनिक और पारा वाष्प आदि जैसे उत्पन्न विषाक्त धुएं को बाहर निकालने में सहायक उत्पादों के प्रसंस्करण पर विशेष ध्यान दिया जाए। जब सामग्री को गरम करने और उबालने की आवश्यकता हो तब उचित वायु संचार और वायु निकास प्रवाह तंत्र प्रदान किया जाना चाहिए ताकिअनायास धुएं और वाष्प के संचय को रोका जा सके। ऐसे क्षेत्रों में निकास प्रणाली और उचित स्क्रबिंग प्रणाली से सुसज्जित चिमनी या नलिकाएं प्रदान की जा सकती हैं,ताकि कर्मियों और पर्यावरण की सुरक्षा का ध्यान रखा जाए।

29.4भस्मिकरण की पूरी प्रक्रिया के दौरान प्राप्त तापमान के लिए विशेष रूप से रिकॉर्ड रखा जाएगा, जबकि विभिन्न प्रकार के शास्त्रीय पुट, तेल, गैस या बिजली का उपयोग करने वाले भट्टियों को लगाया जाएगा। कंप्यूटर से जुड़े हीट सेंसर की मैनुअल रीडिंग या रिकॉर्डिंग के लिएउपयुक्त तापमान मापने वाले यंत्र का प्रयोग किया जाना चाहिए, जैसे कि पायरोमीटर या पाइरोग्राफ,जैसा भी मामला हो।बड़ी मात्रा को संभालने के लिए, चक्रिका या छर्रों को बनाने के लिए हाथ से संचालित एक्सट्रूडर जैसी उपयुक्त तकनीक को अपनाया जा सकता है। हालांकि, एल्यूमीनियम या इसके मिश्र धातुओं से बने ऐसे उपकरणों का उपयोग नहीं किया जाना चाहिए।

29.5 उत्पाद का गुणवत्ता नियंत्रण:-समाप्त रासौषधि के लिए विशिष्टताओं का उद्देश्य मुख्य रूप से गुणवत्ता को परिभाषित करना है, न कि पूर्ण लक्षण वर्णन की स्थापना करना, और उन विशेषताओं पर ध्यान केंद्रित करना चाहिए जो गुणवत्ता सुनिश्चित करने में उपयोगी साबित होती हैं। रसौषधि की लगातार गुणवत्ता केवल तभी सुनिश्चित की जा सकती है जब भेषजसंहितागत मानकों के शुरुआती सामग्री-धातुओं और खनिजों का उपयोग किया जाता है। कुछ मामलों में उनकी प्रक्रिया के पहलुओं पर अधिक विस्तृत जानकारी की आवश्यकता हो सकती है। विनिर्माता उत्पाद की एक समान गुणवत्ता के लिए इन-हाउस मानकों को सुनिश्चित करेगा। यह सुनिश्चित करने के लिए विशेष देखभाल की आवश्यकता है कि रसौषधि से निकली हवा अन्य उत्पादन क्षेत्र को दूषित नहीं कर रही है, विशेष रूप से बंद या केंद्रीय रूप से वातानुकूलित परिसर में।

29.6 वापस बुलाई गई रस औषधियों के सुरक्षित अलग क्षेत्र में भंडारण के लिए मानक प्रचालन प्रक्रियाएं(एसओपी) शामिल की जानी चाहिए जो उनके अंतिम निपटान तक भंडारण के लिए निर्दिष्ट आवश्यकताओं का अनुपालन करती हैं।

29.7 कर्मचारियों की चिकित्सीय जांच:– विनिर्माण में लगे कर्मचारियों की नियुक्ति के समय चिकित्सीय जांच की जानी चाहिए और तत्पश्चात वर्ष में कम से कम एक बार विनिर्माण प्रक्रिया के दौरान औषध के किसी भी प्रतिकूल प्रभाव के लिए आवश्यक जांच की जाएगी ताकि यह सुनिश्चित हो सके कि कर्मचारियों के महत्वपूर्ण अंगों पर सामग्री का कोई प्रभाव नहीं पड़ा। अच्छे विनिर्माण अभ्यासों के निरीक्षण के दौरान कर्मचारियों की वार्षिक जांच रिपोर्ट वैधानिक निरीक्षकों को उपलब्ध कराई जाएगी।

29.8 रसौषधि/कुष्टजत का खुराक रूप:- रस औषधियों को समय-समय पर अद्यतन, भारतीय आयुर्वेद भेषजसंहिता अथवा भारतीय भेषजसंहिता के तहत अनुमेय उपयुक्त अनुमत फिलर या बाध्यकारी एजेंटों को जोड़ने को जोड़ने के बाद चूर्ण, वटी, गुटी,गोली या कैप्सूल आदि के रूप में स्वीकार्य खुराक के रूपों में बनाया जा सकता है। ऐसे मामलों में लेबल पर भराव के अलावा एक टिकिया या गोली या कैप्सूल में आयुर्वेद,सिद्ध और यूनानी औषधियों की मात्रा का उल्लेख अवश्य होना चाहिए। क्रिस्टलीय उत्पाद को पैकिंग से पहले अलग-अलग वितरण आकार में पीसा जा सकता है। सभी रस औषधि या रसमरुथुकल या कुष्टजत को एक खुराक के रूप में पैक किया जाएगा जो उपभोक्ता के प्रयोग के लिए तैयार होगी। रोगी उपभोक्ता पैक में संभावित रूप से जहरीले उत्पादों की एक-एक खुराक को पीसना और तौलना अनुमेय नहीं होगा। इस व्यवस्था से रस औषधि की प्रतिकूल औषध प्रतिक्रिया को कम किया जा सकता है जो खुराक में भिन्नता के कारण होती है। हालांकि,अस्पताल के थोक पैक के लिए,यह लागू नहीं होगा और लेबल पर स्पष्ट रूप से "अस्पताल पैक" उल्लिखित होगा।

30. जीवाणुरहित उत्पादों के विनिर्माण के लिए विशिष्ट आवश्यकताएं

30.1 विनिर्माण क्षेत्र:–जीवाणुरहित आयुर्वेदिक,यूनानी और सिद्ध औषधों के विनिर्माण के लिए इस उद्देश्य हेतु विशेष रूप से डिज़ाइन किए गए अलग-अलग बंद क्षेत्र प्रदान किए जाएंगे। इन क्षेत्रों में वायु के प्रवेश को रोका जाएगा और यह अनिवार्य रूप से धूल रहित होंगे तथा वायु की आपूर्ति सहित इन्हें हवादार बनाया जाएगा। उन सभी क्षेत्रों के लिए, जहां निर्जीवाणुक विनिर्माण किया जाना है, वायु आपूर्ति को बैक्टीरिया बनाए रखने वाले फिल्टर (हेपा फिल्टर) के माध्यम से फ़िल्टर किया जाएगा और निकटवर्ती क्षेत्रों की तुलना में अधिक दबाव में होगा। फ़िल्टर के कार्य निष्पादन की जाँच उसकी स्थापना के समय की जाएगी और समय-समय पर की गई जाँच के रिकॉर्ड रखे जाएंगे। जीवाणुरहितविनिर्माण क्षेत्रों में सभी सतहों को सफाई और कीटाणुनाशन की सुविधा के लिए डिज़ाइन किया जाएगा। जीवाणुरहित विनिर्माण के लिए सभी आयुर्वेदिक,सिद्ध और यूनानी औषध निर्माण क्षेत्र का संचालन के दौरान दैनिक माइक्रोबियल काउंट किया जाएगा। इस तरह की गिनती के परिणामों की आंतरिक रूप से स्थापित मानकों के प्रति जांच की जाएगी और रिकॉर्ड रखा जाएगा।

विनिर्माण क्षेत्रों में प्रवेश प्राधिकृत कर्मियों की न्यूनतम संख्या तक सीमित रखा जाएगा। विनिर्माण क्षेत्रों में प्रवेश करने और बाहर आने के लिए अपनाई जाने वाली विशेष प्रक्रिया को लिखा और प्रदर्शित किया जाएगा।

आयुर्वेदिक,सिद्ध और यूनानी औषधों, जिन्हें उनके अंतिम कंटेनरों में जीवाणुरहित किया जा सकता है, के विनिर्माण के लिए क्षेत्रों का डिज़ाइन जीवाणुरहित करने वाले उत्पादों के साथ मिश्रित होने अथवा पहले से ही जीवाणुरहित हो चुके उत्पादों की संभावना को रोकने वाला होगा। अंतिम रूप से जीवाणुरहित होने वाले उत्पादों के मामले में क्षेत्रों का डिज़ाइन गैर-जीवाणुरहित उत्पादों के बीच मिश्रण की संभावना को रोकने वाला होगा।

30.2 संदूषण और मिश्रण के प्रति सावधानियां:

(क) यथेष्टतया पृथक भवन के एक अलग ब्लॉक में विनिर्माण कार्यों को करना या भवन के भीतर एक अलग बाड़े में संचालन करना,

(ख) प्रक्रिया क्षेत्र में उचित दबाव अवकल का उपयोग करना।

(ग) एक उपयुक्त निकास प्रणाली प्रदान करना।

(घ) जीवाणुरहित उत्पादों के लिए लैमिनर प्रवाह जीवाणुरहित वायु प्रणाली को डिजाइन करना।

(ङ) यूवी लैंप की कीटाणुनाशक प्रभाविकता को जांचा और रिकॉर्ड किया जाएगा जिसमें जलने के घंटों का उल्लेख होगा अथवा तीव्रता का उपयोग करके जांचा जाएगा।

(च) तरल पदार्थ और नेत्र संबंधी घोल के अलग-अलग कंटेनरों को भरने के बाद विसरित प्रकाश के साथ काली-सफेद पृष्ठभूमि के सामने बाह्य पदार्थों के साथ संदूषण से मुक्ति सुनिश्चित करने के लिए जांच की जाएगी।

(छ) लाइसेंसिंग प्राधिकरण द्वारा अनुमोदित विशेषज्ञ तकनीकी कर्मचारी, बैच के अंतिम वितरण से पहले लिखित उत्पादन के प्रति वास्तविक उत्पादन की जांच और तुलना करेंगे।

मास्टर फॉर्मूला के तहत आवश्यक सभी प्रक्रिया नियंत्रणों जिनमें कमरे का तापमान,सापेक्षिक आर्द्रता,भरा गया परिमाण, रिसाव और स्पष्टता शामिल है, को जाँचा और दर्ज किया जाएगा।

घोल का कण आकार या कणिका तत्व का उल्लेख किया जाना है।

स्तर ख का भाग II

क. आयुर्वेदिक,सिद्ध और यूनानी चिकित्सा पद्धतियों

की विभिन्न श्रेणियों के विनिर्माण के लिए अपेक्षित

मशीनरी,उपकरण और न्यूनतम क्षेत्र की सूची

औषधियों की एक श्रेणी के लिए निर्दिष्ट एक मशीन औषधियों की दूसरी श्रेणी के विनिर्माण के लिए भी प्रयोग हो सकती है, इसी प्रकार विनिर्माण की कुछ क्रियाएं जैसे पीसना, भट्टी, तरल पदार्थों की पैकिंग और अवलेह, पाक माजून आदि भी इनके लिए साझा किए जा सकते हैं।

क्र. सं.	औषधि की श्रेणी	न्यूनतम विनिर्माण स्थान की आवश्यकता	अनुशंसित मशीनरी/उपकरण
(1)	(2)	(3)	(4)
1.	इतरीफल/तिर्यक/माजून/लौक/ज्वारिश/खमीरस पाक/अवलेह/खांड/मोदक/लकयम/मुरब्बा	100 वर्ग फुट	चक्की/पल्वराइजर, छलनी, पाउडर मिक्सर (यदि आवश्यक हो), एस.एस. पतीले, फर्नेस/भट्टी और अन्य सामान, खमीरस के लिएप्लांट मिक्सर,औखल और मूसल/खरल, एल्यूमीनियम बर्तन,एस. एस.भंडारण कंटेनर
2.	अर्क/तिमिर/अर्क	100 वर्ग फुट	आसवन संयंत्र (गैरेम्बिक) एस.एस. भंडारण टैंक, उबालने के लिए बर्तन, ग्रेविटी फ़िल्टर, बोतल

			भरने की मशीन, बोतल धोने की मशीन, बोतल सुखाने की मशीन, कैप सील मशीन
3.	चूर्ण/सफूफ (पाउडर)	100 वर्ग फुट	ग्राइंडर/पल्वराइजर, डिस्इंटीग्रटर, पाउडर मिक्सर, छलनी, शिफ्टर।
4.	हब (गोलियां)/वटी/गुटिका/मटियारी/गोलियाँ/कुरस (टैब)।	100 वर्ग फुट	बॉल मिल, ग्राइंडर/पल्वराइजर, छलनी, मास मिक्सर/पाउडर मिक्सर, ग्रेनुलेटर, ड्रायर, टैबलेट कंप्रेसिंग मशीन, डाई पंच ट्रे, ओ.टी. उपकरण, गोली/वटी काटने की मशीन, भंडारण और चीनी कोटिंग के लिए स्टेनलेस स्टील ट्रे/कंटेनर, चीनी-लेपित गोलियों के लिएपॉलिशिंग पैन, मैकेनाइज्ड चेट्टू (गुग्गुलु मिलाने के लिए) जहां आवश्यक हो, वजन के साथ तौल, स्कूप, हीटर, काउंटर और पैकिंग मशीनरी
5	रोगन (तेल)/तेल (पीसना और उबालना)/घृत	100 वर्ग फुट	ऑयल एक्सपेलर, एस.एस. पतीले, ऑयल फिल्टर बॉटल, फिलिंग एंड सीलिंग मशीन, बॉटल ड्रायर, भट्टी, कड़ाही/एस.एस. पतीले, एस.एस. भंडारण कंटेनर, निस्पंदन उपकरण, नल वाला टैंक/तरल भरने की मशीन
6.	कुपिपक्वा/क्षार/परपती/लावण्या/भस्म/कुष्ट/सत्व/सिंदुर/कर्पू/उप्पू/परम	100 वर्ग फुट	भट्टी, कड़ाही/स्टेनलेस स्टील बर्तन/पतीले, फ्लास्क, मिट्टी के पात्र, गज पुट भट्टी, मफल भट्टी

			(विद्युत संचालित) एंड/ एज रनर, लकड़ी/स्टेनलस स्टील की लेपनी।
7	काजल, शियफ, सूरमा, अंजना/पिस्टी	100 वर्ग फुट	ओखली एवं मूसल/खरल, शिफ्टर, काजल के संग्रह के लिए मिट्टी के दीपक, ट्रिपल रोलर मिल, एंड रनर, छलनी, मिक्सिंग एस.एस. वर्तन, एस. एस. पतीले
8	कैप्सूल	100 वर्ग फुट	एयर कंडीशनर, डी-ह्यूमिडिफ़ायर, हायग्रोमीटर, थर्मामीटर, कैप्सूल भरने की मशीन और रासायनिक तौल। पल्वेराइजर, पाउडर मिक्सर (जहां आवश्यक हो), वजन के साथ तौल, भंडारण कंटेनर, ग्लास, काउंटर और पैकिंग मशीनरी।
9	मरहम/मरहम पसाई,मरहम, ज़िमद (मरहम)/साबुन/एरोसोल	100 वर्ग फुट	ट्यूब भरने की मशीन,क्रिम्पिंग मशीन/मरहम मिक्सर, एंड रनर/मिल (जहां आवश्यक हो), स्टेनलेस स्टील के वर्तन, स्टेनलेस स्टील का पतीला, ओखल और मूसल/ खरल, भट्टी, एंड रनर, चक्की, पल्वेराइजर, ट्रिपल रोलर मिल (यदि आवश्यक हो), ऐरोसोल भरने की मशीन
10	पनक/सिरप/प्रवाही क्वाथ/मनापकु/शरबत और जोशांदा	100 वर्ग फुट	टिंचर प्रेस, ओखल और मूसल/भट्टी खंड,फिल्टर प्रेस/ ग्रेविटी फ़िल्टर,तरल भरने की मशीन पी.पी. कैपिंग मशीन।
11	असवा/अरिष्ट/सुरा	100 वर्ग फुट	किण्वन टैंक, कंटेनर और आसवन संयंत्र जहां

			आवश्यक हो,फ़िल्टर प्रेस। आसवन संयंत्र और ट्रांसफर पंप (इसके अलावा सूरा के लिए आवश्यक)
12	अच्छयोतन/नेत्र मल्हम/पनीर/कर्ण बिंदू/नासबिंदु/कुतूर-ए-चश्म और मरहम	100 वर्ग फुट	विद्युत थर्मोस्टैटिक नियंत्रण, गर्म हवा वाला ओवन,केतली गैस या विद्युत के साथ उपयुक्त मिश्रण व्यवस्था, कोलेशन मिल या मरहम मिल,ट्यूब भरने के उपकरण, मिश्रण और स्टेनलेस स्टील के भंडारण टैंक या अन्य उपयुक्त सामग्री सिन्टर्ड कांच की नली साईटज फिल्टर या फिल्टर मोमबत्ती,तरल भरने के उपकरण, आटोक्लेव।
13	सूखा अर्क/गीला अर्क	200 वर्ग फुट	
14	पैरेंट्रल को छोड़कर कोई अन्य श्रेणी	100 वर्ग फुट	
15	कच्चे माल का गोदाम	100 वर्ग फुट	
16	पैकिंग सामग्री भंडारण	100 वर्ग फुट	
17	तैयार माल का भंडारण	100 वर्ग फुट	
18	तैयार माल के लिए क्वारंटीन क्षेत्र	100 वर्ग फुट	
19	नियंत्रण नमूने के भंडारण सहित गुणवत्ता नियंत्रण क्षेत्र	150 वर्ग फुट	
20	स्थिरता चैंबर कक्ष	200 वर्ग फुट	
21	नमूना कक्ष	80 वर्ग फुट	
22	अस्वीकृत माल का गोदाम	पर्याप्त	
23	चेंजिंग रूम (पुरुष/महिला)	50 वर्ग फुट	
24	कार्यालय सह रिकॉर्ड रूम	पर्याप्त	
25	सूखने का क्षेत्र	80 वर्ग फुट	
26	पीसने/पल्वेराइजिंग करने वाला क्षेत्र	80 वर्ग फुट	
27	ढुलाई और मिश्रण क्षेत्र	80 वर्ग फुट	

28	ग्रेन्यूलेशन क्षेत्र	80 वर्ग फुट	
			नलके साथ तरल भरने वाला टैंक/तरल भरने की मशीन,थर्मोस्टेटिक नियंत्रण के साथ बिजली से गरम होने वाला ओवन,केतली।

स्तरख का भाग।।।

जीएमपी निरीक्षण की जाँच सूची

क्र. सं.	लेखा परीक्षित किए जाने वाले क्षेत्र/क्रियाकलाप	टिप्पणियां	
		दस्तावेज़ समीक्षा	टिप्पणी
1.	**सामान्य**		
	यूनिट का नाम और पता विनिर्माण लाइसेंस संख्या,टेलीफोन फैक्स: ईमेल: निरीक्षण दल का नाम और पदनाम:		
2.	**स्टॉफ**		
	प्रभारी का नाम क) उत्पादन ख)गुणवत्ता नियंत्रण		
	उत्पादन पर्यवेक्षकों/सहायक उत्पादनकर्ता रसायनज्ञ की संख्या		
	विश्लेषकों की संख्या		
	क्या सभी कार्मिकों ने जीएमपी प्रशिक्षण प्राप्त किया है?		
	क्या प्रशिक्षण प्रलेखित है?		
	प्रशिक्षण की आवधिकता क्या है?		
3.	**फैक्ट्री परिसर**		
	क्या विनिर्माण इकाई में निम्नलिखित के लिए पर्याप्त स्थान है कच्ची सामग्री की प्राप्ति और भंडारण। विनिर्माण प्रक्रिया क्षेत्र। गुणवत्ता नियंत्रण अनुभाग। तैयार माल का गोदाम। कार्यालय अस्वीकृत सामान/औषध गोदाम।		
4.	**स्थान और परिवेश**		

	क्या स्थापना पर्यावरणीय रूप से प्रदूषित क्षेत्रों से दूर स्थित है?		
	क्या स्थापना किसी सीवरेज,नाले/सार्वजनिक शौचालय या किसी फैक्ट्री जो अत्यधिक, असहनीय गंध फैलाती है, से सटे क्षेत्रों से दूर है।		
	क्या मैल,कचरे और अन्य अपशिष्ट का निपटान किया जाता है?		
5.	**भवन**		
	क्या स्थापना का आंतरिक डिजाइन और नक्शा क्रॉस-संदूषण से सुरक्षा सहित बेहतर स्वच्छता अभ्यासों का वातावरण बनाता है?		
	क्या दीवारों,विभाजनों और फर्श की सतहों को अभेद्य सामग्रियों से बनाया गया है और साफ रखने में सक्षम हैं?		
	क्या दीवारों और विभाजनों की सतह चिकनी है?		
	क्या फर्श का निर्माण पर्याप्त सफाई और जल निकासी के योग्य बनाया गया है?		
	क्या दरवाजे,खिड़कियां,छत और ऊपरी जुड़नारों का निर्माण गंदगी,संक्षेपण और धूल कणों को कम करने और आसानी से साफ करने के लिए तैयार किया गया है?		
	क्या औषधों के सीधे सम्पर्क में आने वाली कार्य करने की सतह अच्छी स्थिति, टिकाऊ और आसानी से साफ करने वाली तथा रखरखाव में आसान और कीटाणु रहित है? क्या कोई कोई खुली गंदी नाली या सार्वजनिक शौचालय पास है? क्या औषधों के अलावा कोई अन्य उत्पाद इसी भवन में विनिर्मित किए जाते हैं?		
	क्या उपकरण,सामग्री और कार्मिकों तथा सामग्री की आवाजाही के लिए पर्याप्त जगह है?		
	क्या पक्षियों, कृन्तकों और कीटों को रोकने के लिए कोई कार्यक्रम/प्रणाली है?		
	क्या प्रकाश और वायुसंचार पर्याप्त हैं?		
	क्या कपड़ों, जूतों को बदलने, धोने और शौचालय की पर्याप्त सुविधा है तथा क्या संतोषजनक ढंग से उसका रखरखाव होता है?		
	क्या कच्ची सामग्रियों को सुखाने के लिए स्थान संतोषजनक है?		
6.	**जलापूर्ति**		
	क्या पीने योग्य पानी की पर्याप्त आपूर्ति है?		
	क्या पीने योग्य पानी एपीआई के विनिर्देशों को पूरा करता है?		
	क्या एएसयूऔषधों में केवल पीने योग्य पानी का उपयोग किया जाता है?		
7.	**कचरे का निपटान**		
	क्या जल निकासी और जल निस्तारण प्रणाली का इस तरह से डिजाइन, निर्माण और रखरखाव किया जाता है कि एएसयू उत्पादों में		

	प्रदूषण से बचा जा सके?		
	क्याप्रदूषण नियंत्रण अधिकारियों के दिशा निर्देशों के अनुसार उपयुक्त उपचार के पश्चात अपशिष्ट जल और अवशेषों का निपटान किया जाता है?		
	क्या निम्नलिखित के लिए व्यवस्था पर्याप्त है? ठोस/अर्ध ठोस कचरे के निपटान हेतु सीवेज का निपटान प्रयोगशाला तरल अपशिष्ट का निपटान? गैसीय प्रदूषकों के प्रबंधन का निपटान?		
	क्या कुशल उपचार संयंत्र अस्तित्व में है/यदि हाँ, तो उस पर टिप्पणी दें?		
	क्या उपयुक्त डिजाइन के धूम्र हुड अस्तित्व में हैं और जहां भी आवश्यक हो उनका उपयोग किया जाता है?		
8.	**कंटेनरों की सफाई**		
	क्या कंटेनरों का धुलाई, सफाई और सुखाने के लिए उचित व्यवस्था है? क्या यह क्षेत्र विनिर्माण क्षेत्र से अलग है?		
9.	**स्टोर**		
	क्या विभिन्न प्रकार की सामग्रियों जैसे कच्चे माल, पैकेजिंग सामग्री और तैयार उत्पादों के भंडारण के लिए स्वतंत्र रूप से पर्याप्त जगह है?		
	एएसयू औषध भंडारण सुविधाओं को पर्याप्त रखरखाव और सफाई के लिए डिजायन और निर्मित किया गया है ताकि कीड़े-मकोड़ों तथा उनके एकत्र होने से बचा जा सके। औषधों को प्रदूषण से प्रभावी रूप से बचाव के लिए पर्याप्त सुविधा प्रदान की गई है? खराब होने से बचाने के लिए उपयुक्त वातावरण निर्मित किया गया है?		
	क्या भंडारण सुविधाओं कानिर्माण और रखरखाव यह सुनिश्चित करने के लिए डिजायन किया गया है कि हानिकारक सामग्रियों से एएसयू औषधों के दुर्भावनापूर्ण या आकस्मिक संदूषण को रोका जा सके?		
10.	**कच्ची सामग्री स्टोर**		
	परजीवी, अवांछनीय सूक्ष्मजीव, कीटनाशक या विघटित होने वाले या विजातीय पदार्थों के लिए कच्चीसामग्री या अवयवों की जाँच की जाती है?		
	क्या कच्चे माल या सामग्री का प्रसंस्करण से पहले निरीक्षण और परीक्षण किया जाता है?		
	कच्ची सामग्री या अवयव प्रभावी स्टॉक रोटेशन के अधीन हैं?		
	क्या क्षेत्र पर्याप्त है?		
	क्या स्टोर कीवायुसंचार और प्रकाश व्यवस्था पर्याप्त है?		

	कच्चीसामग्री स्टोर को विभिन्न प्रकार कीकच्चीसामग्री के लिए अलग रखा गया है? धातु मूल कीकच्चीसामग्री,खनिज मूल कीकच्चीसामग्री,पशु स्रोत कीकच्चीसामग्री,ताजा जड़ी बूटियां सूखी जड़ी-बूटियाँ या पौधों के हिस्से एक्सीपीएंट्स आदि। वाष्पशील तेल/इत्र और फ्लेवर पौध अर्क और स्रावी/राल वाले अन्य		
	विशिष्टकच्ची सामग्री के लिए प्रदान की गई विशेष स्थिति के साथ विशिष्ट क्षेत्र है?		
	क्या भिन्न स्थिति की सामग्री के लिए भिन्न लेबल हैं अर्थात् संगरोध, परीक्षित और उपयोग के लिए जारी और निरस्त कर दी गई सामग्री हेतु?		
	क्या ये लेबल विभिन्न रंगों के हैं?		
	पहचान, मात्रा और क्यूए अनुमोदन के संबंध में आरएम के कंटेनरों पर लेबल का उपयोग किया जाता है? यदि विवरण नहीं दिया गया हो तो।		
	लेबल पर निम्नलिखित जानकारी है? सामग्री का नाम, बैच संख्या, विश्लेषण संख्या जारी करने/अस्वीकृति की तिथि? परीक्षण की तिथि? समाप्ति तिथि?		
	क्या नमूना चयन गुणवत्ता नियंत्रण कार्मिक द्वारा किया गया है?		
	क्या नमूने की प्रक्रियाएं हैं?		
	क्या कच्चे माल के भंडारण के लिए उपलब्ध कराए गए कंटेनर गुणवत्ता को संरक्षित करने के लिए उपयुक्त है?		
	क्या बाहरी संग्रहण निम्नलिखित के लिए उपलब्ध है: विलायक द्रव भंडारण क्षेत्र? ज्वलनशील सामग्री भंडारण क्षेत्र? क्या प्रदान किए गए सुरक्षा उपायों यदि कोई हो, का मूल्यांकन नियामक एजेंसी द्वारा किया गया है या नहीं? क्या इन सामग्रियों के संचालन के लिए एसओपी उपलब्ध है? उत्पादों की पैकिंग से पहले कंटेनर और क्लोजर की सफाई के लिए एसओपी हैं?		
	वजन करने वाले क्षेत्र को अलग किया गया है?		
	क्या प्रकाश और वायुसंचार पर्याप्त हैं?		
	क्या क्षेत्र साफ है?		
	क्या कार्मिक उपयुक्त वर्दी पहनते हैं?		

	क्या वजन करने के दौरान क्रॉस संदूषण का खतरा है?		
	क्या पैमाने और संतुलन की नियमित रूप से जाँच की जाती है और रिकॉर्ड रखा जाता हैं?		
	क्या कच्चे माल के कंटेनरों को तोलने, खोलने से पहले साफ किया जाता है?		
	क्या वजन करने के बादइन कंटेनरों को सील किया गया है?		
	वजन करने के बाद प्रत्येक बैच के कच्चे माल कीठीक से पहचान और जाँच की जाती है? कंटेनरों से सामग्री को वितरण के लिए पर्याप्त रूप से साफ और सूखे उपकरण का उपयोग किया जाता है?		
	क्या पहले आया पहले गयासिद्धांत को अपनाया जाता है?		
11	**पैकिंग सामग्री**		
	क्या पैकिंग सामग्री के संदर्भ में क्षेत्र पर्याप्त है?		
	क्या कंटेनर और क्लोजर की पर्याप्त रूप से सफाई और जाँच की जाती हैं?		
12.	**तैयार माल स्टोर**		
	क्या क्षेत्र संग्रहीत सामग्री के संदर्भ में पर्याप्त है?		
	क्या प्रकाश और वायुसंचार पर्याप्त हैं?		
	क्या यह दिखाने के लिए सूची रिकॉर्ड हैं:		
	मात्रा		
	बैच संख्या		
	प्राप्ति की तिथि		
	क्या वितरण रिकॉर्ड रखा गया है?		
	क्या वितरण रिकॉर्ड औषध का स्मरण रखनेके उद्देश्य के लिए पर्याप्त जानकारी प्रदान करते हैं?		
	क्या सामान को खोजने के लिए पृथक्करण क्षेत्र है?		
	क्या सामान खोजने हेतु रिकॉर्ड उपलब्ध हैं?		
	क्या कोई चिह्नित संगरोध क्षेत्र है?		
	क्या विशेष भंडारण स्थिति (पर्यावरणीय स्थिति) के लिए स्थल है, यदि आवश्यक हो?		
13.	**कार्यस्थल**		
	क्या विनिर्माण कार्यों के अनुसार स्थान पर्याप्त है?		
	क्या कार्यशील मैनुअल के साथ-साथ मशीनरी को पर्याप्त स्थान के साथ व्यवस्थित किया गया है?		
	क्या संदूषण को क्रॉस चेक करने के लिए पर्याप्त सावधानियां बरती जाती हैं?		

14.	**कार्मिकों के स्वास्थ्य, वर्दी, स्वच्छता और साफ-सफाई की व्यवस्था**		
	क्या कार्मिकसंक्रामक बीमारी से मुक्त हैं?		
	क्या कार्मिक उपयुक्त वर्दी में हैं?		
	क्या पुरुषों और महिलाओं के लिए अलग-अलग शौचालय हैं?		
	क्या उनके कपड़े बदलने और व्यक्तिगत सामान रखने के लिए प्रावधान है?		
	उत्पादन के क्षेत्र में प्रवेश करने से पहले व्यक्तिगत स्वच्छता के लिए चलते पानी के साथ हैंड ड्रायर उपलब्ध है और साफ तौलिये आदि के साथ वाश-बेसिन जैसी पर्याप्त सुविधाएं उपलब्ध हैं?		
	क्या कार्मियों को व्यक्तिगत स्वच्छता का पालन करने का निर्देश दिया जाता है?		
	क्या प्रभावशीलता के लिए सफाई व्यवस्था की निगरानी की जाती है?		
	क्या स्वच्छता प्रणाली को समय-समय पर निरीक्षण द्वारा सत्यापित किया जाता है? क्या पर्यावरण और एएसयू औषधों की संपर्क सतहों का सूक्ष्मजीवविज्ञानी नमूना लिया जाता है?		
	क्या सफाई व्यवस्था की नियमित रूप से समीक्षा की जाती है और उसको अनुकूल बनाया जाता है?		
15	**चिकित्सा सेवाएं**		
	क्या प्रत्येक कार्मिक की मेडिकल फाइल अलग से रखी गई है?		
	क्या किसी कर्मचारी की भर्ती से पहले चिकित्सा जांच की जाती है		
	बाद की चिकित्सा परीक्षा की आवधिकता क्या है?		
	क्या एक कर्मचारी जिसकी स्वास्थ्य की स्थिति संदिग्ध है उसे तुरंत कार्य स्थल से हटा दिया जाता है? जब तक कि वह पूरी तरह से ठीक नहीं हो जाता है?		
16.	**मशीनरी और उपकरण**		
	क्या मैन्युअल रूप से संचालित या अर्ध-संचालित या स्वचालित मशीनों का उपयोग कुचलने, पीसने, चूर्ण बनाने,उबालने, मिलाने, जलाने, भूनने, छानने, सुखाने, भरने, लेबलिंग और पैकिंग के लिए किया जाता है?		
	क्या जो उपकरण और कंटेनर एएसयू औषधों के संपर्क में आते हैं उन्हें इस तरह से डिजाइन किया जाता है कि वे पर्याप्त रूप से साफ, कीटाणुरहित और रखरखाव किए जाने के योग्य हैं?		
	क्या उपकरण विषक्तताहितसामग्री से बने हैं?		
	क्या डिज़ाइन किए गए उपकरण आवश्यक तापमान में पकाने, गर्म करने, उपयोग करने, ठंडा, स्टोर करने के लिए उपयोग किए जाते हैं?		
	क्या पकाने, गर्म करने, उपयोग करने, ठंडा, स्टोर करने के लिए प्रयुक्त उपकरणों कोअपेक्षित तापमान हेतु निगरानी और नियंत्रण के लिए डिजायन किया गया है		

	क्या कचरे के लिए कंटेनरोंकी पहचान आसानी मे हो जाती है?		
	एएसयू औषधों मेंदुर्भावनापूर्ण और आकस्मिक संदूषण को रोकने के लिए कचरे के कंटेनर बंद किए जाने वाले होते हैं?		
	क्या उपकरण इच्छित उपयोग के लिए पर्याप्त हैं?		
	क्या इसका निर्माण इस तरह मे किया जाता है कि चिकनाई वाले, शीतलकआदि औषध उत्पाद को दूषित नहीं कर सकें?		
	क्या उपकरण सफाई और रखरखाव वाले होते हैं?		
	क्या उपकरण की स्थिति अर्थात स्वच्छ, गंदगीयुक्त, बैच सामग्री को देखा जा सकता है?		
	उस उत्पाद की पहचान करने के लिए सभी औजार/उपकरण उपयुक्त लेबल वाले होते हैं, जिसके लिए उपकरण का उपयोग किया जाता है, इसका बैच नंबर, निर्माण की तारीख आदि।		
	क्या प्रमुख उपकरणों की सफाई, रखरखाव और स्वच्छता के लिए एसओपीएस उपलब्ध हैं?		
	क्या प्रमुख उपकरणों की सफाई के रखरखाव और स्वच्छता हेतु लॉग बुक रखी गई है?		
	क्या ऑपरेटरों के लिए एसओपी आसानी से उपलब्ध है।		
	यदि स्वचालित इलेक्ट्रॉनिक या यांत्रिक उपकरणों का उपयोग किया जाता है, तो क्या ये उपलब्ध हैं? अंशांकन/निरीक्षण के लिए लिखित कार्यक्रम यह सुनिश्चित करने के लिए जांच बिंदुहैं कि परिवर्तन केवल अधिकृत व्यक्तियों द्वारा किए गए हैं/ क्या बाहरी वातावरण के संपर्क में आने वाले पदार्थों के गुणों की सुरक्षा के लिए उपयुक्त क्लोजर या ह्रक्कन उपलब्ध हैं?		
17.	**बैच विनिर्माण रिकॉर्ड**		
	क्या प्रसंस्करण, उत्पादन और वितरण के उपयुक्त रिकॉर्ड रखे गए हैं?		
	निम्नलिखित के लिए एसओपी उपलब्ध हैं कच्चे माल और अन्य घटकों की प्राप्ति? संगरोध और भंडारण? गुणवत्ता नियंत्रण प्रणाली और उत्पादन की स्वीकृति/अस्वीकृति, उत्पादन को जारी करना प्रक्रियाधीन परीक्षण और नियंत्रण तैयार उत्पाद? तैयार उत्पाद का भंडारण? वितरण वापस प्राप्त माल का स्मरण और शिकायतें सफाई और रखरखाव? अस्तित्व वाले गैर-अनुरूपक बैचों के पुनःनिर्माण के लिए/पानी का गुणवत्ता नियंत्रण? यदि हाँ, जाँच करें)		

	क्या विभिन्न कार्यों के निष्पादन के लिए अतिरिक्त दस्तावेज़ जैसे लॉग बुक, नोटबुक या अन्य समान रिकॉर्ड उपलब्ध हैं?		
	क्या सामग्रियों की प्राप्तियों के रिकॉर्ड हैं और क्या इनमें निम्नलिखित जानकारी है? (माल रसीद नोट-जीआरएन) जीआरएन दस्तावेज संख्या प्राप्त करना? प्राप्ति की तिथि? आपूर्तिकर्ता? निर्माता? निर्माण का बैच नंबर? कंटेनरों का प्रकार और आकार? कंटेनरों की संख्या और स्थिति?		
	क्या सभी सामग्रियों के लिए विनिर्देश उपलब्ध हैं?		
	क्या वे अधिकृत रूप से दिनांकित हैं?		
	क्या परीक्षण के तरीके मान्य हैं?		
	नई/संशोधित राष्ट्रीय/अंतर्राष्ट्रीय फार्माकोपिया के अनुपालन को सुनिश्चित करने के लिए क्या विनिर्देशन की आवधिक समीक्षा की जाती है?		
	क्या कच्चे माल के स्टॉक और जारीकरने के रिकॉर्ड हैं और इनमें निम्नलिखित जानकारी है:? प्रारंभिक शेष? प्राप्ति की तिथि? प्राप्त मात्रा? निर्माता द्वारा निर्दिष्ट नाम और बैच संख्या? चालान संख्या, आपूर्तिकर्ता का नाम और पता? विश्लेषण रसीद नम्बर और तारीख? समाप्ति की तारीख, यदि कोई हो? विनिर्माण के उत्पाद का नाम और बैच संख्या जो जारी किया गया है? शेष? जारीकर्ता के हस्ताक्षर?		
	क्या विनिर्मित प्रत्येक औषध उत्पाद के लिए मास्टर उत्पादन रिकॉर्ड हैं?		
	क्या प्रत्येक खुराक फॉर्म/बैच आकार के लिए एक अलग मास्टर उत्पादन दस्तावेज है?		
	क्या ये मास्टर प्रोडक्शन रिकॉर्ड सक्षम व्यक्ति द्वारा हस्ताक्षरित और दिनांकित हैं?		
	क्या प्रत्येक बैच के लिए एक बैच उत्पादन रिकॉर्ड तैयार किया जाता है?		
	क्या यह उपयुक्त मास्टर उत्पादन दस्तावेजों कीप्रतिकृति है या इसमें बैच के बारे में सभी महत्वपूर्ण जानकारी है?		
	क्या समाप्ति तारीख के बाद कम से कम एक साल तक बैच रिकॉर्ड रखा जाता है?		
	क्या इसकी सटीकता के लिए जाँच की गई है, स्ताक्षरित और दिनांकित		

	है		
	क्या सभी परीक्षणों के लिए क्यूसीद्वारा रिकॉर्ड रखा गया है? क्या ये रिकॉर्ड शामिल हैं: उत्पाद का नाम निर्मित बैच की संख्या? प्रयोगशाला की संदर्भ संख्या के साथ जारी पर्ची? जॉब कार्ड रेखांकन, चार्ट, स्पेक्ट्रा, आदि? प्रयुक्त प्रमुख उपकरणों की सूची? प्रक्रियाधीन परीक्षण रिपोर्ट? उत्पाद की गणना? विचलन नोट्स पर प्राधिकृत प्राधिकारी के हस्ताक्षर?परीक्षणों का प्रदर्शन करने वाले व्यक्तियों के हस्ताक्षर? स्टोर को लौटाई गई सामग्री? अंतिम उत्पाद की प्रयोगशाला रिपोर्ट? "सकारात्मक स्मरण" के तहत जारी किए गए किसी भी कच्चे माल/कच्ची सामग्री के परिणामों की समीक्षा? निर्धारित मानकों के साथ सटीकता और अनुपालन के लिए रिकॉर्ड की समीक्षा के लिए जिम्मेदार नामित व्यक्ति के हस्ताक्षर?		
	क्या अन्य संबद्ध रिकॉर्ड उपलब्ध हैं?		
	क्या प्रलेखन परीक्षा के लिए आसानी से उपलब्ध है?		
	क्या बैच उत्पादन रिकॉर्ड, कच्चे माल के स्तर से तैयार उत्पादों के वितरण तक के लिए बैच के पूर्ण विवरण को देने में सक्षम हैं?		
18	**वितरण रिकॉर्ड**		
	एएसयू औषधों के प्रत्येक बैच की बिक्री और वितरण के रिकॉर्ड रखे जाते हैं? स्टॉक खत्म हो जाने के बाद रिकॉर्ड कम से कम 5 साल तक रखा जाता है?		
19	**बाजार की शिकायतों का रिकार्ड**		
	क्या फर्म में बाज़ार से प्राप्त शिकायत का रिकॉर्ड रखा जाता है?		
	क्या फर्म ने शिकायत की जांच की है और कोई सुधारात्मक कार्रवाई की है?		
	क्या फर्म ने लाइसेंसिंग प्राधिकरण को इस तरह की शिकायत की छमाही रूप में सूचना दी है?		
	क्या फर्म में किसी एडीआर रिपोर्ट के रजिस्टर का रखरखाव कियागया है?		
	लौटाए गए उत्पादों की रसीद और नियंत्रण के लिए लिखित प्रक्रिया उपलब्ध है?		

	जब तक गुणवत्ता नियंत्रण किसी वापस लौटाए गए अथवा क्षति से बचाए गए औषध उत्पादों की पुनःप्रक्रिया निर्धारित नहीं करता उनको नष्ट नहीं किया जाता है?		
	क्या लौटाए गए उत्पादों का रिकॉर्ड उनके स्वभाव सहित बनाए रखा गया है?		
	क्या एक सुरक्षा नियमावली उपलब्ध है?		
20.	**गुणवत्ता नियंत्रण**		
	क्या गुणवत्ता नियंत्रण क्षेत्र 150 वर्ग मीटर से अधिक है?		
	क्या न्यूनतम रूप से गुणवत्ता नियंत्रण अनुभाग है: क) आयुर्वेद/सिद्ध/यूनानी में डिग्री योग्यता वाला एक व्यक्ति; ख) विज्ञान या फार्मेसी या फार्मेसी (आयुर्वेद) में स्नातक के साथ एक रसायनज्ञ और; ग) विज्ञान (चिकित्सा) या फार्मेसी या फार्मेसी (आयुर्वेद) में स्नातक के साथ एक वनस्पति विज्ञानी (फार्माकोग्नोजिस्ट)?		
	क्या मास्टर नियंत्रण प्रक्रियाएं अधिकृत व्यक्तियों द्वारा हस्ताक्षरित और बताई गई हैं?		
	क्या इन नियंत्रण प्रक्रिया में विनिर्देश, परीक्षण प्रक्रिया या अन्य नियंत्रण प्रक्रिया शामिल हैं:		
	कच्चा माल		
	प्रक्रिया सामग्री		
	पैकेजिंग और लेबलिंग सामग्री?		
	तैयार उत्पाद?		
	पुनर्संसाधन सामग्री की स्वीकृति के लिए क्यूसी कार्मिक को प्रक्रिया लिखित रूप में और आसानी से उपलब्ध हैं?		
	क्या पुनः संशाधित सामग्री की स्वीकृति के लिए प्रक्रिया लिखित रूप में और आसानी से उपलब्ध है?		
	क्या इन नियंत्रण प्रक्रिया में किए गए परीक्षण या अन्य नियंत्रण प्रक्रिया हेतु विनिर्देश शामिल हैं:		
	कच्चा माल		
	प्रक्रिया सामग्री		
	पैकेजिंग और लेबलिंग सामग्री		
	तैयार उत्पाद?		
	क्या गुणवत्ता नियंत्रण कार्मिक द्वारा नमूने एकत्र किए गए हैं?		
	क्या सूक्ष्मजीवविज्ञानी और बाँझपन परीक्षण के लिए विशेष स्थल है?		
	क्या कमरे का वातावरण नियंत्रित है?		
	क्या हाथ में उपलब्ध कार्य हेतु निर्माण क्षेत्र में केवल सामग्री, कंटेनर और उपकरण आवश्यक हैं और इन पर उत्पाद के नाम के साथ बैच नम्बर		

	तारीख आदि के माथ ठीक से लेबल लगाया गया है?		
	औषध उत्पादों के विनिर्माण में उपयोग के लिए सभी कच्चे माल, कंटेनर, क्लोजर, लेबल और मुद्रित पैकेजिंग सामग्री क्यूसी द्वारा स्वीकृत और जारी की जाती हैं		
	प्रक्रियाधीन नियंत्रण क्यूसी कर्मियों द्वारा जाता है?		
	क्या आवश्यक होने पर उपयुक्त परीक्षणों के लिए तैयार हो रहे उत्पादों का परीक्षण किया जाता है?		
	पैकेजिंग से पूर्व नियत विनिर्देशनों के लिए थोक, तैयार उत्पाद की जांच की जाती है?		
	क्या बिक्री के लिए जारी करने से पहले प्रत्येक तैयार उत्पाद का नियत विनिर्देशों के लिए परीक्षण किया गया है?		
	क्या क्यूसीद्वारा किए गए सभी परीक्षणों के रिकॉर्ड को रखे जाते हैं?		
	क्या बिक्री के लिए उत्पाद के एक बैच को जारी करने से पहले लिखित प्रक्रिया के अनुपालन को सुनिश्चित करने के लिए क्यूसी सभी उत्पादन और नियंत्रण रिकॉर्ड की समीक्षा करता है?		
	मानक संदर्भ: क्या संदर्भ मानक (आर.एस) उपलब्ध हैं? क्या ये आरएसया कार्य मानक (डब्ल्यूएस) हैं? क्या आरएस या सीआरएस के लिए डब्ल्यूएस मानकीकृत हैं? क्या आरएस को सही तरीके से संग्रहित किया जाता है (नमी वाले स्थितियों में उपयुक्त तापमान पर)? आरएस और उनके मानक के रिकॉर्ड रखे जाते हैं?		
	क्या आवश्यकताकी स्थिति में भावी परीक्षा के लिए सामग्रियों और तैयार उत्पादों की दो बार की जांच हेतु रखने के लिए पर्याप्त मात्रा में नमूने हैं?		
	क्या गुणवत्ता नियंत्रण प्रक्रियाएं मान्य हैं?		
	क्या निम्नलिखित सहित स्थायित्व के लिए लिखित कार्यक्रम उपलब्ध हैं:		
	नमूना भंडारण की स्थिति		
	कमरे का तापमान?		
	नमूना आकार और परीक्षण अंतराल?		
	विश्वसनीय और विशिष्ट परीक्षण विधियाँ?		
	बंद करने की प्रणाली वाले एक ही कंटेनर में परीक्षण जिसमें इसका विपणन किया जाता है?		
	दिनांक और समाप्ति तिथि यदि कोई हो?		
	आंतरिक विनिर्देश बनाए गए हैं?		
	क्या फर्म भाग II सी में अनुशंसित उपकरण फर्म को मुहैया किया गया है?		

21	**विसंक्रमित उत्पाद के लिए अपेक्षाएं**		
	विनिर्माण क्षेत्र		
	क्या अलग विनिर्माण क्षेत्र है		
	क्या प्रवेश के लिए एयरलॉक हैं?		
	क्या वायु आपूर्ति के लिए धूल मुक्त और हवादार स्थान है		
	संदूषण और मिश्रण के खिलाफ सावधानियां।		
	क्या निर्माण कार्य पर्याप्त रूप से पृथक भवन के एक अलग ब्लॉक में किए जा रहे हैं		
	क्या प्रक्रिया क्षेत्र में उपयुक्त दबाव अंतर है।		
	क्या उपयुक्त निकास प्रणाली प्रदान की गई है?		
	कीटाणुनाशक विनिर्माण के लिए उचित वायु आपूर्ति (हेपाके माध्यम से फ़िल्टर) प्रदान की गई है?		

निरीक्षण दल के सदस्यों के हस्ताक्षर"

37. टीए प्रपत्र के पश्चात निम्नलिखित संलग्नक अंतर-स्थापित किया जाएगा अर्थात्:-

"टीए प्रपत्र के लिए संलग्नक

(नियम 157क देखें)

खेती/मूल उत्पादन का प्रमाण पत्र

यह प्रमाणित किया जाता है कि ..... ने वित्तीय वर्ष.....के दौरान निम्नलिखित औषधीय पादपों की खेती की है अथवा उगाए गए औषधीय पादपों में से जड़ी-बूटी वाली कच्ची सामग्री का उपयोग किया है। खेती की किस्में और क्षेत्र/कटाई/उपज की मात्रा/उपयोग की मात्रा/प्रत्येक सामग्री हेतु प्राप्त उपज निम्नवत है:

क्र. सं.	**फसल का नाम**	**गांव सर्वेक्षण/खसरा सं.**	**कुल क्षेत्र (देशांतर/अक्षांश में क्षेत्र)**	**भूमालिक का नाम**	**किसानों/किसान उत्पादक संगठन/समूह/स्व सहायता समूह आदि**	**आधार सं.**	**मोबाइल नं.**	**खेती/उपज वाली कुल कच्ची सामग्री की मात्रा**	**जारी करने की तिथि**

दिनांक: प्रमाणीकरण प्राधिकारी

स्थान:

कार्यान्वयन एजेंसी हेतु पदनामित अधिकारी

(राज्य औषधीय पादप बोर्ड अथवा राष्ट्रीय औषधीय पादप बोर्ड)"

[फा.सं. टी-11011/05/2019-डीसीसी(आयुष)]

पी.एन.रण्जीत कुमार, संयुक्त सचिव

MINISTRY OF AYUSH

NOTIFICATION

New Delhi, the 2nd July, 2021

G.S.R. 473(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940) and after consultation of Ayurveda, Siddha, Unani Drug Technical Advisory Board , is hereby published as required by the said section, for the information of all persons likely to be affected thereby; and notice is hereby given that the objections or suggestions of the stakeholders on the said draft rules will be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Any objection or suggestion, which may be received from any person with respect to the said draft rules within the period specified above, will be taken into consideration by the Central Government;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of AYUSH, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi – 110023 or emailed at dce-ayush@nic.in.

DRAFT RULES

1. Short title, extent and commencement. ___

(1) These Rules may be called the draft Drugs and Cosmetics (Amendment) Rules, 2021.

(2) They shall come into force from the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to be as the principal Rules) rule 2(dd) shall be substituted namely-

"(dd) Homoeopathic medicines include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative literature of Homoeopathy as mentioned in first and second schedule of the Act and which is prepared according to the techniques of the official Homoeopathic Pharmacopoeia of India and abroad and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route."

3. After rule 2 (ec) the following rule shall be inserted namely-

"(ed) "Registered Ayurvedic or Siddha or Sowa-Rigpa or Unani medical practitioner" means a person -

(i) holding a qualification granted by an authority specified or notified in the Schedules to the Indian Medicine Central Council Act, 1970 (48 of 1970); or

(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practising the Ayurveda or Siddha or Sowa-Rigpa or Unani system of medicine;"

4. After Rule 2 (h) following rules shall be inserted namely-

"(hh) Sowa Rigpa drugs .— Sowa Rigpa drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Sowa Rigpa systems of medicine, specified in the First Schedule of the Drugs and Cosmetic Act, 1940.

(hi) Sowa-Rigpa Proprietary medicine.- In relation to Sowa Rigpa systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Sowa Rigpa systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (hh)."

5. Under Rule 67A

i. subrule (2) shall be substituted namely.-

" (2) Application for the grant of a licence to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines shall be made in Form19-B to the Licensing Authority and shall be accompanied by a fee of rupees two thousand.

ii. subrule (3) shall be substituted namely.- (3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the sale license of Homoeopathic Medicines.

Provided that this rule shall not be applicable to licence obtained under Form 20C or 20D prior to the date of commencement of this Amendment Rules, 2021. Such licence holders have to deposit a license retention fee of rupees one thousand for perpetuity of existing licence."

6. Rule 67C shall be substituted namely.-

"**67C. Forms of licences to sell drugs.**-(1) A licence to sell, stock or exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in **Form 20C or 20D** as the case may be.

Form of licence to manufacture Ayurvedic, Siddha or Unani drugs. — (1) Subject to the conditions of rule 67F being fulfilled, a licence to sell, stock or exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in **Form 20C or 20D** as the case may be. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 20C or 20D issued online as per the format provided in the said portal."

7. Rule 67E shall be substituted with the following rule namely.-

"**67E Duration of licences.**(1) A licence issued in Form 20C or 20D shall remain valid perpetually.

Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every five years from the date of issue of license in form 20C or 20D or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within one month of completion of five years from the date of issue of license in Form 20C or 20D or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled."

8. Rule 67EE shall be omitted.

9. Second Proviso under Rule 67F shall be substituted namely.-

"Provided further that registered Homoeopathic medical practitioner who is practising Homoeopathy in the premises licensed under 20C or 20D shall only prescribe medicines to his patients and not take part in the retail sale of Homoeopathic medicines."

10. Subclause 6 of Rule 67G shall be omitted.

11. Rule 85B shall be substituted with the following rule namely.-

"85B. Application for licence to manufacture Homoeopathic medicines.

(1) An application for the grant of a licence to manufacture for sale of Homoeopathic medicines falling under clause (dd) of Rule 2 shall be made in Form 24C to the licensing authority along with a fee of rupees five thousand.

(3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the license for manufacture for sale of Homoeopathic medicines.

Provided that this rule shall not be applicable to licence obtained under Form 25C prior to the date of commencement of this Amendment Rules, 2021. Such licence holders having factory premises complying with the requirements and conditions as specified in Schedule M1 have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence."

12. Rule 85D shall be substituted with the following rule namely.-

"**85D. Form of licence to manufacture Homeopathic medicines.** — (1) Subject to the conditions of rule 85E being fulfilled, a licence to manufacture for sale of Homeopathic medicines shall be issued in Form 25-C. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Homoeopathic Systems of medicine as the case may be, which the State Government may approve in this behalf.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 25C issued online as per the format provided in the said portal."

13. In rule 85 E the words "or renewal" and "or renewed" shall be omitted.

14. The proviso to rule 85E namely "Provided that in case potentised preparations are made in a Pharmacy holding licence in Form 20-C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label" shall be omitted.

15. Rule 85EA shall be substituted with following rule namely.-

"**85EA. Inspection for grant of license and verification of compliance.**-(1) Before a GMP certificate for License under Form 25C is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more inspectors appointed by the State Government under this Act, with or without an expert in the field concerned. The inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The establishment licensed under sub-rule (1) shall be inspected by the drug inspectors appointed by the State Government under this Act to verify the self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules not less than once in three years or as needed as per risk based approach.

(3) Provided the drug inspectors are allotted the inspection duty in a randomized manner ensuring same drug inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than three years duration."

16. Rule 85EB shall be substituted with following rule namely.-

"**85EB. Report by Inspector.**– (1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and the Requirements of Plant and Equipments as laid down in Schedule M1.

(2) The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the sub- rule (1), to the Licensing Authority.

17. Rule 85EC shall be substituted with following rule namely.-

"**85EC.-Procedure of Licensing Authority.**-(1) If the Licensing Authority after such further enquiry,

if any, as he may consider necessary, is satisfied that the requirements of the Rules under the Act have been complied with and that the conditions of the licence and the Rules under the Act shall be observed, he shall issue a licence under this Part.

(2) If the Licensing Authority is not satisfied, he shall issue a memorandum of shortcoming, and the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.

(3) Such memorandum of shortcomings as under sub-rule (2) is to be replied back by the applicant within two months of issue of such memorandum.

(4) On non submission of requirements in sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.

(5) For this purpose, the licensing authority shall intimate the applicant and process the application through portal e-AUSHADHI (www.e-aushadhi.gov.in).

18. Rule 85ED shall be substituted with following rule namely.-

"**85ED.**- Further application after rejection. –If within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices as the case may be, the applicant informs the Licensing Authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees one thousand the Licensing Authority may after causing a further inspection to be made, he is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part."

19. Rule 85F shall be substituted with following rule namely.-

"**85F. Duration of licence**—(1) A licence issued in Form 25C shall remain valid perpetually.

Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every three years from the date of issue of license in form 25 C or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within one month of completion of three years from the date of issue of license in form 25 C or from the date of submission of last self declaration as the case may, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled."

20. Rule 85G shall be omitted.

21. In rule 157

(i) In sub clause (1A), for the words "as per Schedule T" the words "as per Schedule T, Level (a) for a micro enterprise, where the investment in Plant and Machinery or Equipment does not exceed one crore rupees and turnover does not exceed five crore rupees and a small enterprise, where the investment in Plant and Machinery or Equipment does not exceed ten crore rupees and turnover does not exceed fifty crore rupees; Level (b) for enterprise, where the investment in Plant and Machinery or Equipment exceeds ten crore rupees and turnover exceeds fifty crore rupees." shall be substituted.

(ii) sub clause (2)(b) shall be omitted.

(iii) sub clause (2)(c) shall be substituted namely-"(b) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government with experience of at least three years in manufacturing of Ayurveda, Sidhha, Unani drugs in a licensed manufacturing unit or MD Ras-shastra/Bhaishajya Kalpana/Medicinal plants/Dravyaguna/Saidala/Gunapadam.

(iv) sub clause (2)(d) shall be omitted.

(v) sub clause (2)(e) shall be omitted.

22. In rule 157A

i. For the words "to the State Licensing Authority of Ayurveda, Siddha and Unani drugs and" shall be omitted.

ii After the first proviso the following proviso shall be inserted namely-

"(ii) The manufacturers / farmers who wish to declare the cultivated produce separately may follow one of the following two procedures:

(a) they may take prior registration of specific medicinal plant cultivation (for harvesting raw material) on www.echarak.in portal as per the area of cultivation and estimated yield on the basis of the agro-techniques published by National Medicinal Plant Board from time to time. In the case of such applications National Medicinal Plant Board through its evaluation team will issue a certificate to the farmer(s) / Farmer Producer Organisation(s)/ Cluster(s) / Non Government Organisation(s) / Self Help Group(s) / Fast Moving Consumer Good(s) manufacturer(s) on the basis of an online application through e-Charak portal.

(b) Those who are not registered with National Medicinal Plant Board or State Medicinal Plant Board or Regional Cum Facilitation Centre for the certification prior to initiation of cultivation should apply for Certificate of Cultivation / Origin in the Annexure to Form TA prior to harvesting.

Any material failing to comply with one of these above clauses may be considered as extracted raw material and may attract Access Benefit Sharing as per the provisions of Biological Diversity Act 2002.

The Certificate of Cultivation / Origin may be issued by those authorities who are nominated by National Medicinal Plant Board or State Medicinal Plant Board or Regional Cum Facilitation Centre or any designated officer as decided by National Medicinal Plant Board from time to time."

23. Rule 158 (B)

i. in subrule I (A) for the words "Ayurvedic, Siddha and Unani Tibb system of medicine as specified in the First Schedule;" following words "First Schedule either by using the traditional methods of manufacturing or by using the modern equipment / machinery. The methods of technology transfer may be provided as the proof of no deviation from the original texts in the form of a note at the time of new license application or at the time of perpetuity of existing license;

In subrule I(A) following clause may be inserted namely.-

"(i) The ingredients of ASU Drugs mentioned in the authoritative books of First Schedule are of two categories viz., crude herbs / raw material; and intermediates - value added product - extracts / volatile oils / fixed oils etc.

a. **Raw Material** - Raw material is the plant, mineral metal or animal material which is harvested or collected and used in the formulation without subjecting them to processes other than washing, cleaning, powdering etc.

b. **Intermediates / Value Added Products / Extracts / Volatile oils / Fixed oils** – are the semi processed raw material or processed raw material which is physically not identified with the raw material. The following are the examples –

i.) Amla pishti, kwatha, and prakshepa churna are three different intermediates which will go into Chyawanprash with sugar as the base. Asavarishtas and Ghrita-taila formats also have similar intermediates in 2-3 stages.

ii.) Camphor, Kattha, Kanyasar, Lavang tel, Chandan tel, Sesame oil, Chaulmoghra oil etc are examples of VAPs, Volatile oils & Fixed oils.

iii.) Wherever, the Aushadh Ghana / Rasakriya or Kshirapaka or Taila-Ghrita are used in the traditional method, the same may be recognized as traditional water extract or traditional milk extract or traditional emulsion extract respectively. These will be separately considered as intermediates / value added products / semi-processed finished goods."

ii. subrule I (B) shall be substituted namely-

"(B) Patent and Proprietary Ayurvedic, Siddha, Unani medicines as defined under section 3(h)(i) and also of following subtypes-

i) **Raw Material** – Any plant material which is harvested and used in the formulation without subjecting them to processes other than washing, cleaning, powdering etc.

ii) **Intermediates/Value Added Products/Extracts / Volatile oils / Fixed oils** – Semi processed raw material or processed raw material which is physically not identified with the raw material. They may be extracts made using solvents or super-critical extraction or any other new method as may be developed through research.

iii) **Aushadh Ghana (Medicinal plant extracts - dry/wet)** extract obtained either from plant(s) mentioned in books of First Schedule of the Act or from the herb(s) approved by PCIM&H and/or ASUDTAB.

Provided that in case of preparations of Intermediates / Value Added Products / Extracts / Volatile oils / Fixed oils for a Pharmacy holding a valid GMP certificate issued under Form 26 E-1, the license under Form 25D or 25E shall not be required. Such manufacturers shall ensure voluntary registration with the Licensing Authority."

iii. In Table under subrule II.(A) column 2 row 4 after the words "as referred in" the words "Section" shall be inserted.

iv. For the table under subrule II (B) the following shall be substituted namely-

"Sl. No.	Category	Ingredient (s)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
1	2	3	4	5	6	
					Published Literature	Proof of Effectiveness
1	(A) Patent or Proprietary medicine as mentioned in rule 158 B and in Section 3(h)(i) of the Act	Ingredients from books of First Schedule of the Act	Textual Rationale for one, two or three ingredient mixtures / combinations	Not Required for one, two or three ingredient mixtures / combinations	For one, two or three ingredient mixtures / combinations	Pre-clinical or Clinical Study as per Guidelines issued by Ministry of Ayush; or OECD guidelines.
	(B) Patent or Proprietary	Ingredients of Schedule	Textual Rationale	Required if published	Required if published	Required if published literature

2	medicine, with Ayurveda, Siddha and Unani ingredients of Schedule E(1) of the Act	E(1) of the Act		literature is not available (90 to 180 toxicity of the Schedule E(1) ingredient is minimum. Special toxicity studies may be provided on the basis of the outcome of acute and/or chronic toxicity studies following the OECD guidelines.	literature is not available	is not available. (Clinical Study as per Guidelines issued by Ministry of Ayush; or OECD guidelines.)
3	(C) Patent or Proprietary medicine, with Ayurveda, siddha and Unani ingredients from books of First Schedule the Act with new dosage forms or new ingredients or new indications**	Ingredients from books of First Schedule of the Act or any new ingredient which is accepted by PCIM&H and/or ASUDTAB	New Indication	Required if published literature is not available (90 to 180 toxicity of the E(1) ingredient is minimum. Special toxicity studies may be provided on the basis of the outcome of acute and/or chronic toxicity studies following the OECD guidelines.	Required if published literature is not available	Required if published literature is not available. (Clinical Study as per Guidelines issued by Ministry of Ayush; or OECD guidelines.)

***Explanation.*-For the purpose of this Rule**

1) **'New dosage form'** means any dosage forms covered under the existing formulary or pharmacopoeia (except parenterals)

2) **'New ingredient'** means any ingredient which is not part of books of First Schedule but being practiced / recommended by the registered practitioners of AYUSH systems which is subsequently vetted by the PCIM&H and/or ASUDTAB.

3) **'New indication'** means any indication which is not mentioned in the books of first schedule either for the single ingredient or for a group of ingredients.

V. For registration with respect to Aushadh Ghana/extract of medicinal plant (dry or wet).

Sl. No.	Category	Ingredient (s)	Indication (s)
1	2	3	4
1	(A) Aqueous	As per text	As per text
2	(A-I)	As per text or New	New indication
3	(B) Hydro-alcoholic	As per text or New	As per text
4	(B-I) Hydro-alcoholic	As specified	New indication
5	(C) Other solvent extract	As specified	As per text
6	(C-I) Other solvent extract	As specified	New indication
7	Supercritical extract etc	As specified	As per text
8	Supercritical extract etc	As specified	New indication"

24. Rule 160A shall be substituted with the following rule namely.-

"**160A Institutions for carrying out tests on Ayurvedic, Siddha and Unani Drugs and Raw materials used in their manufacture on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs.** All such institutions which have facilities as required for Quality Control Section as laid down under Schedule T and accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) for the category of chemical and biological testing for identity, purity, quality and strength of Ayurvedic, Siddha and Unani Drugs and raw materials will be notified as approved drug testing laboratories for the purpose of this rule by the central government.

Provided the rule shall be applicable for approved laboratories under Form 48 within two years from the date of notification of the said rules or from the date of next renewal of Form 48 whichever is earlier."

25. Rule 160 B to J shall be omitted.

26. In subrule (2) of Rule 161B

(i) the words "Real time" shall be substituted with "Real time and accelerated".

(ii) the following proviso shall be inserted namely.-" Licensee who wish to claim 1-2 years shelf life alone may submit the 3 months or 6 months accelerated stability at the time of license application or at the time of perpetuity of existing license.

27. After rule 162A following rules shall be inserted namely.-

"**162-AA. Controlling Authority.** - (1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.

(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.

(3) For the purposes of these rules an officer appointed by the Central Government under sub- rule (1), or as the case may be, an officer appointed by the State Government under sub-rule (2), shall be a controlling authority.

162.AB: Qualification of a Controlling Authority. -(1) No person shall be qualified to be a Controlling Authority under the Act unless: -

(i) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years or

(ii) MD Ras-shastra/Bhaisajya Kalpana/Dravyaguna/Saidala/Gunapadam/Medicinal Plants with a experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of three years."

28. In table under rule 168, for the words "12%" the words "11.40 %" shall be substituted.

29. The Rule 170 shall be omitted.

30. In Form 20C, i. in proviso 1 the words "by wholesale" shall be omitted.

ii. in proviso 2 the words "to ....." shall be omitted.

iii. Proviso 3 under Condition of license shall be omitted.

31. In Form 20D, in proviso 2 the words "to ....." shall be omitted.

32. Form 20E shall be omitted.

33. Form 24C shall be substituted namely.-

"FORM 24C

(See rule 85B)

Application for the grant of a licence to manufacture for sale or for distribution of Homoeopathic medicines

1 .I / We * .... of ..... hereby apply for the grant of licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised preparations on the premises situated at.....

Name of the Homoeopathic preparations .... (Each item to be separately specified)].

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

3. A fee of rupees ..... has been credited to Government under head of account .....

Date..... Signature.....

Note 1. Delete whichever portion is not applicable.

2. The application should be accompanied by a plan of the premises."

34. Form 25C shall be substituted namely.-

"FORM 25C

(See rule 85D)

Licence to manufacture for sale or for distribution of] Homoeopathic medicines

Number of Licence and date of issue .....

1. ..... of..... is hereby licensed to manufacture under mentioned Homoeopathic Mother Tinctures/ potentised and other preparations on the premises situated at .... under the direction and supervision of the following technical staff:

Names of the Homoeopathic preparations. (Each item to be separately specified).

Names of the Technical Staff.....

2. The licence shall be in force from date of issue .....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date..... Signature.....

Designation....

Conditions of Licence

1. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

5. The license is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Homoeopathic drugs as laid down in Schedule M1 of the Drugs and Cosmetics Rules, 1945."

35. Form 26C shall be omitted.

36. In Schedule T, i. Para 1 for the words "as follows in Part I and Part II" the words "as follows in Part I and Part II of Level a and Level b as the case may be" shall be substituted.

ii. for the words "PART I" the words "Part I Level a" shall be substituted.

iii. for the words "PART II" the words "Part II Level a" shall be substituted.

iv. After the end Note of the schedule T the following shall be inserted namely.-

"PART I Level b
PREMISES AND MATERIALS.

1. GENERAL REQUIREMENTS:-

1.1 Location and Surroundings-The factory building shall be so situated and shall have such construction as to avoid risk of contamination from external environment including open sewerage, drain, public lavatory and any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust, smoke, chemical or biological emissions.

1.2 Building & Premises- The buildings used for factory shall be such as to permit manufacturing of drugs under hygienic conditions and should be free from cobwebs and insects/rodents. It should have adequate provision of light and ventilation. The floor and the walls should not be damp or moist.

The premises used for manufacturing, processing, warehousing, packaging, labelling and testing purposes shall be –

(I) Compatible with other manufacturing operations that may be carried out in the same or adjacent premises. (II) Machineries and equipment shall be at least 1.5 meter apart to allow orderly and logical placement of equipment, materials and movement of personnel so as to:

(a) avoid the risk of mix-up between different category of drugs or with raw materials, intermediates and in-process material;

(b) avoid the possibilities of contamination and cross-contamination by providing suitable arrangements;

(III) Designed /constructed/ maintained to prevent entry of insects, pests, birds, vermins and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning, painting and disinfection.

(IV) Air-conditioned be equipped, where prescribed to control environmental factors, for the operations and dosage forms under production. The production and dispensing area shall be well lighted, effectively ventilated, and air control facilities (wherever applicable) and may have proper Air handling units (wherever applicable) to maintain conditions including temperature and, humidity (wherever necessary), as defined for the relevant product. These conditions shall be appropriate to the category of drugs and nature of operation. These conditions shall also be suitable to the comforts of the personnel working with protective clothing, products handled, and operations undertaken within them in relation to external environment. These areas shall be regularly monitored for compliance with required specifications;

(V) Provided with proper drainage system in the processing area. The sanitary fittings and electrical fixtures in the manufacturing area shall be proper and of adequate size and so designed as to prevent back flow and/or prevent insects and rodents entering the premises.

(VI) Furnace/Bhatti section could be covered with tin roof with proper ventilation, but sufficient care should be taken to prevent flies and dust.

(VII) Fire safety measures and proper exits should be provided

(VIII) Drying Space: - Separate space is required for drying of raw material, in process medicine or medicines which require drying before packing. This space shall be protected from flies/ insects/dust etc., by proper flooring, wire mash window, glass panels or other material and shall permit easy & effective cleaning and dis-infection.

(IX) Same manufacturing Facility/ Store shall not be used for any purpose other than manufacturing of Ayurveda, Siddha and Unani Drugs.

1.3 Water System - There shall be validated system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by the Bureau of Indian Standards or Local Municipality, as the case may be, so as to produce Purified Water conforming to Pharmacopoeial specification. Purified Water so produced shall only be used for all the operations except washing and cleaning operations where potable water may be used. Water shall be stored in tanks, which do not adversely affect quality of water and ensure freedom from microbiological growth. The tank shall be cleaned periodically and records shall be maintained by the licensee in this behalf.

1.4 Disposal of Waste- From the manufacturing section and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off with the requirements of Environment Pollution Control Board.

2. WARE HOUSING AREA :-

2.1 Adequate areas shall be designed to allow sufficient and orderly warehousing of various categories of materials and products like raw materials and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned or recalled, machine and equipment spare parts.

2.2 Warehousing areas shall be designed and adapted to ensure good storage conditions. They shall be clean, dry and maintained with acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity), these shall be provided, monitored and recorded. Storage areas shall have appropriate house-keeping and rodent, pests and vermin control procedures and records maintained. Proper racks, bins and platforms shall be provided for the storage of materials.

2.3 Receiving and dispatch bays shall protect materials and products from adverse weather conditions.

2.4 Where quarantine status is ensured by warehousing in separate earmarked areas in the same warehouse or store, these areas shall be clearly demarcated. Any system replacing the physical quarantine, shall give equivalent assurance of segregation. Access to these areas shall be restricted to authorized persons.

2.5 There shall be separate sampling area in the warehousing area for raw materials and excipients. If sampling of active components is performed in any other area, it shall be conducted in such area to prevent contamination, cross-contamination and mix-up.

2.6 Segregation shall be provided for the storage of rejected, recalled or returned materials or products. Such areas, materials or products shall be suitably marked and secured. Access to these areas and materials shall be restricted.

2.7 Highly hazardous, poisonous and explosive materials such as Poisonous drugs and substances presenting potential risks of abuse, fire or explosion shall be stored in safe and secure areas. Adequate fire protection measures shall be provided in conformity with the rules of the concerned civic authority.

2.8 Printed packaging materials shall be stored in safe, separate and secure area.

2.9 Sampling and dispensing of sterile materials shall be conducted under aseptic conditions, which shall also be performed in a dedicated area within the manufacturing facility.

2.10 Regular checks shall be made to ensure adequate steps are taken against spillage, breakage and leakage of containers.

2.11 Rodent treatments (Pest control) should be done regularly and at least once in a year and record maintained.

2.12 Storage containers for raw material, intermediates and finish goods shall be of food grade/ non- reacting material.

3. PRODUCTION AREA:-

3.1 The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations.

3.2 Working and in- process space shall be adequate to permit orderly and logical positioning of equipment **(at least 1.5 meter gap in between)** and materials and movement of personnel to avoid cross- contamination and to minimize risk of omission or wrong application of any manufacturing and control measures.

3.3 The Production area shall be washable and with clean airflow to avoid the risk of cross-contamination.

3.4 Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid accumulation of dust. Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

4. ANCILLARY AREAS: -

4.1 Rest and refreshment rooms shall be separate from stores & production areas. These areas shall not lead directly to the manufacturing and storage areas.

4.2 Facilities for changing, storing clothes and for washing and toilet purposes shall be easily accessible and adequate for the number of users. Toilets, separate for males and females, shall not be directly connected with production or storage areas. There shall be written instructions for routine cleaning and disinfection of such areas and records maintained.

4.3 Maintenance workshops shall be separate and away from production areas. Whenever spares, changed parts and tools are stored in the production area, these shall be kept in dedicated rooms or lockers. Tools and spare parts for use in sterile areas shall be disinfected before these are carried inside the production areas.

5. QUALITY CONTROL AREA: - RP

5.1 Quality Control. - Every licensee is required to provide facility for quality control section in his own premises. Quality Control Laboratories shall be independent of the production areas. The test shall be as per the Ayurveda, Siddha and Unani pharmacopoeial standard including Microbiology, Aflatoxins, Heavy Metals as and where applicable. Where the pharmacopoeial standards are not available, the test should be performed according to the manufacturers' specification or other information available which shall be duly verified by the state licencing authority. The quality control section shall verify all the raw materials (Identification and analysis), monitor in-process quality checks and control the quality of finished product being released to finished goods store/warehouse. The quality control section shall have the following facilities: –

(I) There should be at least 100 sq. feet area for quality control section.

(II) There should be at least facility for physico-chemical analysis.

(III) There should be provided facility for microbiology and other parameters through sophisticated instruments analysis etc in own premises or through Government approved public testing laboratory.

(IV) The design of the laboratory shall take into account the suitability of construction materials and ventilation. Separate air handling units and other requirements shall be provided for microbiological and sophisticated instruments testing areas. The laboratory shall be provided with regular supply of water of appropriate quality for cleaning and testing purposes.

(V) Quality control laboratory shall be divided into separate sections i.e. for physico-chemical, microbiology and sophisticated instruments analysis. This shall have adequate area for basic installation and for ancillary purpose. The microbiology section shall have arrangements such as airlock and laminar air flow work station, whenever considered necessary.

(VI) For identification of raw drugs, reference books and reference samples should be maintained.

(VII) To verify the finished products, At least three sample of each pack size as controlled samples of finished products of each batch will be kept till the expiry date of product.

(VIII) To supervise and monitor adequacy of conditions under which rawmaterials, semi- finished products and finished products are stored.

(IX) Keep record for establishing shelf life and storage requirements of the drugs.

(X) Manufacturers who are manufacturing patent and proprietary Ayurveda, Siddha, and Unani medicines shall provide their own specification and control references in respect of such formulated drugs which shall be duly verified by state licencing authority.

(XI) The standards for identity, purity and strength as given in respective pharmacopoeias of Ayurveda, Siddha and Unani systems of medicines published by Government of India shall be complied with.

(XII) Quality control section will have a minimum whole time employee of: –

(a) Expert in Ayurveda or Siddha or Unani medicine who possesses adegree qualification recognized under Schedule II of Indian Medicine Central Council Act 1970 or Pharmacy (Ayurveda/Unani), awarded by a recognized University;

(b) Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda or Siddha/Unani), awarded by a recognized University; and

(c) Botanist/ Pharmacognosist, who shall possess at least Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) or Diploma in Unani Pharmacy / Diploma in Pharmacy (Ayurveda) (with at least one year experience) awarded by arecognized University.]

(XIII) The manufacturing unit shall have a quality control section. Alternatively, these quality control provisions will be met by getting testing from a recognised laboratory for Ayurveda, Siddha and Unani drugs; under Rule 160-A of the Drugs and Cosmetics Act for certain parameters. The manufacturing company will maintain all the record of various tests got done from outside recognised laboratory. Quality control facility for physicochemical parameters and some basic test is mandatory required.

(XIV) List of equipment recommended for in-house quality control section alternatively, unit can get testing of certain parameters done from the Government approved laboratory).

(A)	CHEMISTRY SECTION	(B)	PHARMACOGNOSY SECTION
1.	Alcohol Determination Apparatus(complete set)	1.	Microscope Binocular.
2.	Volatile Oil Determination Apparatus.	2.	Dissecting Microscope.
3.	Boiling Point Determination Apparatus.	3.	Research Electronic Microscope attached with

			system
4.	Melting Point Determination Apparatus.	4.	Microtome.
5.	Refractometer.	5.	Stage Micrometer
6.	Polarimeter.	6.	Physical Balance.
7.	Viscometer.	7.	Camera Lucida (Prism and Mirror Type)
8.	Tablet Disintegration Apparatus.	8.	Chemicals, Dies & Reagents etc.
9.	Moisture Meter.	9.	Slides & Glassware
10.	Muffle Furnace.	10.	Tray Dryer
11.	Electronic Balance.	11.	Aluminium Slide Trays.
12.	Magnetic Stirrer.	12.	Grinder Machine
13.	Hot Air Oven.	13.	Jucer Machine
14.	Refrigerator.	14.	Clevenger Apparatus
15.	Glass/Steel Distillation Apparatus.	15.	Soxhlet Apparatus
16.	LPG Gas Cylinders with Burners.	16.	Supercritical Fluid Extraction Unit
17	Water Bath (Temperature controlled.)	17.	Percolator
18	Heating Mantles/ Hot Plates.	18.	Magnifying Lens Glass 10x
19.	TLC Apparatus with all accessories(Manual)	19.	Dissection Box
20	Paper Chromatography apparatus with accessories.		
21.	Sieve size 10 to120 with Sieve shaker.		
22	Centrifuge Machine.		
23.	Dehumidifier.		
24	pH Meter.(Digital)		
25.	Limit Test Apparatus.(Arsenic)		
26.	Homogenizer		
27.	Dissolution Apparatus		
28.	Thermometer		
29.	Stop watch		
30.	Physical Balance		
31.	Digital Weighing Balance (Weight in mg)		
32.	Micronizer		
33.	Pastel & Mortar		

6. **QUALITY CONTROL SYSTEM:-** Quality control shall be concerned with sampling, specifications, testing, documentation, release procedures which ensure that the necessary and relevant tests are actually carried and that the materials are not released for use, nor products released for sale or supply until their quality has been judged to be satisfactory. It is not confined to laboratory operations but shall be involved in all decisions concerning the quality of the product. It shall be ensured that all quality control arrangements are effectively and reliably carried out. The department as a whole shall have other duties such as to establish, evaluate, validate and implement all Quality Control Procedures and methods.

6.1 Every manufacturing establishment shall establish its own quality control laboratory (at least for physico-chemical analysis) managed by qualified and experience staff.

6.2 The area of the quality control laboratory may be divided into Physico-Chemical, Instrumentation and Microbiological.

6.3 Adequate area having the required storage conditions shall be provided for keeping reference samples. The quality control department shall evaluate, maintain and store reference samples.

6.4 Standard operating procedures shall be available for sampling, inspecting and testing of raw materials, intermediate bulk finished products and packing materials and, wherever necessary, for monitoring environmental conditions.

6.5 There shall be authorized and dated specifications for all materials, products, reagents and solvents including test of identity, content, purity and quality. These shall include specifications for water, solvents and reagents used in analysis.

6.6 No batch of the product shall be released for sale or supply until it has been certified by the authorized persor(s) that it is in accordance with the requirements of the standards laid down.

6.7 Reference/retained samples from each batch of the products manufactured shall be maintained in quantity which is

at least twice the quantity of the drug required to conduct all the tests, except sterility and pyrogen/ Bacterial Endotoxin. The retained product shall be kept in its final pack or simulated pack for a period of three months after the date of expiry.

6.8 Assessment of records pertaining to finished products shall include all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack. Assessment records should be signed by the in-charge of production and countersigned by the authorised quality control personnel before a product is released for sale or distribution.

6.9 Quality control personnel shall have access to production areas for sampling and investigation, as appropriate.

6.10 The quality control department shall conduct stability studies of the products as per Rule 161-B to ensure and assign their shell life at the prescribed conditions of storage. All records of such studies shall be maintained.

6.11 The in-charge of Quality Assurance shall investigate all product complaints and records thereof shall be maintained.

6.12 Each specification for raw materials, intermediates, final products, and packing materials shall be approved and maintained by the Quality Control Department. Periodic revisions of the specifications shall be carried out wherever changes are necessary.

6.13 Pharmacopoeia, Standard testing procedures (STP), reference standards, reference materials and authoritative & technical books, as required, shall be available in the Quality Control Laboratory of the licensee.

7. PERSONNEL: -

7.1. The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience.

7.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.

7.3. Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.

7.4 Written duties of technical and Quality Control personnel shall be laid and followed strictly.

7.5 Number of personnel employed shall be adequate and in direct proportion to the workload.

7.6 The licensee shall ensure in accordance with a written instruction that all personnel in production area or into Quality Control Laboratories shall receive training appropriate to the duties and responsibility assigned to them. They shall be provided with regular in-service training.

8. HEALTH, CLOTHING AND SANITATION OF WORKERS: –

8.1 Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof. The licensee shall provide the services of a qualified physician for assessing the health status of personnel involved in different activities.

8.2 All persons prior to and during employment shall be trained in practices which ensure personnel hygiene. A high level of personal hygiene shall be observed by all those engaged in the manufacturing processes. Instructions to this effect shall be displayed in change- rooms and other strategic locations.

8.3 No person showing, at any time, apparent illness or open lesions which may adversely affect the quality of products, shall be allowed to handle starting materials, packaging materials, in-process materials, and drug products until his condition is no longer judged to be a risk.

8.4 All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.

8.5 Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.

8.6 All personnel shall wear clean body coverings appropriate to their duties. Before entry into the manufacturing area, there shall be change rooms separate for each sex with adequate facilities for personal cleanliness such as wash basin with running water, clean towels or hand dryers, soaps, disinfectants, etc. The change rooms shall be provided

with cabinets for the storage of personal belongings of the personnel.

8.7 Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicines shall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.

9. MANUFACTURING OPERATIONS AND CONTROLS: –

9.1 All manufacturing operations shall be carried out under the supervision of technical staff approved by the concerned state Licensing Authority. Each critical step in the process relating to the selection, weighing and measuring of raw material addition during various stages shall be performed by trained personnel under the direct personal supervision of approved technical staff.

The contents of all vessels and containers used in manufacture and storage during the various manufacturing stages shall be conspicuously labelled with the name of theproduct, batch number, batch size and stage of manufacture. Each label should beinitialled and dated by the authorised technical staff.

9.2 Precautions against mix-up and cross-contamination:

9.2.1 The licensee shall prevent mix-up and cross-contamination of drug material and drug product (from environmental dust) by proper arrangements, status labelling and cleaning. Proper records and Standard Operating Procedures there of shall be maintained.

9.2.2 To prevent mix-ups during production stages, material under process shall be conspicuously labelled to demonstrate their status. All equipment used for production shall be labelled with their current status.

9.2.3 Packaging lines shall be independent and adequately segregated. It shall be ensured that all left-overs of the previous packaging operations, including labels, cartons and caps are cleared before the closing hour.

9.2.4 Before packaging operations are begun, steps shall be taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials and spillages. The line clearance shall be performed according to an approximate check list and recorded.

9.2.5 The correct details of any printing (for example of batch numbers or expiry dates) done separately or in the course of the packaging shall be rechecked at regular intervals. All printing and overprinting shall be authorized in writing.

9.2.6 The manufacturing environment shall be maintained at the required levels of temperature, humidity and cleanliness.

9.2.7 Authorised persons shall ensure change-over into specific uniforms before undertaking any manufacturing operations including packaging.

9.2.8 There shall be segregated secured areas for recalled or rejected material and for such material which are to be reprocessed or recovered.

10. SANITATION IN THE MANUFACTURING PREMISES: –

10.1 The manufacturing premises shall be cleaned and maintained in an orderly manner, so that it is free from accumulated waste, dust, debris and other similar material. A validated cleaning procedure shall be maintained.

10.2 The manufacturing areas shall not be used for storage of materials, except for the material being processed. It shall not be used as a general thoroughfare.

10.3 A routine sanitation program shall be drawn up and observed, which shall be properly recorded and which shall indicate-

(a) specific areas to be cleaned and cleaning intervals;

(b) cleaning procedure to be followed, including equipment and materials to be used for cleaning; and

(c) personnel assigned to and responsible for the cleaning operation.

10.4 The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of mix-up between different pharmaceutical products or their components to avoid cross contamination, and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.

10.5 Production areas shall be well lit, particularly where visual on-line controls are carried out.

11. RAW MATERIALS:

11.1 The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records.

11.2 All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored under appropriate conditions and in an orderly fashion to permit batch segregation and stock rotation by a 'first in/first-out' principle. All incoming materials shall be checked to ensure that the consignment corresponds to the order placed.

11.3 All incoming materials shall be purchased under valid purchase vouchers. Wherever possible, raw materials should be purchased directly from the producers/farmers.

11.4 Authorized staff appointed by the licensee in this behalf, which may include personnel from the Quality Control Department, shall examine each consignment on receipt and shall check each container for integrity of package and seal. Damaged containers shall be identified, recorded and segregated.

11.5 If a single delivery of material is made up of different batches, each batch shall be considered as a separate batch for sampling, testing and release.

11.6 Raw materials in the storage area shall be appropriately labelled. Labels shall be clearly marked with the following information:

(I) designated name of the product and the internal code reference, (where applicable), and analytical reference number;

(II) manufacturer's / Supplier's name, address and batch number;

(III) the status of the contents (e.g. quarantine, under test, released, approved, rejected); and

(IV) the manufacturing date, expiry date and re-test date.

11.7 There shall be adequate separate areas for materials "under test", "approved" and "rejected" with different standard colour label and arrangements and equipment to allow dry, clean and orderly placement of stored materials and products, wherever necessary, under controlled temperature and humidity.

11.8 Containers from which samples have been drawn shall be identified.

11.9 It shall be ensured that all the containers of raw materials are placed on the raised platforms/racks and not placed directly on the floor, care may be taken to handle the following different categories of raw materials: -

(I). Raw material of metallic origin.

(II). Raw material of mineral origin.

(III). Raw material from animal source.

(IV). Fresh herbs.

(V). Dry herbs or plant parts

(VI). Excipients etc.

(VII). Volatile oils/perfumes and flavours

(VIII). Plant concentrates/ extracts and exudates/resins.

12. EQUIPMENT:-

12.1 Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products. Each equipment shall be provided with a logbook, wherever necessary.

12.2 Balances and other measuring equipment of an appropriate range, accuracy and precision shall be available in the raw material stores, production and in-process control operations and these shall be calibrated and checked on a scheduled basis in accordance with Standard Operating Procedures and records maintained.

12.3The parts of the production equipment that come into contact with the product shall not be reactive, additive or adsorptive to an extent that would affect the quality of the product.

12.4To avoid accidental contamination, wherever possible, non-toxic/edible grade lubricants shall be used and the equipment shall be maintained in a way that lubricants do not contaminate the products being manufactured.

12.5 Defective equipment shall be removed from production and Quality Control areas and appropriately labelled.

13. DOCUMENTATION AND RECORDS: -

13.1 Documents designed, prepared, reviewed and controlled, wherever applicable, shall comply with these rules.

13.2 Documents shall be approved, signed and dated by appropriate and authorized persons.

13.3 Documents shall specify the title, nature and purpose. They shall be laid out in an orderly fashion and be easy to check. Reproduced documents shall be clear and legible. Documents shall be regularly reviewed and kept up to date. Any alteration made in the entry of a document shall be signed and dated.

13.4 The records shall be made or completed at the time of each operation in such a way that all significant activities concerning the manufacture of pharmaceutical products are traceable. Records and associated Standard Operating Procedures (SOP) shall be retained for at least one year after the expiry date of the finished product.

13.5 Data may be recorded by electronic data processing systems or other reliable means, but Master Formulae and detailed operating procedures relating to the system in use shall also be available in a hard copy to facilitate checking of the accuracy of the records. Wherever documentation is handled by electronic data processing methods, authorized persons shall enter modify data in the computer. There shall be record of changed and deletions. Access shall be restricted by passwords or other means and the result of entry of critical data shall be independently checked.Batch records electronically stored shall be protected by a suitable back-up. During the period of retention, all relevant data shall be readily available.

14. LABELS AND OTHER PRINTED MATERIALS: -

The Printing shall be done in bright colours and in a legible manner. The label shall carry all the prescribed details about the product.

14.1 All containers and equipment shall bear appropriate labels. Different colour coded labels shall be used to indicate the status of a product (for example under test, approved, rejected).

14.2 To avoid chance mix-up of printed packaging materials, product leaflets, relating to different products, shall be stored separately.

14.3 Prior to release, all labels for containers, cartons and boxes and all circulars, inserts and leaflets shall be examined by the Quality Control Department of the licensee.

14.4 Prior to packaging and labelling of a given batch of a drug, it shall be ensured by the licensee that samples are drawn from the batch and duly tested, and approved by the quality control personnel. The contents on label shall conform to Rule 161 and Rule 161-B of the Drugs & Cosmetics Rules 1945, the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 & Rule, 1955 and other legal requirements.

14.5 Records of receipt of all labelling and packaging materials shall be maintained for each shipment received indicating receipt, control reference numbers and whether accepted or rejected. Unused coded and damaged labels and packaging materials shall be destroyed and recorded.

14.6 All labels on finished Goods must mention customer help line number/contact to brief complaint or adverse reaction from the product.

15. QUALITY ASSURANCE: -

The system of quality assurance appropriate to the manufacture of ASU products shall ensure that: –

(I) the products are designed, developed and manufactured in a way that takes account of the requirements of Good Manufacturing Practices (hereinafter referred as GMP).

(II) adequate controls on raw materials, intermediate products and bulk products and other in-process controls, calibrations, and validations are carried out.

(III) the finished product is correctly processed and checked in accordance with established procedures;

(IV) the pharmaceutical products are not released for sale or supplied before authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the label claim and any other provisions relevant to production, control and release of pharmaceutical products.

16. SELF INSPECTION AND QUALITY AUDIT: -Firm shall constitute a self-inspection team supplemented with a quality audit procedure for assessment of all or part of a system with the specific purpose of improving it.

16.1 To evaluate the manufacturer's compliance with GMP in all aspects of production and quality control, concept of self-inspection shall be followed. The manufacturer shall constitute a team of independent, experienced, qualified persons from within or outside the company, who can audit objectively the implementation of methodology and

procedures evolved. The procedure for self-inspection shall be documented indicating self-inspection results, evaluation, conclusions and recommended corrective actions with effective follow up program. The recommendations for corrective action shall be adopted.

16.2 The program shall be designed to detect shortcomings in the implementation of Good Manufacturing Practice and to recommend the necessary corrective actions. Self- inspections shall be performed routinely and on specific occasions, like when product recalls or repeated rejections occur or when an inspection by the licensing authorities is announced. The team responsible for self-inspection shall consist of personnel who can evaluate the implementation of Good Manufacturing Practice objectively; all recommendations for corrective action shall be implemented.

16.3 Written instructions for self-inspection shall be drawn up which shall include the following: -

(a) Personnel.

(b) Premises including personnel facilities.

(c) Maintenance of buildings and equipment

(d) Storage of starting materials and finished products.

(e) Equipment.

(f) Production and in-process controls.

(g) Quality control.

(h) Documentation.

(i) Sanitation and hygiene.

(j) Validation and revalidation programmes.

(k) Calibration of instruments or measurement systems.

(l) Recall procedures.

(m) Complaints management.

(n) Labels control.

(o) Results of previous self-inspections and any corrective steps taken.

17.SPECIFICATION:

17.1 For raw materials and packaging materials. –

They shall include-

a) the designated name;

b) reference, if any, to a pharmacopoeial monograph;

c) qualitative and quantitative requirements with acceptance limits;

d) name and address of manufacturer or supplier

e) specimen of printed material;

f) directions for sampling and testing or reference to procedures;

g) storage conditions; and

h) maximum period of storage before re-testing.

17.2 For finished products. - Appropriate specifications for finished products shall include: -

a) the designated name of the product;

b) the formula or a reference to the formula and the pharmacopoeial reference;

c) directions for sampling and testing or a reference to procedures;

d) a description of the dosage form and package details;

e) the storage conditions and precautions, where applicable, and

f) the shelf-life.

18. **MASTER FORMULA RECORDS:** -

There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be

manufactured. These shall be prepared and endorsed by the competent technical staff i.e. head of production and quality control. The master Formula shall include: -

(a) the name of the product relating to its specifications;

(b) the patent or proprietary/ Classical name of the product, a description of the dosage form, composition of the product and batch size;

(c) name, quantity, and reference number of all the raw materials to be used.

(d) detailed stepwise processing instructions and the time taken for each step;

(e) the instructions for in-process control with their limits;

(f) the requirements for storage conditions of the products, including the container, labelling and special storage conditions where applicable;

(g) any special precautions to be observed; and

(h) packing details and specimen labels.

19. **PACKAGING RECORDS: -**

There shall be authorised packaging instructions for each product, pack size and type. These shall include or have a reference to the following: -

(a) name of the product;

(b) description of the dosage form, strength and composition;

(c) the pack size expressed in terms of the number of doses, weight or volume of the product in the final container;

(d) complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types with the code of reference number relating to the specifications of each packaging material.

(e) reproduction of the relevant printed packaging materials and specimens indicating where batch number and expiry date of the product have been applied;

(f) description of the packaging operation, including any significant subsidiary operations and equipment to be used;

(g) details of in-process controls with instructions for sampling and acceptance; and

(h) upon completion of the packing and labelling operation, a reconciliation shall be made between number of labelling and packaging units issued, number of units labelled, packed and excess returned or destroyed. Any significant or unusual discrepancy in the numbers shall be carefully investigated before releasing the final batch.

20. BATCH PACKAGING RECORDS:-

20.1 A batch packaging record shall be kept for each batch or part batch processed. It shall be based on the relevant parts of the packaging instructions, and the method of preparation of such records shall be designed to avoid transcription errors.

20.2 Before any packaging operation begins, check shall be made and recorded that the equipment and the work stations are clear of the previous products, documents or materials not required for the planned packaging operations, and that the equipment is clean and suitable for use.

21. BATCH PROCESSING RECORDS:-

21.1 There shall be Batch Processing Record for each product. It shall be based on the relevant parts of the currently approved Master Formula.

21.2 Before any processing begins, check shall be performed and recorded to ensure that the equipment and work station are clear of previous products, documents or materials not required for the planned process are removed and the equipment is clean and suitable for use.

21.3 During processing, the following information shall be recorded at the time each action is taken and the record shall be dated and signed by the person responsible for the processing operations: -

(a) the name of the product

(b) the number of the batch being manufactured,

(c) dates and time of commencement, of significant intermediate stages and of completion of production,

(d) initials of the operator of different significant steps of production and where appropriate, of the person who checked each of these operations.

(e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed.

(f) any relevant processing operation or event and major equipment used.

(g) a record of the in-process controls and the initials of the person

(h) carrying them out, and the results obtained.

(i) the amount of product obtained after different and critical stages of manufacture (yield).

22. STANDARD OPERATING PROCEDURES (SOPs) AND RECORDS, REGARDING: –

22.1 Receipt of materials:

22.1.1 there shall be written Standard Operating Procedures and records for the receipt of each delivery of all raw materials, primary and printed packaging material.

22.1.2 the records of the receipts shall include:

(a) the name of the material on the delivery note and the number of containers;

(b) the date of receipt;

(c) the manufacturers and/ or suppliers name;

(d) the manufacturers batch or reference number;

(e) the total quantity, and number of containers, quantity in each container received;

(f) the control reference number assigned after receipt;

(g) any other relevant comment or information.

22.1.3 There shall be written standard operating procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.

22.1.4 There shall be Standard Operating Procedures available for each instrument and equipment and these shall be placed in close proximity to the related instrument and equipment.

22.2 Sampling: -

22.2.1 There shall be written Standard Operating Procedures for sampling which include the person(s) authorized to take the samples.

22.2.2 The sampling instruction shall include:

(a) The method of sampling and the sampling plan,

(b) any precautions to be observed to avoid contamination of the material or any deterioration in its quality, (d) The quantity of samples to be taken,

(c) The types of sample containers to be used,

(d) any specific precautions to be observed.

22.3. Batch Numbering. - There shall be Standard Operating Procedures describing the details of the batch (lot) numbering set up with the objective of ensuring that each batch of intermediate, bulk or finished product is identified with a specific batch number.

22.4. Testing: There shall be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed shall be recorded.

22.5 Records of Analysis. –

22.5.1 The records shall include the following data:

(a) name of the raw material or product and the dosage form

(b) batch number and, where appropriate the manufacturer and/ or supplier,

(c) reference to the relevant specifications and testing procedures,

(d) test results, including observations and calculations, and reference to any specifications (limits),

(e) dates of testing,

(f) initials of the persons who performed the testing,

(g) initials of the persons who verified the testing and the detailed calculations,

(h) A statement of release or rejection, and

(i) signature and date of the designated responsible person.

22.5.2 There shall be written standard operating procedures and the associated records of actions taken for:

(a) equipment assembly and validation

(b) analytical apparatus and calibration,

(c) maintenance, cleaning and sanitation;

(d) personnel matters including qualification, training, clothing, hygiene

(e) environmental monitoring;

(f) pest control;

(g) complaints;

(h) recalls made; and

(i) returns received.

23. REFERENCE SAMPLES:-

23.1 Test Report of every raw material, shall be retained for a period of 3 months after the date of expiry of the last batch produced from that raw material.

23.2. Reference Samples of finished formulations shall be stored in the same or simulated containers in which the drug has been actually marketed, till the end of shelf life

24. Validation and process validation:

24.1 Validation studies shall be an essential part of Good Manufacturing Practices and shall be conducted as per the pre-defined protocols. These shall include validation of processing, testing and cleaning procedures.

24.2 A written report summarizing recorded results and conclusions shall be prepared, documented and maintained.

24.3 Processes and procedures shall be established on the basis of validation study and undergo periodic revalidation to ensure that they remain capable of achieving the intended results. Critical processes shall be validated, prospectively or retrospectively.

24.4 When any new Master Formula or method of preparation is adopted, steps shall be taken to demonstrate its suitability for routine processing. The defined process, using the materials and equipment specified shall be demonstrated to yield a product consistently of the required quality.

24.5 Significant changes to the manufacturing process, including any change in equipment or materials that may affect product quality and/or the reproducibility of the process, shall be validated.

25. DISTRIBUTION RECORDS:-

25.1 Prior to distribution or dispatch of given batch of a drug, it shall be ensuring that the batch has been duly tested, approved and released by the quality control personnel. Pre-dispatch inspection shall be performed on each consignment on a random basis to ensure that only the correct goods are dispatched. Periodic audits of warehousing practices followed at distribution centres shall be carried out and records thereof shall be maintained. Standard Operating Procedures shall be developed for warehousing of products.

25.2 Records for distribution shall be maintained in a manner such that finished batch of a drug can be traced to the retail level to facilitate prompt and complete recall of the batch, if and when necessary.

26. PRODUCT RECALLS: -

26.1 A prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockists, wholesalers, suppliers, upto the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard.

26.2. There shall be an established written procedure in the form of Standard Operating Procedure for effective recall of products distributed by the licensee. Recall operations shall be capable of being initiated promptly so as to

effectively reach at the level of each distribution channel.

26.3 The distribution records shall be readily made available to the persons designated for recalls.

26.4 The designated person shall record a final report issued, including reconciliation between the delivered and the recovered quantities of the products.

26.5 The effectiveness of the arrangements for recalls shall be evaluated from time to time.

26.6 The recalled products shall be stored separately in a secured segregated area pending final decision on them.

27. COMPLAINTS AND ADVERSE REACTIONS: -

27.1. Record of Market Complaints - Manufacturers shall maintain a register torecord all reports of market complaints received regarding the products sold in the market.

27.2. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in aperiod of six months the manufacturer shall submit the record of such complaints to thelicensing authority. The Register shall also be available for inspection during any inspection of the premises.

27.3 Reports of any adverse reaction resulting from the use of manufactured Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or itis a new observation and documents shall be forthwith reported to the concerned licensing authority

27.4. There shall be written procedure describing the action to be taken, recall to be made of the defective product.

28. Site Master File. –The licensee shall prepare a succinct document in the form of_Site Master File' containing specific and factual Good Manufacturing Practices about the production and/or control of pharmaceutical manufacturing preparations carried out at the licensed premises. It shall contain the information on various areas likes General information, Personnel, Premises, Equipment, Sanitation, Documentation, Production, Quality Control, Loan licence manufacture and licensee, Distribution, complaints and product recall, Self inspection, Export of drugs etc.

29. Specific Requirements For Manufacture Of Rasaushadhies Or Rasamarunthukal And Kushtajat (Herbomineral-Metallic Compounds) Of Ayurveda, Siddha And Unani Medicines : In addition to general requirements, following Specific Requirements shall also be followed, namely:

29.1 Bhatti or Heating Device Section for Bhasma and Rasaushadhies:- for heating, burning, putta and any heat related work with proper ventilation, exhaust and chimney. This could be tin shed also.

29.2 Grinding, Drying and Processing Section for Kushta, Bhasma and Rasaushadhies (Manual or Mechanical, oven etc.). Drying shall be done in a space which is covered by glass or other transparent material to allow entry of sunrays on the material to keep for the purpose. If drying is being done in oven the temperature of the same may be selected specific temperature.

29.3 The manufacturing area should be designed with special attention to process the products that help evacuate the generated toxic fumes like SO2, arsenic and mercury vapour, etc. When heating and boiling of the materials is necessary, suitable ventilation and air exhaust flow mechanism should be provided to prevent accumulation of unintended fumes and vapours. Such areas may be provided with properly designed chimneys or ducts fitted with exhaust system and suitable scrubbing system to remove fumes and smoke, so that safety of personnel and environment is taken care of.

29.4 Records shall be maintained specially for temperatures attained during the entire process of Bhasmikaran, while employing different kinds of classical puta, furnaces using oil, gas or electricity. Appropriate temperature measuring instrument should be employed such as pyrometer and, pyrograph for manual reading or recording by heat sensors, connected to computer as the case may be.

In order to handle large quantities, appropriate technology like use of hand operated extruders for making chakrikas or pellets may be adopted. However, such equipments made of aluminium or its alloys should not be used.

29.5 Product Quality Control:-The specifications for finished Rasaushadhi are primarily intended to define the quality rather than to establish full characterization, and should focus on those characteristics found to be useful in ensuring the quality. Consistent quality for Rasaushadhi can only be assured if the starting material-metals and minerals are used of pharmacopoeial standards. In some cases more detailed information may be needed on aspects of their process. The manufacturer will ensure in-house standards for the uniform quality of product. Special care is required to assure that the eliminated air from Rasaushadhi air is not contaminating other production area, particularly in closed

or centrally air conditioned premises.

29.6 Standard Operating Procedures (SOP) should be included for storage of recalled Rasaushadhies in a secure segregated area, complying with the requirements specified for storage till their final disposal.

29.7. Medical examination of the employees: - Employees engaged in manufacturing should be medially examined at the time of employment and then periodically at least once a year for any adverse effect of the drug during manufacturing process for which necessary investigations Shall be carried out for ensuring that there is no effect of material on the vital organs of the employees. Annual examination reports of the employees shall be made available to statutory inspectors during Good Manufacturing Practices inspections.

29.8. Dosage form of Rasaushadhi/Kushtajat:- The Rasaushadhies may be made into an acceptable dosage forms such as churna, vati, guti, tablet or capsules etc. after adding suitable permissible fillers or binding agents as permissible under the Ayurvedic Pharmacopoeia of India or Indian pharmacopoeia as updated from time to time. In such cases the label must indicate the quantity of Ayurveda, Siddha and Unani medicines in one Tablet or Pill or Capsule in addition to the filler. The crystalline product may be grinded before packing in the individual dispensing size. All the Rasaushadhi or Rasamaruthukal or Kushtajat shall be packed in a dosage form which is ready for use for the consumer. Grinding and weighing of individual dose of potentially poisonous products will not be permissible in patient consumer pack. This arrangement may reduce the Adverse Drug Reaction of Rasaushadhi which takes place due to dose variation. However, for hospital bulk pack, it will not be applicable and label will clearly indicate the "Hospital pack".

30. SPECIFIC REQUIREMENTS FOR MANUFACTURE OF STERILE PRODUCTS

30.1 Manufacturing Areas: – For the manufacture of sterile Ayurvedic, Unani and Siddha drugs, separate enclosed areas specifically designed for the purpose shall be provided. These areas shall be provided with air locks for entry and shall be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas. The filters shall be checked for performance on installation and periodically thereafter the record of checks shall be maintained. All the surfaces in sterile manufacturing areas shall be designed to facilitate cleaning and disinfection. For sterile manufacturing routine microbial counts of all Ayurvedic, Siddha and Unani drug manufacturing areas shall be carried out during operations. Results of such count shall be checked against established in-house standards and record maintained.

Access to manufacturing areas shall be restricted to minimum number of authorized personnel. Special procedure to be followed for entering and leaving the manufacturing areas shall be written down and displayed.

For the manufacturing of Ayurvedic, Siddha and Unani drug that can be sterilized in their final containers, the design of the areas shall preclude the possibility of the products intended for sterilization being mixed with or taken to be products already sterilized. In case of terminally sterilized products, the design of the areas shall preclude the possibility of mix-up between non-sterile products.

30.2 Precautions against contamination and mix:

(a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated enclosure within the building,

(b) Using appropriate pressure differential in the process area.

(c) Providing a suitable exhaust system.

(d) Designing laminar flow sterile air system for sterile products.

(e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.

(f) Individual containers of liquids and ophthalmic solutions shall be examined against black-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.

(g) Expert technical staff approved by the Licensing Authority shall check and compare actual yield against theoretical yield before final distribution of the batch.

All process controls as required under master formula including room temperature, relative humidity, volume filled, leakage and clarity shall be checked and recorded.

PARTICLE SIZE OR PARTICULATE MATTER OF SOLUTION IS TO BE MENTIONED

PART II of Level b

A. LIST OF MACHINERY, EQUIPMENT AND MINIMUM AREA REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF AYURVEDIC, SIDDHA & UNANI SYSTEM OF MEDICINES

One machine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. Similarly some of the manufacturing areas like powdering, furnace, packing of liquids and Avaleha, Paks, Majoon etc could also be shared for these items.

Sl. No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
(1)	(2)	(3)	(4)
1.	Itrifal/Tiryaq/Majoon/ Laooq/ Jawarish/Khamiras Pak/Avaleh/Khand/Modak/Lakayam/Murabba	100 sq. feet	Grinder/ Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Furnace/Bhatti and other accessories, plant mixer for Khamiras, Mortar and Pestle/Kharal, Aluminium Vessels, S. S. Storage Container
2.	Arq/Timir/Ark	100 sq. feet	Distillation Plant (garembic) S.S. storage tank, Boiling Vessel, Gravity filter, Bottle filling machine, Bottle washing machine, Bottle drier, Cap sealing machine
3.	Churna /Sufoof (Powder)	100 sq feet	Grinder/ Pulveriser, disintegrator, Powder mixer, sieves, shifter.
4.	Habb(Pills) /Vati /Gutika/Matirai / tablets/ Qurs (Tab.)	100 sq. feet	Ball Mill, Grinder/Pulveriser, Sieves, Mass mixer/powder mixer, Granulator, drier, tablet compressing machine, Die punches Trays, O.T. Apparatus, pill/Vati cutting machine, stainless steel trays/container for storage and sugar coating, polishing pan in case of sugar-coated tablets, mechanised chattoo (for mixing guggulu) where required, Balance with weights, Scoops, Heater, Counter & packing machineries
5	Raughan (oils)/Taila (Crushing and boiling)/Ghrit	100 sq. feet	Oil Expeller, S.S. Patilas, Oil filter bottle, Filling & sealing machine, Bottle drier, Bhatti, Kadahi/S.S. Patila, S.S.Storage Containers, Filtration equipment, filling tank with tap/Liquid filling machine.
6.	Kupipakava/Ksara/Parpati/Lavana /Bhasma/ Kushta/Satva/ Sindura /Karpu/ Uppu / Param	100 sq. feet	Bhatti, Karahi/Stainless steel Vessels/Patila, Flask, Earthen container, Gaj Put Bhatti, Muffle furnace (Electrically operated) End/ Edge Runner, Wooden/S.S.Spatula.

7	Kajal, Shiyaf, Surma, Anjana/Pisti	100 sq. feet	Mortar and Pestle /Kharal, Shifter, Earthen lamps for collection of Kajal, Triple Roller Mill, End Runner, Sieves, mixing S.S. Vessel, S.S.Patila,
8	Capsules	100 sq. feet	Air Conditioner, De-humidifier, hygrometer, thermometer, Capsule filling machine and chemical balance. Pulveriser, Powder mixer (where needed), Balance with weights, storage containers, glass, counter and packing machinery.
9	Ointment / Marham Pasai, Marham, Zimad (Ointment)/Soap/Aerosol	100 sq. feet	Tube filling machine, Crimping Machine/Ointment Mixer, End Runner/ Mill (Where required) S.S.Storage Container, S.S.Patila, Mortar and Pestle /Kharal, Bhatti, End runner, Grinder, Pulveriser, Triple Roller Mill (if required), Aerosol filling machine.
10	Panak/ Syrup / Pravahi Kwath/ Manapaku/ Sharbat and Joshanda	100 sq, feet	Tincture press, Mortar and Pestle /Bhatti section, filter press / Gravity filter, liquid filling machine P.P. Capping Machine. Liquid filling tank with tap/liquid filling machine, hot air oven electrically heated with thermostatic control, kettle.
11	Asava / Arishta/Sura	100 sq. feet	Fermentation tanks, containers and distillation plant where necessary, Filter Press. Distillation plant and Transfer pump (additionally required for Sura)
12	Aschyotan / Netra Malham/Panir/Karn Bindu/Nasabindu/ Qutoor-e- Chashm and Marham (Eye drops, eye ointment)	100 sq. feet	Hot air oven electrically heated with thermostatic control, kettle gas or electrically heated with suitable mixing arrangements, collation mill, or ointment mill, tube filling equipment, mixing and storage tanks of stainless steel or of other suitable material sintered glass funnel, seitz filter or filter candle, liquid filling equipment, autoclave.
13	Dry extract / wet extract	200 sq. ft.	
14	Any other category except parenteral	100 sq. ft.	
15	Raw material store	100 sq. ft.	
16	Packing material storage	100 sq. ft.	
17	Finished goods storage	100 sq. ft.	
18	Quarantine Area for Finished Goods	100 Sq. Ft	

19	Quality Control Section including storage of control sample	150 sq. ft.	
20	Stability Chamber Room	200 sq. ft	
21	Retain sample room	80 sq. ft	
22	Rejected goods store	Adequate	
23	Changing Room (Male/Female)	50 sq. ft.	
24	Office cum record room	Adequate	
25	Drying area	80 sq. ft.	
26	Grinding / pulverising area	80 sq. ft.	
27	Shifting and mixing area	80 sq. ft.	
28	Granulation area	80 sq. ft.	

Part III of Level b
CHECKLIST OF GMP INSPECTION

S. No	Areas/Activities to be Audited	Observations	
		Document Review	Remark
1.	**GENERAL**		
	Name and address of Unit MFG.Lic No. Telephone Fax: Email: Names and designation of the inspection team:		
2.	**PERSONAL**		
	Name of In charge क) production ख)quality control		
	Number of Production Supervisors/Asstt. Mfg./Chemist		
	Number of Analysts		
	Have all personal received GMP Training?		
	Is Training Documented?		
	What is the periodicity of the training?		
3.	**FACTORY PREMISES**		
	Does manufacturing unit have adequate space for Receiving and storing raw material. Manufacturing process areas. Quality control section. Finished goods store. Office Rejected goods/drugs store.		
4.	**LOCATION AND SURROUNDINGS**		

	Is the establishment located away from environmentally polluted areas?		
	Is the establishment located away from areas adjacent to open sewerage, drain/public lavatory or any factory which produces excessive, disagreeable odour.		
	Are sewage, trash and other effluent disposal provided?		
5.	**BUILDINGS**		
	Do the internal design and layout of establishment permit good hygiene practices including protection from cross- contamination?		
	Are surfaces of walls, partitions and floors made of impervious materials and capable of being kept clean?		
	Do walls and partitions have smooth surface?		
	Are floors constructed to allow adequate cleaning and drainage?		
	Are doors, windows, ceiling and overhead fixtures constructed and finished to minimize buildup of dirt, condensation and shedding of particles and easy to clean?		
	Are working surfaces that come into direct contact with drugs of sound condition, durable and easy to clean, maintain and disinfect? Any open drain blocked sewer or public lavatory nearby? Are any products other than drugs manufactured in the same building?		
	Is there adequate space for equipment, material and movement of personal and materials?		
	Is there any programme/system to check of birds, rodents and insects?		
	Are lightening and ventilation adequate?		
	Are facilities for changing street clothes, footwear, washing and toilets adequately and satisfactorily maintained?		
	Is the space for drying of raw materials satisfactory?		
6.	**WATER SUPPLY**		
	Is there adequate supply of potable water?		
	Does the potable water meet the specifications published API specifications?		
	Is only potable water Used in ASU medicines?		
7.	**DISPOSAL OF WASTE**		
	Are drainage and water disposal systems designed, constructed and maintained in such a way as to avoid contamination of ASU products?		
	Are the waste water and residues disposed of after suitable treatment as per guidelines of pollution control authorities?		
	Are the arrangements for the following adequate? Disposal of solid/semi solid waste Disposal of sewage Disposal of Liquid laboratory waste? Disposal of Management of gaseous pollutants?		

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	Is efficient treatment plant in existence if yes, give comment on it?		
	Are fume hoods of adequate design in existence and used wherever necessary?		
8.	**CLEANING OF CONTAINERS**		
	Is there proper arrangement for washing, cleaning and drying of containers? Is this area separated from manufacturing area?		
9.	**STORES**		
	Is there independent adequate space for storage of different types of materials such as raw material, packaging material and finished products?		
	Are ASU medicine storage facilities designed and constructed to Permit adequate maintenance and cleaning? Avoid pest ace and harbourage? Enable drugs to be effectively protected from contamination? Provided the necessary environment to prevent spoilage?		
	Are storage facilities deigned, constructed and maintained to ensure that malicious or accidental contamination of ASU medicines with harmful materials is prevented?		
10.	**RAW MATERIALS STORES**		
	Are raw materials or ingredients checked for parasites, undesirable microorganisms, pesticide or decomposed or extraneous substances		
	Are raw materials or ingredients inspected and tested before processing?		
	Are raw materials or ingredients subjected to effective stock rotation?		
	Is the area adequate?		
	Are the ventilation and lighting of stores adequate?		
	Is the Raw Material store segregated for different types of Raw Material? Raw materials of metallic origin Raw materials of mineral origin Raw materials of animal source Fresh herbs Dry herbs or plant parts Excipients etc. Volatile oils/perfumes and flavours Plant extracts and exudates/resins Others		
	Is special area with special condition provided for special Raw Materials?		
	Are there labels for material of different status i.e. quarantine, tested and releases for use and rejected?		
	Are these labels of different colours?		
	Are labels on containers of RM to be used in manufacture checked with regard to identity, quantity and QA approval? If not give details/		
	Is there the following information on the labels? Name of material Batch number Analysis number		

	Date of release/rejection? Date of testing? Date of expiry?		
	Is the sampling performed by quality control personal?		
	Are there sampling procedures?		
	Are the containers provided for storage of raw material suitable to preserve the quality?		
	Is exterior storage available for : Solvent storage area? Inflammable material storage area? Whether safety measures provided have been assessed by regulatory agency if any? Is SOP's available for handling of these materials? Are SOP's for cleaning of containers and closures available before packing of products?		
	Is the weighing area segregated?		
	Are lighting and ventilation adequate?		
	Is the area clean?		
	Do the personal wear appropriate clothing?		
	Is there danger of cross contamination during weighing?		
	Are the scales and balance calibrated regularly and records maintained?		
	Are the containers of the raw materials to be weighed, cleaned before opening?		
	After weighing, are these containers sealed?		
	Are the raw materials for each batch, after weighing properly identified and checked? Are adequately clean and dried equipment used for dispensing materials from the containers?		
	Is FIFO principle adopted?		
11	**PACKING MATERIALS**		
	Is the area adequate with reference to packing material?		
	Are the containers and closures adequately cleared and checked?		
12.	**FINISHED GOODS STORES**		
	Is the area adequate with reference to materials stored?		
	Are lighting and ventilation adequate?		
	Are there inventory records to show:		
	Quantities		
	Batch number		

	Date of receipt		
	Have the distribution records been maintained?		
	Do distribution records provide sufficient information for drug recall purpose?		
	Is there segregation area for retrieved good?		
	Are records available for the retrieved goods?		
	Is there any marked quarantine area?		
	Is there space for special storage conditions (environmental condition), if required?		
13.	**WORKING SPACE**		
	Is space adequate as per manufacturing operations?		
	Is machinery alongwith working manual orderly placed with adequate space?		
	Are there adequate precautions to check cross contamination?		
14.	**HEALTH ,CLOTHING, SANITATION AND HYGIENE OF WORKERS**		
	Are workers free from contagious disease?		
	Are workers properly uniformed?		
	Are there separate lavatories for men and women?		
	Is there provision for changing their cloth and to keep personal belongings?		
	Are adequate facilities like wash-basin with running water hand drier & clean towels, etc., available for personal hygiene before entering into production area?		
	Are personnel instructed to observe personal hygiene?		
	Are hygiene instructions displayed in change rooms and strategic locations?		
	Is the sanitation system monitored for effectiveness?		
	Is the sanitation system periodically verified by inspections? Is microbiological sampling of environment and ASU drugs contact surfaces carried out?		
	Is the sanitation system regularly reviewed and adapted to reflect changed circumstances?		
15	**MEDICAL SERVICES**		
	Is medical file of each worker maintained separately?		
	Is recruitment of an employee preceded by medical examinations?		
	What is the periodicity of subsequent medical examinations?		
	Is an employee whose state of health is doubtful immediately removed from work site until he is fully recovered?		
16.	**MACHINERY AND EQUIPMENT**		

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	Is manually operated or semioperated or automatic machines are used for Crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labelling and packing ?		
	Are equipment and containers coming into contact with ASU drugs designed such that they can be adequately cleaned, disinfected and maintained?		
	Are equipment made of nontoxic materials?		
	Are equipment used to cook, heat, treat, cool, store designed to achieve the required temperature as rapidly as necessary?		
	Are equipments used to cook, heat, treat, cool, store designed to monitor and control the required temperature?		
	Are containers for waste suitably identified?		
	Are containers for waste closable to prevent malicious or accidental contamination of ASU Medicines?		
	Is the equipment adequate for intended use?		
	Is it constructed in such a way that lubricants, coolant, etc. cannot contaminate the drug product?		
	Does the equipment permit cleaning and maintenance?		
	Does the equipment show its status i.e. clean, dirty, batch contents?		
	Do all apparatus/equipment bear appropriate labels to identify the product for which the equipment is used, its batch no., date of manufacturing etc.		
	Are SOPS available for cleaning maintenance and sanitation of major equipment?		
	Are log books maintained for cleaning maintenance and sanitation of major equipment?		
	Are SOP's readily available to operators		
	If automatic electronic or mechanical equipment is used ,are there: Written programs for calibration/inspection Checks to ensure that may changes are made only by authorized persons/ Are suitable closures or lids available to protect the changes in properties of material exposed to outside atmosphere?		
17.	**BATCH MANUFACTURING RECORDS**		
	Are appropriate records of processing, production and distribution kept?		
	Are SOP's available for the following Receipt of raw material and other components? Quarantine and storage? Quality control system and approval/rejection Release of production In process testing and control Finished product? Storage of finished product?		

	Distribution Returned goods Recalls and complaints Cleaning and maintenance? Quality control of water For reworking of non-conforming batches in existence? If yes, check)		
	Are there additional documents like log books, notebooks or other similar records available to show execution of various functions?		
	Are there records of receipts of materials and do these have following information? (goods receipt Note-GRN) Receiving GRN documents number? Date of receipt? Supplier? Manufacturer? Manufacture's batch number? Type and size of containers? Number of containers and conditions?		
	Are specifications available for all materials?		
	Are they dated authorized?		
	Are test methods validated?		
	Are periodic reviews of specification carried out to ensure compliance with new /revised National/international pharmacopocia?		
	Are these records of stock and issue of raw materials and do these have following information: Opening balance? Date of receipt? Quantity received? Name and batch number assigned by the manufacturer? Invoice number,date name and address of supplier? Analysis receipt no. and date? Date of expiry ,if any? Name and batch number of product for manufacture for which issued? Balance? Signature of issuing person?		
	Are there master formulation records for each drug product being produced?		
	Is there a separate master production documents for each dosage form/batch size?		
	Are these master production records signed and dated by competent person?		
	Is a batch production record prepared for every batch produced?		
	Is it reproduction of the appropriate master production documents or it has all critical information about the batch?		
	Are batch records retained for at least one year after expiry date?		

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	Has it been checked for accuracy, signed and dated by a responsible person?		
	Are the records maintained by QC for all the tests carried out? Do these records include: The name of the product Number of the batch being manufactured? Issue slip with lab ref. No Job cards? Graphs, chart, spectra, etc? List of major equipment used? In-process testing reports? Calculations of yield? Notes on deviations with signed authorization? Signature of individuals of who performed the tests? Material returns to store slip? Lab report of final product? Review of results for any raw material issued under "positive Recall"? Signature of the designated person responsible for the review of records for accuracy and compliance with established standards?		
	Are other associated records available?		
	Is documentation available readily for examination?		
	Are batch production records capable of giving complete history of the batch right from the raw material stage to the distribution of finished products?		
18	**DISTRIBUTION RECORD**		
	Are records of sale and distribution of each batch of ASU drugs maintained? Are records maintained at least up to 5 years of the exhausting of stock?		
19	**RECORD OF MARKET COMPLAINTS**		
	Are the firm maintain a record of complaint received from market?		
	Does the firm have investigated the complaint and has taken any corrective action?		
	Does the firm has intimated such complaint six monthly to the Licensing Authority?		
	Does the firm maintain register of any ADR report received?		
	Are written procedure available for receipt and control of return products?		
	Are returned or salvaged drug products destroyed unless QC determines their reprocessing?		
	Are records of the returned products maintained including their disposition?		
	Is a safety manual available?		
20.	**QUALITY CONTROL**		

	Is the QC area more than 150 sq ft?		
	Has Quality Control section minimum of: a) One person with Degree qualification in Ayurveda Siddha Unani: b) One chemist with bachelor in Science or Pharmacy or Pharmacy (Ayurveda) and: c) One Botanist (Pharmacognosist) with bachelor in Science (medical) or Pharmacy or Pharmacy (Ayurveda)?		
	Are master control procedures signed and stated by authorised persons?		
	Do these control procedure include specifications, test procedure or other control procedure for:		
	Raw materials		
	In process materials		
	Packaging and labelling materials?		
	Finished products?		
	Are the procedure in written form and readily available to QC personnel for acceptance of reprocessed material?		
	Are the procedure in written form and readily available for acceptance of reprocessed material?		
	Do these control procedure include specifications test procured or other control procedure for :		
	Raw material		
	In process material		
	Packaging and labelling materials		
	Finished products?		
	Are samples collected by QC personal		
	Is there special room for microbiological and sterility testing?		
	Is the environment of room controlled?		
	Are only materials, containers and appliance necessary for the job in hand stored in the vicinity of the manufacturing areas and are these properly labelled with name of the product, batch no. date etc.?		
	Are all raw materials, containers, closures, label and printed packaging material approved and released by QC for use in manufacture of drugs products		
	Are in-process controls carried out by QC personnel?		
	Are semi-finished products tested for appropriate tests when necessary?		
	Is bulk finished product tested for established specifications before packing?		
	Is every finished product tested for established specifications before release for sale?		
	Does the QC maintain records of all the tests carried out?		
	Does the QC review all production and control records to ensure compliance with established written procedure before a batch of the product is released for		

	sale?		
	Reference standards: Are reference standards (R.S) available? Are these RS or working standards (WS)? Are WS standardised against RS or CRS? Are RS stored properly (at appropriate temperature under dehumidified conditions)? Are records of R.S and their standard maintained?		
	Are samples in sufficient quantity for testing twice retained of starting materials and finished products for future examination, in case of need?		
	Are quality control procedures validated?		
	Is written programs available for stability including the following:		
	Sample storage condition		
	Room temperature?		
	Sample size and test intervals?		
	Reliable and specific test methods?		
	Testing in the same containers closure system in which it is marketed?		
	Date and expiration date if any?		
	Established of in-house specification?		-
	Does the firm provided the equipment as recommended in Part II C ?		
21	**REQUIREMENT FOR STERILE PRODUCT**		
	Manufacturing areas		
	Is there separate manufacturing area		
	Are their air locks for entry?		
	Is there dust free and ventilated for air supply		
	Precautions against contaminations and mix.		
	Are manufacturing operations being carried out in a separate block of adequately isolated building		
	Is there appropriate pressure differential in the process area.		
	Is suitable exhaust system provided?		
	For aseptic manufacturing proper air supply (filtered through HEPA) provided?		

Signatures of Inspecting Team Members"

37. After form TA the following annexure will be inserted namely.-

"Annexure to TA form
(*See Rule 157A*)

Certificate of Cultivation / Certificate of Origin

This is to certify that M/s..... has cultivated the following medicinal plants OR utilized the herbal raw material from the following cultivated medicinal plants during the financial year ..... . The varieties and area of cultivation / quantities harvested / quantities utilized / yield obtained for each material are as under:

S. No.	Crop Name	Village Survey/ Khasra No(s)	Total Extent (Area with Longitude/ Latitude)	Name of the Land Owner	Name of the Farmer(s) / FPO / Cluster / SHG etc	Aadhar No	Mobile No	Total Quantity cultivated/ harvested raw material	Date of Issue

Date:
Place:

Certifying authority

Designated officer of implementing agency
(State Medicinal Plant Board or National Medicinal Plant Board)"

[F.No. T-11011/05/2019-DCC(AYUSH)]
P.N. RANJIT KUMAR, Jt. Secy.

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

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Draft minutes of the meeting of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held under the Chairmanship of Prof. (Dr.) Atul Goel, Director General of Health Services (DGHS), Government of India on 27th June , 2022, Room no. 445 A, Nirman Bhawan, New Delhi.

A meeting of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) was held under the Chairmanship of **Prof. (Dr.) Atul Goel, Director General of Health Services (DGHS), Government of India** on 27th June, 2022, Room No. 445 A, Nirman Bhawan, New Delhi on hybrid mode. List of the Participants is placed at **Annexure I.**

At the outset **Dr. Kousthubha Upadhyaya, Adviser (Ay.), Ministry of Ayush and Member-Secretary, ASUDTAB** welcomed the Chairman, members of the Board, Special invitees and the participants and briefed the mandate & background of the board. This was followed by a round of introduction of all the participants. Dr. Kousthubha Upadhyaya then requested Chairman, ASUDTAB for his opening remarks.

Chairman in his opening remarks welcomed all participants and expressed his pleasure to chair this meeting. Chairman further appreciated the relevant agenda items and desired for an outcome oriented deliberations. He then requested Dr. Kousthubha Upadhyaya to initiate agenda-wise discussion and board members to express their views independently so as to take a considered view and make focused recommendations/ suggestions.

Agenda-wise discussions and outcomes were as follows:

Agenda Item No. 1	**Confirmation of the minutes of the last meeting of ASUDTAB held on 15.03.2021.**

Dr. Kousthubha Upadhyaya informed all Board members that no suggestions/comments/inputs from the members have been received on the minutes of the last meeting of ASUDTAB held on 15.03.2021. However, regarding omission of Rule170, Dr. V.G. Somani, DGC (I) suggested that, it is not ethical to omit the existing Rule in anticipation of its inclusion in proposed amendment of DMR Act. Once the concerned provisions were adopted and notified in the proposed Act we may go ahead with the omission of this Rule. **Since there were no comments received from the members and hence the minutes were confirmed unanimously except omission of Rule 170 .**

Agenda Item No. 2	**Action Taken Report (ATR) on the last recommendations of ASUDTAB**

Dr. Kousthubha Upadhyaya explained following Action Taken Report to all the board members

i. Final Notification for the proposed merger of central appellate laboratories for ASU&H drugs - Pharmacopoieal Laboratories of Indian Medicine and Homoeopathy (PLIM and HPL) into Pharmacopoiea Commission of Indian Medicine & Homoeopathy has been made vide Gazette notification with G.S.R. no. 202 (E) dated 22.03.2021.
ii. Draft amendment rules regarding Compliances by ASU drugs and Industry were notified on 17.03.2021 and final notification has been published vide Gazette notification with G.S.R. no. 716 (E) on 04.10.2021 to reduce compliance burden.
iii. Draft regarding the amendment in the respective rules in respect of Homoeopathy drugs rules as per the recommendations of expert committee on Homoeopathy, Sowa Rigpa drugs as per the recommendation of sub-committee for Sowa-Rigpa, Rule 157, Rule 158 B and amendments of the existing GMP provisions, as agreed in the last ASUDTAB meeting was notified vide Gazette notification vide GSR no. 473 (E) dated 02.07.2021 for the objections or suggestions of the stakeholders on the said draft rules. Comments received from the stakeholders on the said notification were examined by a committee formed in the Ministry and the recommendations are placed once again as agenda no. 3 in this ASUDTAB meeting.

Agenda Item No. 3	**Comments received on draft notification GSR No. 473(E) dated 02.07.2021 for Amendment in Drugs Rules 1945, published by the Ministry of AYUSH**

Dr. Kousthubha Upadhyaya informed all Board members that a review committee has been constituted for consideration of comments received on Draft Notification GSR no. 473(E) by Ministry of Ayush. He requested all board members to provide their inputs/ recommendations over the recommendations of said review committee. Based on the point- wise discussions, recommendations of board are placed at **Annexure-II.**

Thereafter, a detailed discussion on Draft notification GSR No. 473(E) dated 02.07.2021 was held among the board members. **Dr. V.G. Somani, DGC (I)** suggested that draft notification GSR No. 473(E) dated 02.07.2021 may be re-drafted as a separate part in Drugs & Cosmetics Rules, 1945 having all provisions related to Homoeopathy and Sowa-Rigpa system of medicine as *Part XVI AA*. It has also been suggested that prior legal consultation may be done in this regard. He further added that it may not be appropriate to omit Rule 170 regarding "Prohibition of advertisements of Ayurvedic, Siddha or Unani drugs" in anticipation of its inclusion of the similar provisions in Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

Dr. Somani drew the attention on Rule 161-B as per which Shelf Life was supposed to be decided basis real time stability studies. He added that this is totally impractical and there should be provision of assigning shelf life basis Accelerated Shelf Life studies. Dr C K Katiyar

informed that the Ministry of AYUSH has already issued an advisory to consider Accelerated Stability Study also as basis to assign shelf life. Dr. Somani informed that this advisory has no value without converting it into Gazette Notification since current Rule 161 B is limited to real time study only. The advisory from the Ministry of AYUSH is attached herewith and should be converted into Gazette Notification.

Dr. G.V.R. Joseph, PCIM&H opined that it is not appropriate to add separate part for Homoeopathy and Sowa-Rigpa systems as it may require amendment in Drugs and Cosmetics Act, 1940. However, Dr. V.G. Somani, DGC (I) informed that they have already introduced one new part in D&C Rules regarding medical devices on the similar lines which can also be adopted in this case.

After detailed deliberations, **following has been recommended –**

i. **GSR No. 473(E) dated 02.07.2021 may be re-drafted as a separate part in Drugs & Cosmetics Rules, 1945 having all provisions related to Homoeopathy and Sowa-Rigpa system of medicine in light of recommendations of ASUDTAB at annexure II. Contents of remaining provisions of the said notification are deemed as approved by the ASUDTAB which will adopt as such.**
ii. **Omission of Rule 170 is not required.**
iii. **An expert committee may be constituted by Ministry of Ayush to review or revisit the existing provisions of GMP, which will be placed before ASUDTAB.**
iv. **With regard to submission of information under Schedule TA form, it is suggested that Ministry of Ayush may look into compilation and analysis of data submitted under this provision for developing suitable policy initiatives.**
v. Order no. T.13011/3/2019-DCC (Ayush) dated 29.07.2019 issued by Ministry of Ayush regarding consideration and acceptance of stability study data for fixing the shelf- life of ASU drugs under Rule 161-B of the Drugs & Cosmetics Rules 1945 for the purpose of grant of license and renewal of license in reference to GSR no. 789 (E) dated 18.08.20216 may be converted into Gazette Notification.

Agenda Item No. 4	**Inclusion of additional Siddha Text books recommended by Central council for Research in Siddha, National Institute of Siddha under Schedule I Books of the Drugs and Cosmetics Act 1940 and Rules 1945.**

Dr. Kousthubha Upadhyaya informed all Board members that additional Siddha Text books was recommended by Central Council for Research in Siddha, National Institute of Siddha and reviewed by PCIM for their inclusion in the Schedule I Books of the Drugs and Cosmetics Act 1940 and Rules 1945. ASUDTAB had already recommended list of additional books in 2012.

Further, a Sub-committee was constituted under ASUDTAB for Sowa-Rigpa drugs. The meeting of the said sub-committee was held on 10th -11th July, 2018 under the chairmanship of Dr. Shriram S. Savrikar Chairman Scientific Body, PCIM&H, Govt. of India at Central Institute of Higher Tibetan Studies, Sarnath, Varansi. The sub- committee in its report had recommended list of some classical texts of Sowa-Rigpa to be included in Schedule 1 of Drugs & Cosmetics Act of 1940 **(Annexure-III).**

Dr. Padma Gurmet, Director, NISR has informed that the Sowa-Rigpa system of medicine was formally incorporated under AYUSH on 27 September 2010 by amendment to The Indian Medicine Central Council Act, 1970 and the Act is in force from 1 Jan, 2012. Since then, the issues of making provisions in the Drugs and Cosmetic Act to regulate the drugs used in Sowa-Rigpa have been discussed. It is requested by him that Sowa-Rigpa should be also brought under the main ambit of ASUDTAB by restructuring ASUDTAB as Ayurveda, Siddha, Sowa-Rigpa and Unani Drug Technical Advisory Board (ASSUDTAB) and also incorporate one or two Sowa-Rigpa members in the ASSUDTAB. He has also requested to consider the recommendations of Report of the ASUDTAB Sub-committee of Sowa-Rigpa under the Chairmanship of Prof. S.S. Savrikar.

Dr. L. Sivakumar highlighted that the notification of Siddha books in Schedule 1 of Drugs & Cosmetics Act of 1940 is pending since long and the same should be notified at the earliest. Dr. L. Sivakumar had also submitted a list of Mineral drugs which are to be added in the Schedule E-1 List of Siddha **(Annexure- IV).**

After detailed deliberations, **it has been recommended that an expert committee may be constituted by Ministry of Ayush to review/ revise the Schedule I Books of the Drugs and Cosmetics Act 1940 and Rules 1945. The committee may directly include books of Sowa-Rigpa recommended by Sub-committee for Sowa-Rigpa drugs under ASUDTAB respectively. The committee will review the existing Schedule-I and prepare a draft regarding the revision of Schedule I. The same will be placed before ASUDTAB.**

Agenda Item No. 5	**Update of Schedule E1 List of Drugs and Cosmetics Act 1940 and Rules 1945**

All board members were informed that list of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine are mentioned in Schedule E (1) under Rule 161 (2) of Drugs and Cosmetics Act Rules 1945 wherein it has been specified that Schedule E (1) drugs should be labeled conspicuously with the words "Caution: To be taken under medical supervision" both in English and Hindi language. Dr. Kousthubha Upadhyaya informed that –

- Schedule E (1) drugs mentioned for Ayurveda, Siddha and Unani systems is also not harmonized. Drug mentioned under Schedule E (1) for one system may not come under Schedule E (1) for other system. Further, list of Schedule E (1) drugs may be revised as some of the poisonous metal like *Naga* (Lead) is not mentioned under Schedule E (1) drugs.
- It has been brought to the notice of Ministry of Ayush that Schedule E (1) drugs are also available for online purchase. In this regard, Ministry of Ayush has requested Ministry of Electronic and Information Technology and Department of Consumer Affairs to issue direction/order to all online sellers that Ayureveda, Siddha and Unani drugs, wherein the caution "To be taken under Medical supervision" is printed on the label of its container and / or contains any of the ingredient/s as listed in Schedule E (1) of Drugs and Cosmetics Rules, 1945 , the same shall be sold, only on the basis of a valid prescription of registered medical practitioner which is uploaded by the purchaser/ patients on the online portal.

Vd. Santosh Nevpurkar also submitted that list of Schedule E (1) should be reviewed as only basic material in raw form is toxic and not after it has undergone all Ayurved processing to render it safe for ingestion. He also highlighted that formulations comprising *Ahiphena* and *Bhanga* are well indicated in Ayurveda systems for the treatment of various ailments. Use of such drugs has been restricted as these drugs come under the category of narcotic drugs, which deeply impact clinical practice of Ayurveda system. Further, it is also being witnessed that certain Hemp / Cannabidiol (CBD) versions of Cannabis are being mislabelled as Ayurved. Board may recommend to issue an Advisory to State License authorities for cancellation of all ASU licenses issued for products containing CBD.

In this regard, Dr. Kousthubha Upadhyaya informed all board members that Ministry of Ayush has already taken cognizance of this issue and requested all State Drug License Authority to provide information regarding the license issued for the ASU products containing *Ahiphena* and *Bhanga*.

Dr. C.K. Katiyar has also suggested that the provisions of Schedule E-1 should be reviewed. Further cognizance of CCRAS publication of safety 2019 should be taken on record as evidence of safety of Schedule E-1 enlisted formulations/ compounds. He further added that use of *manahshila* also should be regularized as it is restricted in some states under explosive act.

After detailed deliberations, **board members unanimously recommended that –**

i. **National Commission for Indian Medicine (NCISM) may be requested to direct all registered Ayush practitioner to clearly mention duration of intake of formulations containing Schedule E (1) drugs.**
ii. **An expert committee may be constituted by Ministry of Ayush to review/ revise the Schedule E (1) under Rule 161 (2) of Drugs and Cosmetics Act Rules 1945, with**

representatives of Ayurveda Siddha Unani system of medicine along with a representative from NCISM. The committee will review the existing Schedule E (1) and prepare a draft regarding the revision of Schedule E (1) drugs. The same will be placed before ASUDTAB.

Agenda Item No. 6	**Legal Permission to use animal products including Deer Antler, *Kasturi* (Musk) , *Gorochan* , coral etc in Ayush Medicines**

Dr. Kousthubha Upadhyaya informed all Board members that representation from ASU industry/ Manufactures association to consider excluding Ambergris from the wild Life (protection) Act, 1972 and Supply of shed Deer Antler or Deer antler burnt Ash to ASU industry were received in Ministry. Ministry of Ayush has taken this matter with Ministry of Environment, Forest and Climate Change.

Dr. L. Siva Kumar informed all the members that Siddha industry represented by IMCOPS had met Secretary, Ministry of Environment, Forest and Climate Change regarding supply of Deer antler burnt Ash from zoological parks which was positively responded. He insisted to use the term 'Antler' (shed naturally every year) instead of 'horn' which is permanent structure of animals.

Dr. C.K. Katiyar has also suggested that Ministry of Ayush may push the concerned Ministry to come out with simplified procedures for use of only animal products.

After detailed deliberations, **all board members unanimously recommended that Ministry of Ayush may once again approach Ministry of Environment, Forest and Climate Change with a request to device a mechanism for providing shed Deer Antler or Deer antler burnt Ash or any other animal products used in ASU industry from zoo/reserved forests through respective State Authorities when collection of such animal products do not cause any harm to the biodiversity.**

Agenda Item No. 7	**Amendment in Rule 153 and 153 (a) of Drugs and Cosmetics Act 1940 and Rules 1945 vide gazette notification G.S.R. 293 (E) dated 04.04.2022**

All board members was informed that Ministry of Ayush vide notification G.S.R. 716 (E) dated 01.10.2021 had amended Rule 153 to Rule 156 of Drugs and Cosmetics Act 1940 and Rules 1945. Thereafter, vide gazette notification G.S.R. 293 (E) dated 04.04.2022, following amendment has been made –

(a) in rule 153, in the second proviso, for the words "within six months" the words "within eighteen months" shall be substituted;

(b) in Rule 153A, in the second proviso, for the words "within six months", the words "within eighteen months" shall be substituted;

(c) FORM 26 D and FORM 26 E shall be omitted.

Dr. Kousthubha Upadhyaya requested ASUDTAB board members for the ratification of gazette notification G.S.R. 293 (E) dated 04.04.2022. **The same has been agreed by all board members unanimously.**

Agenda Item No.8	**Any other item with the permission of the Chair**

8.1. Clarification about the Notification GSR. No. 716 E dated 1.10.2021.

Dr. Kousthubha Upadhyaya informed all board members that Ministry of Ayush had issued gazette notification related to licensing process of ASU drugs on 1.10.2021. In this regard, Ministry had received representation from State Licensing Authorities seeking clarification regarding new licensing fees structure for approval of ASU drugs and GMP certificate notified in the Gazette Notification No. GSR 716 (E), dated 01.10.2021.

Ministry of Ayush had issued clarification on the said notification to all State Licensing Authority vide letter no. T. 14020/4/2021-DCC (Ayush) dated 12.11.2021 and letter no. T. 18011/2/2022- DCC (Ayush) 16.06.2022 wherein each queries raised by State Licensing Authorities were addressed for better understanding of the SLAs and the manufacturers.

All board members were requested to go through the above mentioned clarifications for suggestions and recommendations. **All board members unanimously agreed to the clarification issued by Ministry of Ayush regarding Gazette Notification No. GSR 716 (E), dated 01.10.2021**

Other recommendations of ASUDTAB –

Dr. C.K Katiyar has suggested that agenda and Minutes of the ASUDTAB meeting should be posted on the website of Ministry of Ayush like practice followed by CDSCO also, for higher level of transparency. **The same has been agreed by ASUDTAB unanimously.**

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Annexure I

List of participants of ASUDAB meeting held on 27.06.2022 -

S No.	Participants
1.	**Prof. (Dr.) Atul Goel,** Director General of Health Services (DGHS), Government of India
2.	**Dr. V. G. Somani,** Drugs Controller General of India, DCG(I)
3.	**Dr. Kousthubha Upadhyaya,** Adv.(Ay.), Ministry of Ayush, Member Secretary-ASUDTAB
4.	**The Director, Central Drugs Laboratory,** 3, Kyd Street Kolkatta-700016
5.	**Dr. G.V.R. Joseph,** **Government Analyst,** PCIM&H, Ghaziabad, U.P.
6.	**Dr. Neeraj Tandon,** **Scientist-G and Head,** Divisions of Publications & Information and Medicinal Plants, Indian Council of Medical Research, Ansari Nagar, New Delhi 110029
7.	**Prof. Pulok K. Mukherjee,** **Director,** Institute of Bio resources and Sustainable Development Manipur and Professor (on lien), Dept. of Pharmaceutical Technology, Jadavpiir University, Kolkata - 700 032.
8.	**Dr. Prakash Hegde,** Department of Dravya Guna, Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan
9.	**Dr C. K. Katiyar, CEO Health Care (Technical),** Emami Ltd, 687, Anandpur, EM Bypass, Kolkata-700 007.
10.	**Prof. Tajuddin,** Department of Ilmul Advia, Aligarh Muslim University, Aligarh
11.	**Dr. Sumit Nathani,** Associate Professor, Department of Dravya Guna, National Institute of Ayurveda , Madhav Vilas Palace, Jaipur - 302002 (Rajasthan).
12.	**Dr. F. S. Shernani,** Professor and Dean, Aligarh Muslim University, Aligarh, Uttar Pradesh.
13.	**Dr. M. Krishnaveni,** Professor, Gunapadam, Government Siddha Medical College, 6, Anna Arch Road, NSK Nagar, Arumbakkam Chennai, Tamil Nadu, 600106.
14.	**Shri. Lal Hingorani,** Pharmanza Herbal Private Limited, 214, Borsad Tarapur Road, Near vadalda Patia, Kaniya, Dharmaraj, Gujarat, India-388435.
15.	**Dr. L. Sivakumar,** Dr. Siva Siddha Ayurveda Pharma & Food, Arrubakkam, Chennai-600106
16.	**Dr. Asad Mueed,** Trustee and Governing body member of Hamdard National Foundation (India).
17.	**Vd. Santosh Nepurkar,** Deerghayu Ayurved Swasthyalay,Nandigram colony, Garkheda, Aurangabad- 431005.
18.	**Dr. P. Selva Shunmugam,** President, Global centre for Siddha Medicine & Research , 3A, 1, Park street, Kilpauk Garden, Chennai- 600017.
19.	**Dr. Sabahat Ullah Amoroha,**

	H. No. 134 Qazizada Street Amoroha, Uttar Pradesh.
Special Invitee	
20.	**Dr. Anil Khurana,** Chairperson, NCH
21.	**Dr. Padma Gurmeet,** Director, NISR
Office of Director General of health Services (DGHS)	
22.	**Dr. A.Raghu,** DDG-Ayush, DGHS
Drug Policy Section , Ministry of Ayush	
23.	**Dr. Raman Kaushik** Research Officer (Ay.), Drug Policy Section, Ministry of Ayush

ANNEXURE-II

Recommendations of ASUDTAB on the Comments/ inputs of Stakeholders on Draft Notification GSR no. 473(E) to be placed in ASUDTAB

S.no.	Issue particulars	Existing Rules	Draft Notification	Comments Received from Stakeholders	Remarks of the committee	Recommendation of ASUDTAB
1.	**Provisions related to perpetuity of Sale and Manufacturing license of Homoeopathic Drugs and online process**	Rule 67(F) Provided that no registered Homoeopathic medical practitioner who is practising Homoeopathy in the premises where Homoeopathic medicines are sold shall deal in Homoeopathic medicines.	Second Proviso under Rule 67F shall be substituted namely.- "Provided further that registered Homoeopathic medical practitioner who is practising Homoeopathy in the premises licensed under 20C or 20D shall only prescribe medicines to his patients and not take part in the retail sale of Homoeopathic medicines."	**01. Subash Gupta (Secretary), Homoeopathic Pharmaceutical Association of India** **Point 9 Rule 67F** The association requests that this amendment be reconsidered and as requested in past, this second Proviso under rule 67F should be deleted in view of special circumstances applicable to Homoeopathy.	Suggestion not considered.	ASUDTAB agreed with the remarks of the committee.
		(i) **Rule 85B.** Application for licence to manufacture Homoeopathic medicines. (1) Application for grant or renewal of [licence to manufacture for sale or for distribution] of Homoeopathic	Rule 85B shall be substituted with the following rule namely. — **"85B. Application for licence to manufacture Homoeopathic medicines.** (1) An application for the grant of a licence to manufacture for sale of Homoeopathic medicines falling under clause (dd) of Rule 2 shall be made in Form 24C to the licensing authority along with a fee of	**01.ADMA** Rule 85B. Provision for Loan License for Homeopathic medicines should be considered. **02. AMAM** Rule 85B Suggest to include provisions & scope of Loan license manufacturing / third party manufacturing also in homoeopathy medicine under this rule. (Justification: Scope & provision of Loan license manufacturing are	Loan license requires ASUDTAB consultation as the same is not the part of draft notification	ASUDTAB agreed for including loan license provisions in the suggested new draft.

		medicines shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the Licensing Authority) and shall be made in Form 24- C. [(2) The application in Form 24-C shall be accompanied (a) by a fee of [rupees two hundred] for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of [rupees one hundred] for the first inspection or [rupees fifty] in case of inspection for renewal of	rupees five thousand. (3) The application shall be made through portal eAUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the license for manufacture for sale of Homoeopathic medicines. Provided that this rule shall not be applicable to licence obtained under Form 25C prior to the date of commencement of this Amendment Rules, 2021. Such licence holders having factory premises complying with the requirements and conditions as specified in Schedule M1 have to deposit a license retention fee of rupees five thousand for perpetuity of existing licence."	provided for Allopathic & ASU medicines in current D&C Act & rules which facilitate wide spread of these medicines in society. It has been observed that scope for Loan license manufacturing are not provided for Homoeopathic medicine in current D&C Act & rules. Loan license manufacturing helps industry to enhance reach of their system of medicine in society for better adaptability & benefits **03.Dr. Hardik Soni – Sr. Manager – R&D Vasu Research Centre** Form 24C shall be substituted namely		

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		licence; (b) by a fee of [rupees two hundred] for the manufacture of Homoeopathic potentised preparations only, and an inspection fee of [rupees one hundred] for the first inspection or [rupees fifty] in case of inspection for renewal of licence; (c) by a fee of [rupees two hundred] for the manufacture of potentised preparations from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of [rupees one hundred] for the				

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					first inspection or [rupees fifty] in case of inspection for renewal of licence. (3) If a person applies for renewal of a licence after its expiry but within six months of such expiry, the fee payable for the renewal of such a licence shall be (a) [rupees two hundred] plus an additional fee at the rate of [rupees one hundred] per month or part thereof and an inspection fee of [rupees fifty] for the manufacture of Homoeopathic mother tinctures and potentised preparations. (b)[rupees two hundred] plus an additional fee at the rate of 2[rupees one

		hundred] per month or part thereof and an inspection fee of [rupees fifty] for the manufacture of Homoeopathic potentised preparations only;] (c) [rupees two hundred] plus an additional fee at the rate of [rupees one hundred] per month or part thereof and aninspection fee of [rupees fifty] for the manufacture of Homoeopathic mother tinctures and potentised preparations from back potencies by pharmacies who are already licensed to sell Homoeopathic medicines by retail.] (4) A fee of [rupees fifty] shall be paid for				

a duplicate copy of the licence for the manufacture of Homoeopathic mother tinctures and potentised preparations issued under sub-rule (1) if the original is defaced, damaged or lost, while the fee to be paid for such a duplicate copy of the licence for the manufacture of Homoeopathic potentised preparations only shall be [rupees fifty]. 5) Applications by licensee to manufacture additional items of Homoeopathic medicines shall be made to the Licensing Authority and such applications shall be accompanied by a fee of [rupees fifty] for each

		additional item.]				
2.	**Two levels of GMP under Schedule T**	**Rule 157(1A)** For issuing of the certificate of Good Manufacturing Practices, the Licensing Authority shall verify the requirements as per schedule T and issue the Good Manufacturing Practices certificate in form 26 E-I, simultaneously along with grant or renewal of licence in form 25D.	In rule 157 (i) In sub clause (1A), for the words "as per Schedule T" the words "as per Schedule T, Level (a) for a micro enterprise, where the investment in Plant and Machinery or Equipment does not exceed one crore rupees and turnover does not exceed five crore rupees and a small enterprise, where the investment in Plant and Machinery or Equipment does not exceed ten crore rupees and turnover does not exceed fifty crore rupees; Level (b) for enterprise, where the investment in Plant and Machinery or Equipment exceeds ten crore rupees and turnover exceeds fifty crore rupees." shall be substituted.	**01.AMAM** Recommends same Rules & Regulations for full A.S.U. Industry. A tie period / window of 2 to 3 years maximum be given for Full Industry to achieve the LEVEL (B) which should be the minimum requirement of schedule-T. **02. IBHA** **Entry 21** (i) While enhancing the GMP compliance of manufacturers is always a welcome step, the rules pertaining to GMP should not vary on the basis of the turnover of the manufacturers as GMP requirements are directly related to the quality of the products and safety of consumers. Enhancement of GMP may be addressed by providing incentives, subsidies or such kind of credit provisions to upgrade the facilities and equipment through different governmental schemes. **Suggestion:** It is our humble request to call for wider discussions on this issue amongst the industry members in the form of seminars/symposia so that a consensus can be built. Till such time, the current Schedule T should be continued and modifications should be made in consultation with the broader section of the industry bodies. An approach which may be considered could be to improvise the current	Committee is of the opinion that no grading is required in GMP as in the Drugs Rules the GMP required should be of minimum standards which should be followed by all domestic manufacturing. Separate Voluntary Certificate for upgrading the manufacturing practices is available for the industry which can afford or intends to achieve it and depends on requirement of importing	ASUDTAB noticed that most of the comments were against the provisions of creating two levels in GMP. However the recommendation of the committee to re-visit the existing GMP provisions has been accepted and it has been recommended to form a committee for this purpose.

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				Schedule T where required with provisions stating that certain clauses/provisions will not be applicable for MSMEs. In addition, we propose to include a clause for parametric release of raw materials/finished goods in the Schedule T, similar to that in the Seventh Schedule of Cosmetic Rules, 2020 (clause I). **03. CHAI** **CHAI'S Feed Back :** There should be a classification for cottage industry, in which investment does not exceed Rs.25 Lakhs and turnover does not exceed 1 crore. Scheduled T shall be exempted for these cottage industries to preserve heritage of Ayurveda. As these industries are continuing from the ancestral origin we can preserve traditional method of preparations which are heritage of Ayurveda. The establishment of quality control laboratory also shall be exempted by allowing them to continue the Q.C tests by outsoureing from a NABL accredited labs. **04. Girish S Soman, Director of R&D, Nisarga Biotech Pvt. Ltd** In part I level B IX it is stated that the facility shouldn't be used for manufacturing other items other than ayurvedic medicines. Recent	country. Committee also recommends that the proposed Level A and Level B should be avoided. **Two levels will create confusion amongst the consumers and in ease of doing business the provision of two levels of GMP is not appropriate.** **However, existing provisions of GMP is required to be revised/ re-visited as per proposed rationale and doable GMP requirement.**	

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				amendments in FSSAI have resulted in addition of over 400 herbs used in Ayurvedic medicine that are now included in Nutraceuticals coming under FSSAI license. Ayurvedic drugs are manufactured by the pharmacies with a GMP certificate issued under form 26E-1 which is more stringent than the food and nutraceutical regulations. Therefore, we request that in order to avoid duplication of efforts in licensing, companies holding a GMP certification for manufacturing Ayurvedic products should be allowed to manufacture nutraceutical products under the same dosage form in the same premises. A suitable amendment may please be included. **05.AMMOI** **Rule 157 :** **Sub clause (1A)** Classification of enterprises and micro-enterprises may be reconsidered. Expense mentioned and qualification criteria of technical staff will be a challenge. Hence maybe reconsidered. **06. AMAM** **Rule 157** AMAM recommends same Rules & Regulations for full A.S.U. Industry. A tie period / window of 2 to 3 years maximum be given for Full Industry to achieve the LEVEL (B) which should		

					be the minimum requirement of schedule-T **07. Dabur Research & Development Centre, Dabur India Limited, Sahibabad – Ghaziabad** Rule 157 N.A. (Justification: An industry need timeline of 3 to 5 years to implement level B GMP requirements). **08. Dr. J.P. Singh (President), Punjab Ayurvedic Drugs Manufacturers Association Rule157** 1. Two levels of GMP will give wrong message to the consumer about the quality/efficacy of ASU medicines, hence there should be only one GMP. 2.The manufacturing covered area mentioned in the schedule T earlier and now proposed is too less for each section. it should be suitably enchanced **09. UDMA** **Suggestion:** UDMA suggests that a time window of 3 years be given for industries failing in Level (b) to implement the same. Also in Level (b) the size of Section for Dry Extract / Wet Extract should be 100 sq.ft as against the proposed 200 sq.ft. The Quarantine Area for Finished Goods should be 50 sq.ft. as opposed to 100 sq.ft. because the area mentioned for Finished Goods Store is only 100 sq.ft.		

				and as the goods are kept in Quarantine area for a day or two 100 sq.ft. is not justified. Another point of concern is a separate area for a Stability Chamber. Since it is an instrument it can be kept along with the other instruments / equipments in the QC Section. A waiver of inspection fees for industries falling in Level (a) will give a boost to the micro and small enterprises. **10. All India Unani Tibbi Conference** **Draft Rules-** Relaxation in proposed GMP guidelines will help small manufacturer of ASU Medicines their sustenance in business. **Draft Rules- Part I Level b** Premises and Materials(IX) Same manufacturing facility/Store not be used for any Purpose other than manufacturing of Ayurveda, Siddha, Unani Drugs to be further clarified as – Dedicated manufacturing facility/Store shall be used for manufacturing of Ayurveda, Siddha and Unani Drugs. It will rule out any confusion that in a location of a factory there can be dedicated facilities for ASU Drugs, Pharma Drugs and Cosmetics products. May we request you to kindly consider our above objection/suggestions while finalizing these draft rules since these		

					suggestions will be helpful for entire AYUSH industry? 11. sarveshbhuimsay@gmail.com 1-Total Quality control area ie 100 sq. feet is very less for each section ie physico chemical, microbiology and instrumental (Part -II Level b 5.1) this should be little more. **In Schedule T, i. Para 1 for the words "as follows in Part I and Part II" the words "as follows in Part I and Part II of Level a and Level b as the case may be" shall be substituted.** **12. Dr. S.K. Sharma, Former Advisor Ayurveda Baijnath Pharmacy** i) The Prevailing Schedule T must be continued and further Upgradation should be made voluntarily by all those who want to for various reasons. ii) It is not logical to introduce two level of GMP Certificate and requirement. Legally all the safety and essential premises requirement are all type of industry, micro, small, medium, enlarge. Only the space requirement will increase with the size of operations. Therefore only one type of GMP should be implemented. **15.Dr. D.B Anantha Narayana**		

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				Several provisions are introduced in the draft regulations referred to in the subject, related to Schedule-T. Schedule-T in the Drugs & Cosmetics Rules refer to the Good Manufacturing Practices and their requirements. These provisions are creating Level-A and Level-B etc. requirements for GMP. The proposal is not in tune with global policy and requirements and if notified may attract ridicule and criticism globally. GMP requirements are basic to ensure quality of AYUSH products to be right and free from contamination to ensure safety and efficacy. Creation of these levels is perhaps attempting to provide different sets of requirements to micro, small, medium scale and large scale manufacturers, which is not in the right direction. The current Schedule-T has been in place for about 2 decades and these are "prescriptive regulations" demanding various requirements of space personnel, location, equipment's, testing facilities etc. There is a need to think differently. USFDA or other global regulatory bodies do not have such prescriptive GMPs. Schedule-T should change the approach and make provisions for what aspects need to be taken care –location, building, personnel, facilities, practice and documenting the Good Manufacturing Practices followed from start to finish		

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				of manufacturing. Nature and number of equipments required to be seen in the premises, either for production or for quality testing should be deleted from the regulations with one broad statement that "the manufacturers should have adequate equipment of suitable capacities for use all stages of production namely- during procurement, storage, dispensing, production, packing and testing of AYUSH products.\, relevant to the type of Ayush products being manufactured in that premises". It needs to be recognized that AYUSH products' manufacturers are more akin to food products processing than pharmaceuticals drugs. GMP for AYUSH products should stress on building quality by design. GMP should aim and require firms to have documented procedures at all steps of manufacture till the products is released to the market, how correct material would be used, written down processes would be followed, steps to prevent contamination from microbes, moisture, other pollutants, cross contamination, environmental control, cleanliness in the full premises, sanitation of the premises, intermediate storage, etc. Manufacturers must then be required to document all the processes and steps that have been followed during the production and packing. Requirement		

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				of equipment for production and testing would then be dictated by the nature of products and processes which can be "administratively checked". Such an approach would then provide necessary flexibilities to micro, small, medium and large scale AYUSH industry. It is suggested strongly to avoid notifying the proposed provisions related to Schedule-T as given in the draft regulations and draft a new set of Schedule-T provisions entirely. **16. PADMA** Sir, we welcome the acceptance of the definition of Micro and Small Enterprises (MSEs) by the department of AYUSH. It would have been highly appreciated had the benefits to the MSEs were enumerated too. Our Suggestions is to kindly include the benefits vis a vis MSEs in this Section.		
3.	**Qualification of competent technical staff in ASU drug manufacturing**	**Rule 157 sub clause (2)** The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff	Rule 157 (ii) sub clause (2)(b) shall be omitted. (iii) sub clause (2)(c) shall be substituted namely- "(b) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government with experience of at least three years in manufacturing of	**01.ADMA** **In addition to B Pharm in ASU, the said rule should provide for the inclusion of BAMS, B Pharm and M Pharm also.** iv) sub clause (2)(d) shall be omitted. Sub Clause (2) d should be implemented prospectively from the date of final notification v) sub clause (2)(e) shall be omitted. SubClause (2) e should be retained	The committee recommended omitting the word Ayurvedic Pharmacy from clause (a) as it is covered under new clause (b).	It has been recommended by ASUDTAB that Rule 157(2) will stand as: "The manufacture of Ayurvedic (including

		consisting at least of one person, who is a whole time employee and who possesses the following qualifications, namely: – (a) A degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicines recognized by the Central Government or a State Government for this purpose, or (b) a diploma in Ayurveda, Siddha or Unani	Ayurveda, Sidhha, Unani drugs in a licensed manufacturing unit or MD Rasshastra/BhaishajyaKalpana/ Medicinal plants/Dravyaguna/Saidala/Gun apadam. (iv) sub clause (2)(d) shall be omitted. (v) sub clause (2)(e) shall be omitted.	**02. C.S. Bhargava, President PMA, Kanpur and Mr. Sameer Bhargava (Director)S.P Biotech Pvt. Ltd** Rule 157 sub clause (2)(b)Diploma in Ayurveda, Siddha or Unani Persons will be unemployed. Moreover very less Colleges of Diploma in Ayurveda, Siddha or Unani is available in India which will create shortage of experieneed technical staff. **This must not be omitted.** There are approximate 10000 Ayurvedic factories in India for which we require at least 20000 Pharmacy/Chemistry/Botany Graduates. No of students passing as graduate in pharmacy (Ayurveda, Siddha or Unani) are very less in comparison to B.Pharm/Graduate in Chemistry/ Botany students (approximate 2 Lakh) passing out from different colleges. Moreover we are enclosing syllabus of B.Pharm(Ayurved) and B.Pharm(Allopath) approved by Pharmacy Council of India which is enforced all over India for Pharmacy Graduates (B.Pharm). All the subjects of B. Pharm Ayurved are almost similar to B.Pharm(Allopath) with much more practical work. **In our opinion B.Pharm Allopath must be allowed to conduct manufacturing of Ayurvedic formulations including Siddha or Unani Drugs as a competent technical staff..** **For 5(XII)** Expert in Ayurvda or	Thus the amended Rule 157(2) will stand as: "The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole time employee and who possesses the following qualifications, namely: (a) A degree in Ayurveda, Siddha or Unani system of Medicine, as the case may be conferred by	Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole time employee and who possesses the following qualificatio ns, namely: – (a) A degree in Ayurveda, Siddha or Unani system of Medicine, as the case may be conferred by a University/

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		system of medicine granted by a State Government for this purpose, or (c) Graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany of a University recognized by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani systems of medicines or (d) a Vaid or Hakim registered in a State Register of Practitioners of indigenous systems of medicines having experience of at least four years in the manufacture of		Siddha or Unani medicine who possesses a degree qualification has no practical experience in laboratory for testing Medicament and formulation. as per the syllabus in Gazette of India dated April 26th 2012/Vaisakha 6, 1934. Our Association has objections on this. **Chemist, who shall posses at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda or Siddha/Unnai), awarded by a recognized University, and Botanist/Pharmacognosit, who shall possess at least Bachelor Degree in Science Medical Pharmacy or Pharmacy (Ayurveda) or Diploma in Unani Pharmacy/Diploma in Pharmacy (Ayurveda) (with at least one year experience) awarded by a recognized University.** I would like to bring to your kind attention the fact that the pharmacy graduate is better skilled for production, development and analysis of all type of formulations. Therefore these amendments will make pharmacy person (who are technically sound as compared to Ayurvedic or Homoeopathic personnel) out of these industries which will make it very difficult to compete with China and U.S. where they need all type of study and approval of USFDA. . Sub clause (2B) The present system to	a University a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central Government or a State Government for this purpose, or (b) A graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government or a State Government with experience of at least two in manufacturin	State Governmen t or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central Governmen t or a State Governmen t for this purpose, or (b) A graduate in Pharmacy (Ayurveda or Siddha or Unani) of a University recognised by the Central Governmen t or a State Governmen t with experience of at least two in

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		Ayurvedic or Siddha or Unani drugs, or (e) a qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicines, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognized by the Central Government		be continued. Now number of the Diploma Holders are still continuing in Manufacturing Units since last so many years. So, if the present system discontinue, current experienced doctors will be out from this field and it will also effect the licensing system. This is not good for the industry. **So, we suggest A Diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government or Institution recognized by the Central Government for this purpose to be continued.** Sub clause (2B) The present system to be continued. Now number of the Diploma Holders are still continuing in Manufacturing Units since last so many years. So, if the present system discontinue, current experienced doctors will be out from this field and it will also effect the licensing system. This is not good for the industry. So, we suggest A Diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government or Institution recognized by the Central Government for this purpose to be continued. **Sub Clause (2C)** In addition to B Pharm in ASU, the said rule should provide for the inclusion of BAMS. B Pharm and M Pharm also . **Sub Clause (2E)** A qualification as Pharmacist in	g of Ayurveda, Siddha, Unani drugs as the case maybe in a licenced manufacturing unit. Provided that the person already registered with the State Licensing Authority as competent person for the purposes of grant of licence in Form 25D/25E prior to the coming into force of the Drugs (Amendment Rules) 2021, shall continue to be considered as competent person for the said purposes."	manufacturing of Ayurveda, Siddha, Unani drugs as the case maybe in a licensed manufacturing unit. Provided that the person already registered with the State Licensing Authority as competent person for the purposes of grant of license in Form 25D/25E prior to the coming into force of the Drugs (Amendment Rules) 2021, shall continue to

				Ayurvedic (including Siddha) or Unani systems of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognized by the Central Government. **5) Rule 157 Sub clause 2(c)** Sub clause (2)(c) shall be substituted namely-"(b) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry or BAMS or BUMS or post graduate in medicinal plants or MD Dravyaguna of a University recognised by the Central Government with experience of at least three years in manufacturing of Ayurveda, Siddha, Unani drugs in a licensed manufacturing unit or MD Ras-shastra /Bhaishajya Kalpana / Saidala / Gunapadam. (Justification : The qualifications and experience mandated in this rule will limit the number of candidates available for recruitment as competent technical staff for manufacturing of AYUSH products. Hence suggest to include BAMS / BUMS or graduate degree of particular stream with experience of three years. in manufacturing of AYUSH medicines. **03.Dr Galib, Assistant Professor and Associate Editor –AYU, IPGT & RA, Gujarat**	manufacturing of Ayurveda, Siddha, Unani drugs as the case maybe in a licenced manufacturing unit. Provided that the person already registered with the State Licensing Authority as competent person for the manufacturing of Ayurveda, Siddha, Unani drugs as the case maybe in a licenced manufacturing unit. Provided that the person already registered with the State Licensing	be considered as competent person for the said purposes."

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				In rule 157 (iii) - sub clause (2)(e) shall be substituted namely - "(b) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical Chemistry of a University recognised by the Central Government with experience of at least three years in manufacturing of Ayurveda, Sidhha, Unani drugs in a licensed manufacturing unit or MD Rasshastra/Bhaishajya Kalpana/Medicinal plants/Dravyaguna/Saidala/Gunapadam. Suggestion : How a graduate degree in Pharmacy with experience of three years will be equivalent to MD degree. **04. Dr. J.P. Singh (President), Punjab Ayurvedic Drugs Manufacturers Association** Rule157 **iv) sub clause(2)(d)shall be omitted.** Sub Clause(2)d should be implemented Prospectively from the date of final notification **v) sub clause(2) (e) shall be omitted** Sub Clause(2) (e) should be retained **05. UDMA** **5) Rule 157 Sub clause 2(c)** (Objection/Suggestion: In sub clause (2c) shall be substituted namely-"(b) a graduate in Pharmacy (Ayurveda or Siddha or Unani) or Pharmaceutical	Authority as competent person for the purposes of grant of licence in Form 25D/25E prior to the coming into force of the Drugs (Amendment Rules) 2021, shall continue to be considered as competent person for the said purposes." The comment for retaining B. pharma graduates is not recommended by the Committee. **Committee is of the opinion that the MD qualification should be**	

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				Chemistry of a University recognised by the Central Government with experience of at least two years (instead of three years as proposed) in manufacturing of Ayurvedia, Siddha, Unani drugs in a licensed manufacturing unit or BAMS / BUMS or MD Ras-shastra /Bhaishajya Kalpana / Medicinal plants /Dravyaguna / Saidala/ Gunapadam. We should do away with the 2 year experience in manufacturing of Ayurveda, Siddha, Unani drugs in a licensed manufacturing unit criteria for BAMS/BUMS graduates. Rationale : The current status of availability of candidates in Pharmacy (Ayurveda or Siddha or Unani) or BSc Pharmaceutical Chemistry are negligible vis a vis number of pharmacies in the country. There are just 15 colleges which have seats for B Pharma (Ayurveda/Unani). The proposed Amendment would make an upsurge in the demand for this stream but until then, this proposed Amendment would create a chaos in the industry. The Non-availability of the candidates to fulfil the proposed norms would create cases of noncompliance fearing closures of industries. Hence suggestion to include BAMS/MUMS. **06. GAAMA**	**removed as the qualifications mentioned in the D&C rules should be of minimum requirement standards, a firm or organization can form its recruitment rules over and above the minimum requirements. The same may be placed before the ASUDTAB.**	

				Suggestion: Need to insert MD / M.Pharma in Ras-shastra/ Bhaishajya Kalpana/ Medicinal plants/ Dravyaguna/ Saidala/Gunapadam **7.Dr. Hardik Soni – Sr. Manager – R&D Vasu Research Centre** Suggestion :Need to insert MD / M.Pharma in Rasshastra/ Bhaishajya Kalpana/Medicinal plants/ Dravyaguna/ Saidala/ Gunapadam. **8 . sarveshbhuimsay@gmail.com** 2- It is great to insert Pharmacy ayurveda graduate at each place. **9. Dr Debasis Panigrahi-Professor Rasa Shastra & Bhaishajya Kalpana Vivek College of Ayurvedic Sciences & Hospital, Bijnor** Objection a) Graduate in Ayurveda/Unani/Siddha Pharmacy courses are not regulated by any single statutory body like CCIM/NCISM , so the syllabus & training standard are different among university/institute. Request- In place of Graduate in pharmacy it should be Graduate in Ayurveda/Unani/Siddha (BAMS/BUMS.BSMS) with atleast 3 years drug manufacturing experience in respective specialization or MD in Rasa Shastra/Bhaishajya Kalpana/Dravyaguna/Saidal/Gunapada **# MD in Medicinal Plant degree is not known**		

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				10. Dr. S.K. Sharma, Former Advisor Ayurveda Baijnath Pharmacy In addition to B Pharm in ASU, the said rule should provide for the inclusion of BAMS, B Pharm and M Pharm also . iv) sub clause (2)(d) shall be omitted. SubClause (2) d should be implemented prospectively from the date of final notification v) sub clause (2)(e) shall be omitted SubClause (2) e should be retained. **11. PADMA** Sir, we once again welcome the insertion of the above clause since it would help in the propagation of Ayurveda as a students would prefers to enrol themselves to these courses of B Pharm Ayurveda/ Unani or B.Sc pharmaceuticals Sciences. But Sir, the current status of availability of candidates to these streams are negligible vis a vis number of pharmacies in the country. There are just 14 to 15 colleges (http://targetstudy.com/colleges/bpharm-ayurvedadegree-colleges-in-india.html) which have seats for B Pharma Ayurveda/Unani. Even at a liberal estimate of 100 seats per college would fetch just 1400-1500		

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				candidates in which 300-400 would opt for post –graduate course and a few may be interested in setting up their own business and many of them would prefer for other vocations like teaching, research etc. In this scenario, only 500- 700 candidates would be available for the entire country where the number of pharmacies is far too much compared to this availability (for example, uttar Pradesh alone has around 1500+ Ayurvedic pharmacies). Even the pharmaceutical chemistry is a very lesser-known stream and not so popular among the students. The proposed amendment would make an upsurge in the demand for this stream but until then, this proposed amendment would create a chaos in the industry. The other option of having an MD Rasshastra/Kalpana/Dravyaguna/Saisal a/gunapada m as a full-time employee by an MSE is like asking for the moon! The non-availability of the candidates to fulfil the proposed norms would create case of noncompliance fearing closures of industries. Our suggestions is to please continue with sub-clause (2) (e) of Rule 157 till we have appropriate numbers of B Pharm Ayurveda/Unani/B.Sc. (Pharmaceutical Science) through environment promotions and setting up more colleges having more number of seats for the concerned streams.		

				12.National Institute of Ayurveda-Jaipur Suggestions It is point of concern how much a pharmaceutical chemistry expert understands the principles and basic of Ayurvedic drug manufacturing and quality control. It is suggested to the authorities to rethink the inclusion of pharmaceutical chemistry person for good quality Ayurvedic drug. **13. CHAI** **CHAI'S Feed Back** : Graduates in Pharmacy (Ayuveda or Siddha or Unnani) or MD Ras-shastra/ Bhaishajya kalpana / Medicinal Plants / Dravyaguna /saidala /Gunapadam were less available in the country. Hence it is very important to include Graduate in Botany or Chemistry or B.Pharm or M.Pharm as competent technical staff to supervise the manufacture of Ayurvedic ,Siddha,Unani and Homoeopathic Medicine. It is also suggested to include B.A.M.S instead of P.G in Ayurveda		
4.	**Submission of TA form along with Certificate of**	**Rule 157A. Maintaining of records of raw material used by licensed**	**In rule 157A** i. For the words "to the State Licensing Authority of Ayurveda, Siddha and Unani drugs and" shall be omitted. ii	**1.ADMA** **This is a new provision aimed at creating a regulatory linkage between NMPB/SMPB with the D&C Rules. The proposal appears**	Committee observe that the apprehension raised by	ASUDTAB accepted the recommend ation of the

	cultivation issued by NMPB/ any other agency authorized by NMPB	**manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year.-** Each licensed manufacturing unit of Ayurveda or Siddha or Unani drugs shall keep a record of raw material used by each licensed manufacturing unit of Ayurveda, Siddha or Unani drugs as the case may be in the proforma given in Schedule TA in respect of all raw materials utilized by that unit in the manufacture of Ayurveda or Siddha or Unani drugs in the preceding financial year, and shall submit the same by the	After the first proviso the following proviso shall be inserted namely- "(ii) The manufacturers / farmers who wish to declare the cultivated produce separately may follow one of the following two procedures: (a) they may take prior registration of specific medicinal plant cultivation (for harvesting raw material) on www.echarak.in portal as per the area of cultivation and estimated yield on the basis of the agro-techniques published by National Medicinal Plant Board from time to time. In the case of such applications National Medicinal Plant Board through its evaluation team will issue a certificate to the farmer(s) / Farmer Producer Organisation(s)/ Cluster(s) / Non-Government Organisation(s) / Self Help Group(s) / Fast Moving Consumer Good(s) manufacturer(s) on the basis of an online application through e-Charak portal. (b) Those who are not registered with National Medicinal Plant Board or State Medicinal Plant Board or Regional Cum Facilitation	**to be promotion of use of cultivated material which does appear noble, in purpose and intent. However, regarding this matter, ADMA has always maintained from Day-1 that ABS on otherwise source material is not applicable on Raw Materials. Hence, this provision may be deleted. The Industry is of the opinion that creating such regulatory linkages will strengthen the rights of NBA and promote and augment the Inspector Raj further, something which is principally self-defeating and hence not desirous.** **2.AMAM** Rule 157 (A) Should be deleted (Justificaton: The proposal appears to be promotion of use of cultivated material which does appear noble, in purpose and intent. However, regarding this matter, AMAM has always maintained from Day-1 that ABS on otherwise source material is not applicable on Raw Materials. Hence, this provision may be deleted. The Industry is of the opinion that creating such regulatory linkages will strengthen the rights of NBA and promote and augment the Inspector Raj further, something which is principally self defeating and hence not desirous. Farmers are currently registered	Industry Association is valid as the certificating body i.e. NMPB is not presently under the purview of D&C Rules. Also, the certifying bodies are not defined in D&C Rules. Farmers are not stakeholders of D&C Act, thus the proposed Draft Notification with regards to Certificate of Cultivation does not look viable and should be avoided at present. It is also suggested that submission of	committee to withdraw proposed changes.

		30th day of June of the succeeding financial year to the State Drug Licensing Authority of Ayurveda, Siddha and Unani drugs and to the National Medicinal Plants Board or any agency nominated by the National Medicinal Plant Board for this purpose	Centre for the certification prior to initiation of cultivation should apply for Certificate of Cultivation / Origin in the Annexure to Form TA prior to harvesting. Any material failing to comply with one of these above clauses may be considered as extracted raw material and may attract Access Benefit Sharing as per the provisions of Biological Diversity Act 2002. The Certificate of Cultivation / Origin may be issued by those authorities who are nominated by National Medicinal Plant Board or State Medicinal Plant Board or Regional Cum Facilitation Centre or any designated officer as decided by National Medicinal Plant Board from time to time."	under the agri.department which has been engaged in growing herbal medicinal plants and asking them to register again under NMPB seems not a feasible option. Hence AYUSH to relook into this issue once again & delete this provision. This will be against three Farm Laws which gives farmers freedom to cultivate and sell anywhere without middlemen and hindrance. Cultivation of Medicinal Plants is one of the good ways to DOUBLE FARMER'S Income. **3.Dabur Research & Development Centre, Dabur India Limited, Sahibabad – Ghaziabad** (Justification) Clause of Access benefit sharing is related to Bio Diversity Act which overlapping on D&C Act & Rules. **4.AMMOI** **Rule157A** The Industry is of the opinion that creating such regulatory linkages will strengthen the rights of NBA and promote abd augment the Inspector Raj further, something which is principally selfdefeating and hence not desirous. **5. Gujarat Ayurved Aushadh**	raw material records to both SLA and NMPB should be retained. **The same needs to be placed before the ASUDTAB.** Further, the Biodiversity amendment bill 2021 has addressed the issue of ABS exemption for Ayush practitioners, cultivated medicinal plants and their products. The said Bill is referred to Joint Parliamentary Committee in the Winter session of 2021. In view of this the draft notification is	

				Manufacturers Association (GAAMA) **In Rule 157 (A)** After the first proviso the following proviso ..... application through e-Charak **Suggestion:** If some registered ASU Drug Manufacturer is procuring dry extracts from "XYZ" extract manufacturers and the "XYZ" extract manufacturer is collecting raw herbs from cultivated source with prior intimation to NMPB then What will be the scenario of ABS (Access Benefit Sharing) for ASU Drug Manufacturer? Whether ASU Drug Manufacturer has to separately intimate to NMPB or not? What will be the procedure to get ABS exemption for ASU Drug Manufacturer? If extract manufacturer is collecting raw herbs from wild / natural sources for preparation of extracts and the same extract can be utilized by registered ASU Drug Manufacturer, then ABS will be applicable to whom? Clarity needs to be provided for above said points. **6. Dr. S.K. Sharma, Former Advisor Ayurveda Baijnath Pharmacy** **Rule 157 (A)** The draft is co-relating the activities of NMPB/SMPB with the drug	taken back and existing provision needs to be retained. Instead the committee is of the view that the submission of TA form needs to be made mandatory while issuing license.	

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				manufacturing rule of this Act. This is not proper and this clause should be removed from the Draft. 2) No manufacturing activity of any sector in the country is tagged with the cultivation of Raw Material. 3) As per the constitution of India, Revenue record, Crops cultivation is the activity of State revenue Dept. As a regular activity, Patwari of the area records the growing crops in the revenue records during Gardawari every six month. Therefore the record of cultivation of Medicinal Plants etc. should be authorised by revenue Dept. Patwari and Block Agriculture Officers. 4) Manufacturing related Drugs rules should be free from the liability of cultivation etc. **7. UDMA** **Objection / Suggestion :** This subclause should be entirely deleted. Rationale: The proposal to use of cultivated material is appreciated but Access Benefit Sharing on otherwise source material should not be applicable on Raw Materials for the use of AYUSH industry. We think that creating such regulatory linkages will strengthen the rights to National Biodiversity Authority and promote inspector Raj and will go against "Ease of doing Business." Farmers are already registered under agricultural		

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				department. Asking them to further register with NMPB will not be feasible. **8. Vaidyaratnam Oushadhasala Pvt. Ltd.** **Rule 157 A** i) If a situation arises where a company has to directly from farmers/ producers sully chain challenges may become manifold. ii) Access benefit-sharing as per 157 A may further jeopardize the enterprises. iii) Backward utilization especially through the cultivation of critical raw material may become more challenging. **09. IBHA** **Entry 22** Medicinal plants cultivation is under the National Medicinal Plants Board. • Registration of such produce should be kept out of scope of the Drugs and Cosmetics Rules. • The Access Benefit Sharing should be dealt with under the Biodiversity Act and Rules. Suggestion: We propose deletion of this Rule as this is beyond the scope of Drugs and Cosmetics Act. **10. CHAI** **CHAI'S Feed Back :** Manufacturers		

				are strictly objecting ABS and fighting in the court of Law. Secondly coordination between two departments becomes complicated. Hence the link with NMPB shall be avoided. **11. Dr. D.B. Anantha Narayana** It is a welcome step to introduce provisions for promoting cultivation of medicinal plants, their inspection and certification of the cultivated crops / produce and also the need for industry to file annual data of consumption. These new provisions should be supported by benefits to the manufacturers who use medicinal plants for production of AYUSH medicines exempted from several provisions of Biodiversity Act & Regulations. Such a move will promote AYUSH & herbal industry to invest and improve sustainability of these natural resources apart from enhancing authenticity and quality of raw herbs used. The provisions to file annual consumption data demands too much information and the relevant tabulated information requirements needs review and simplified, which will enhance compliance.		
5.		Comments on New Homeopathic Medicine (General Comments)		**01. Dr. D.B Anantha Narayana,** These suggestions are not given individual clausewise but few major points related to the various provisions notified in the draft regulations referred to in the subject of this letter.	These comments are received apart from the comments on the draft	ASUDTAB agreed for including the provisions for new

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				(1) Any system of healthcare should consider updating and modernization and promote innovations. In this amendments there is no provision for "new homoeopathic medicines" and hence homoeopathy will continue to stagnate. I have heard that Homeopathy has "Nosodes" which are like new drugs, and not provisions for such innovations and their requirements are seen in the draft. Even in the current pandemic I have seen a number of homeopaths claiming Nosodes are being used to treat CoVid and such Nosodes have been in use for a number of years to treat many indications. The sector says that there are no provisions for development and introduction of such new Homeopathic drugs, and how they would be evaluated and approved. Similarly, no provision has been included to create "new Ayurvedic medicines" which incorporate newer technologies of processes and methods. Of course there are few provisions for adoption of new formats for dosages. No provision has been included to adopt new ingredients, botanicals into the system which are not listed in the authoritative texts listed in First Schedule to the Drugs and Cosmetics Act. Both these situations stifle the system from growth in my opinion and need a correction which has been a demand for many years. Republic of	notification so not considered by the Committee.	Homoeopathic drugs in the suggested new draft. .

				China, though has a similar TCM with long history of use, has provisions that allow "new TCM Medicines" after proper scrutiny of its safety, quality and efficacy. Of course creating provisions for these current deficiencies will need to have requisite scientific data for evaluation before such new homoeopathic medicines or new ayurvedic medicines or new botanicals and ingredients to be recognized as legally accepted in AYUSH. Such provisions need to be worked out and included in the Draft before it is finally notified. 02. Shri Suresh Gupta – Secretary, Deptt. of Ayurveda and Indian System of Medicine, Rajasthan, Secretary Suggested that: 1) Provision of Licence is required for retail sale and wholesale of Ayurvedic drugs and provision of qualified and registration of Ayurvedic stores. 2) Part VII(A) of the Drugs and Cosmetics Rule 1945 has a provision for retail and wholesale of Homoeopathic medicine. On the same pattern Part XX may be amended wherein rule 171-A, 171-B, 171-C, 171-D should be prepared and amended accordingly. The following qualification are as per the rule 67F of the Drugs and Cosmetics Rule 1945 wherein homoeopathic. seller's educational qualification is Degree in Homoeopathy, Degree in Pharmacy, Diploma in Homeopathy are		

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				prescribed, on the same pattern the recognized qualification for seller of Ayurvedic medicine may be prescribed as under.: a) Degree in Ayurveda (BAMS) b) Diploma in AYUSH Nursing & Pharmacy c) D-Pharma in Ayurvada d) B-Pharma in Ayurveda Presently there are 7200 qualified Diploma in AYUSH Nursing & Pharmacy and 11000 qualified BAMS Degree holders are available in Rajasthan. Out of that 4000 persons are engaged in State Government Services.		
6.	**Approval of only NABL accredited labs as Ayush approved lab under Rule 160A-J**	**160J. *Withdrawal and suspension of approvals.*** (1) The approving authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, withdraw an approval granted under this Part or suspend it for	Rule 160 B to J shall be omitted.	**01. ADMA** Rule 160A shall be substituted with the following rule namely,- "160A Institutions for carrying out tests on Ayurvedic, Siddha and Unani Drugs and Raw materials used in their manufacture on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs. All such institutions which have facilities as required for Quality Control Section as laid down under Schedule T and accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) for the category of chemical and biological testing for identity, purity, quality and strength of Ayurvedic, Siddha and Unani Drugs and raw materials will be notified as approved drug testing laboratories for the purpose of this rule by the central government. Delete reference to	As there is no compulsion under Allopathy side also for NABL so the existing provisions may be retained. Instead Ministry may issue advisory for the approved labs to upgrade for NABL accreditation utilizing the scheme of AOGUSY.	ASUDTAB agreed to the recommend ation of the committee and suggested for the withdrawl of proposed change in Rule 160 A to J.

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		such period as it thinks fit either wholly or in respect of testing of some of the categories of Ayurvedic, Siddha and Unani drugs to which it relates, if in his opinion the approved laboratory had failed to comply with any of the conditions of the approval or with any provision of the Act or the rules made thereunder. (2) Any approved laboratory, whose approval has been suspended or withdrawn, may, within three months of the date of the order of suspension or withdrawal, appeal to the State		Biological testing. **02. AMMOI** "160A Institutions for carrying out tests ..... this rule by the central government. Delete reference to Biological testing. NABL not mentioned before. As per the proposed amendment Schedule T prescribing the Good Manufacturing Practice for ASU medicines is divided into two. One for micro and small scale industries and Macro industries. A new set of standards are prescribed regarding working area, machinery etc. for macro industries. While progressive measures are always welcome, it goes without saying that such measures must be consistent with the prevailing system besides comprehending the challenges faced in such migration. An abrupt implementation of the Rules unmindful of the ramifications it may impose will only compound to the financial and operational constraints faced by the manufacturers more particularly amid the ongoing pandemic. Essentially therefore and as in case of several making it explicitly prospective in nature by restricting the application to those industries that are established after the implementation of the GMP standards for factories and those factories established prior may kindly be exempted. The proposed		

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		Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by the Department of Indian Systems of Medicine & Homoeopathy, Government of India in this behalf and notified in the Official Gazette.]		substitution of rule 160 A which may takes away the power of state government to grant /renewal of application for carrying test for identity, purity, quality and strength of Ayurveda, Sidha and Unani Drugs may be omitted and the power of state government to grant the **03. Raghav Chawla** In point no 25 of draft rules: - Rule 160 – B to 160 – J if be omitted than the purpose of Form – 48namely "Approval for carrying out tests or analysis on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacturing thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs" mentioned in present act. Rule 160 B to 160 J need to be there, if there will be no such checks of State Licensing Authorities on the approved laboratories then work level of approved labs may fall abruptly and affect the quality of Raw Material & Finished Products in the market. **04. Dr. S.K. Sharma, Former Advisor Ayurveda Baijnath Pharmacy** Rule 160A shall be substituted with the following rule namely.- 1) Only the stand alone Drug testing laboratory(not having attached manufacturing facility) shall have the		

				requirement of NABL Accrediation. 2) The manufacturing License holder with inhouse Drug Testing Laboratory shall have no mandatory requirement of NABL Accreditation. The existing provisions of approval of such inhouse Drug Testing Laboratory should continue. **05. Vaidyaratnam Oushadhasala Pvt. Ltd.** 160A The introduction of NABL accreditation to existing AYUS accredited labs will involve infrastructural and financial constraints. **Part I Level b Premises and Materials** Existing GMP holders may need a gross expansion in infrastructure as per the draft rule new schedule T like separate warehouse, temperature control system, logical placement of machinery, raw material and equipment for ASU manufacturing industry. It can have a huge impact on the financial stability.		

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III

Report of the ASUDTAB Sub-committee of Sowa Rigpa drugs

A meeting of the Sub-committee constituted under ASUDTAB for Sowa-Rigpa drugs was held on 10th and 11th July 2018 at Central Institute of Higher Tibetan Studies, Samath, Varansi. Following members were present in the meeting.

1. Prof Dr. Shriram S. Savrikar — Chairman Scientific Body, PCIM&H, Govt. of India
2. Dr. Dinesh Katoch — Advisor Ayurved, Ministry of AYUSH, Govt of India
   Secretary, ASUDTAB
3. Dr. Padma Gurmet — Scientist and Officer In charge National Research Institute for Sowa Rigpa, Leh, Ladakh
4. Prof. Dr. V.K. Joshi, — Chairman, Ayurvedic Pharmacopeia Committee, Govt of India
5. Dr. Dorje Dumdul — Associate Professor, HOD Sowa Rigpa, Central Institute of Higher Tibetan Studies, Samath, Varansi. (Invitee)

Dr. Dinesh Katoch briefed the committee about the object of the meeting of the committee. Accordingly the committee discussed inclusion and regulation of Sowa- Rigpa drugs under Drugs and Cosmetics Act 1940 and thereunder Rule 1945

It was informed by Dr. Katoch that Sowa -Rigpa system of Medicine is now recognized by Govt of India, however, presently there are no provisions in the Drugs and Cosmetics Act to regulate the Drugs used in Sowa- Rigpa system of Medicine. Therefore, appropriate provisions need to be made under the existing Act. Accordingly it was decided that a chapter titled Regulation of Sowa Rigpa Drugs may be included in the Drugs and Cosmetic Rules 1945. Necessary rules may be included in this chapter, which are as follows:

1. Definitions

Following definition of Sowa-Rigpa Drug was suggested by the committee

Sowa- Rigpa Drug

- Sowa - Rigpa drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Sowa-Rigpa system of medicine specified in the .... Schedule.

Proprietary Sowa- Rigpa Drug

- Proprietary Sowa - Rigpa medicines includes all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Sowa Rigpa system of medicine specified in the .... Schedule but does not include a medicine, which is administered by parenteral route and also a formulation included in the authoritative books as specified in sub-rule .....

Committee observed that According to D&C Act 1940, under Section 33B Chapter IV A will be applicable only to Ayurvedic, Siddha and Unani Drugs. On this background legal advice may be taken for inclusion of the following rule:

- Provisions of the Act relating to Ayurvedic, Siidha or Unani drug shall be applicable to Sowa Rigpa drugs.(to be checked from Legal Consultant with reference to provision of Section 33B).

2. **Standards of Sowa-Rigpa drugs**

The committee suggested inclusion of following rules:

- Sowa-Rigpa drugs shall comply with the standards prescribed in the Ayurvedic, Siddha and Unani pharmacopoeia for the time being in force. Manufacturer shall submit in house standards for such Sowa Rigpa drugs, which are not prescribed in the pharmacopoeias.
- Manufacturing of Sowa Rigpa drugs shall be carried out in such premises and under such hygienic conditions as specified in Schedule 'T' pertaining to Good Manufacturing Practices.

3. **Regulation of Manufacture and Sale of Sowa-Rigpa drugs**

The committee suggested inclusion of the following rule:

- Provisions of rules 151 to 170 shall be applicable for regulation of Sowa - Rigpa drugs, subject to the modification that the references to 'Ayurveda, Siddha or Unani drug' in the said rules shall be construed as references to Sowa -Rigpa drug.

4. List of authoritative books of Sow-Rigpa to be included in Schedule 1 of D&C Act 1940

In this respect the committee considered the decision taken in the meeting of ASUDTAB held on 17-9-2013.

6. A list of books was presented to the committee by Dr. Padma Gurmet, member of the committee and Scientist and Officer in charge National Research Institute for Sowa Rigpa, Leh, Ladakh. A letter by Dr. Tsering Tsamchoe, General Secretary Central Council of Tibetan Medicine, Dharmashala (Annexure- I) addressed to Dr. Dinesh Katoch, Advisor, Ayurveda and member of the committee, was also considered by the committee. The committee visited the library of the Institute of Higher Tibetan studies, Samath to physically verify the availability of the books mentioned in the list provided by Dr. Padma Gurmet. The approximate period of the original manuscript as informed by Dr. Dorje Dumdul, Associate Professor, HOD Sowa- Rigpa, and his associates at Central Institute of Higher Tibetan Studies, Sarnath, Varansi, was noted by the committee. In view of the decision of the ASUDTAB (Annexure- II) a template to gather the required information of the Sowa-Rigpa books for inclusion in the schedule was prepared as follows

Sr. No.	Complete title of the book	Original Author	Period of original manuscript	Indian publisher with year of publication	Language

The list of books is enclosed as Annexure- III

The committee resolved that the committee may visit the Pharmacy of Tibetan Medical and Astro Institute, Dharmashala (H.P.) to have the first hand information about the manufacture of Sowa-Rigpa Drugs which will facilitate the committee in formulating the rules and regulations related to Manufacture and Sale of Sow -Rigpa Drugs and its inclusion in Drugs and Cosmetics Act 1940.

It was also decided by the committee that a list of Sowa Rigpa Drug formulations commonly used by the practitioners and manufactured needs to be prepared. Dr. Padma Gurumet will gather this information from all the stakeholders. The committee should discuss these formulations with a view

to recommend the PCIM&H to develop the standards of Sow -Rigpa drugs. The committee resolved that this issue may be taken up in the next meeting of the committee which may be held at National Research Institute of Sowa Rigpa, Leh. Ladkah.

1. Prof Dr. Shriram S. Savrikar
2. Dr. Dinesh Katoch
3. Dr. Padma Gurmet
4. Prof. Dr. V.K. Joshi,
5. Dr. Dorje Dumdul

List of some classical texts of Sowa-Rigpa to be included in Schedule 1 of Drugs & Cosmetics Act of 1940

S.L	Complete title of the book/Manuscripts	Original Author	Approx. period of original Book/ Manuscripts	Indian Publisher with Year of publication	Language
1.	༄༅། བདུད་རྩི་སྙིང་པོ་ཡན་ལག་གྱད་པ་གསང་བ་མན་ངག་གི་རྒྱུད། Dud-tsi nying-po yan-lag gyad-pa sang-wa man-ngag gi-gyud zes-ja-wa (Four Tantras)	Originated from Buddha Shakamuni/ complied by Youthok Yontan Gonbo	12th Century	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
2.	ཡན་ལག་གྱད་པའི་སྙིང་པོ་བདུས་པ། (Yan Lak r Gyad pa Nyingpo bDus pa)	༄༅། རྭགས་བཏ། (Vagh Bhatt)	10th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh-1973	Boti/ Tibetan
3.	ཨན་ངག་རྗེ་བ་རིང་སྲེལ། (Men Ngag Je-wa Ring srel)	༄༅། ཟུར་ཁར་ཉམ་ཉིད། (Zurkhar Nyam Nyid)	15th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
4.	དཔལ་ལྡན་རྒྱུད་བཞི་ལ་སོགས་གསོ་བ་རིག་པའི་གདམས་ངག་ཀུན་གྱི་སྙིང་པོ་ལེགས་པར་བསྡུས་པ་ཕན་བདེ་བསྟན་པའི་ཟེར་སྤྲོ་བ་དེ་བཞིན་གཤེགས་པ་རྣམས་ཀྱི་བཞེད་པ་བཞུགས་སོ། (dPal lDen rGyud bShi la Sog gSowa Rigpe bKa bsTen Men Ngag Kun Gyi gNed bsdus Phen bDe bSil Zer sPro We Dawa gSarpa She Jawa bshug so)	༄༅། ཀརྨ་དེ་ས་ལེགས་པ་བསྟན་འཛིན། (Karma Nyeslek Tenzin)	17th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
5.	གསོ་རིག་སྨན་ངག་མཐའ་དག་གྱི་མཆོག་ཆིག་ཏུ་བསྡུས་པའི་རང་ཉིད་ཀུན་བྱང་ཆུབ་སེམས་དཔའ་ཡོན་ཏན་རྒྱུད་དང་སྨིན་ལས་ཐིན་ལེས་རྒྱུད་ཀྱི་ལྷན་ཐབས་ཀྱི་ཚུལ་དུ་བཀོད་པའི་ཕན་བདེ་ནོར་བུའི་ཚལ་ལེགས་བཞུགས་སོ། (gSowa Rigpe Men Ngag mTha Dag gyi chog chig tu bsDues Nes Men Ngag Yon Ten rGyud Dang Mipham Thin les rGyud Dag gi Lhen Thab Kyi tsul du bKod pa Phen bDe Norbue bang mZod Ches jawa bshug so)	༄༅། ཀརྨ་དེ་ས་ལེགས་པ་བསྟན་འཛིན། (Karma Nyeslek Tenzin)	17th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
6.	ཚངས་སྤྱོད་དཀར་མོའི་རྒྱུད་ལས་བཏུས་ཤིང་ལུང་དུ་མེད་པའི་ཉིན་བྱེད་ཟླ་བ་ཐིག་དང་བཅས་པ་ཡང་ཐིག (Tsang Tod Dhar ma mGon Poe rGud lung Men Ngag du me bchud chung sLob Mc Dhon Zin thig dang bhu la gDhampa yang thig)	༄༅། གཏོར་སྒོན་དར་མ་རབས་གོན་པོ། (Darma Gonpo)	13th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
7.	ཟིང་ཏིག་མཛེས་རྒྱན་འདུ་རྩི་སྨན་ངག་ཆེད་ཅིང་བཞུགས་སོ། (Zing Tig mzes rGyan bDud rtsi sMen mZod ched jaw a bShug so)	༄༅། ཨོ་རྒྱན་བསྟན་འཛིན། (Organ Tenzin)	14th	Men-tseekhang Daramsala,H.P1997	Boti/ Tibetan

8.	(Jor wa rGyad pa bShug so)	(Ludrup/Nagarjuna)	8th	Dege Tangur Mirigs Printing Press 1997 Tibet	Boti/ Tibetan
9.	(Ju Mipham sMen Yig Chestus)	(Ju Mipham)	14th	19th Century Wooden Block reprinted by Mirigs publisher 1989 Tibet	Boti/ Tibetan
10.	(sMan pyad Dawe Gyalpo)	(Nagarjuna)	7th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1975	Boti/ Tibetan
11.	(Cha lag Chogyed Ched jaw a Shug so)	(Youthog Tontan Gonpo)	8th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
12.	(dPal lden Phyagpe Men Ngag Bum Khutsur Shug so)	(MelaChagdum)	9th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1969	Boti/ Tibetan
13.	(Man Ngag Yonten rGyud kyi Lanthabs Zug rNgu Tsa dung Selwe Katpura Due Min Chi Shag gChod pe Ral Gri Che jawa Shug so)	(DesiSangyeGyatso)	15th	Men tseekhang 2005 Dharamsala, H.P India	Boti/ Tibetan
14.	(Zintik gChes bTues bDued rTsi Thig pa)	(Jamyang Kongtrul)	15th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1983	Boti/ Tibetan
15.	(Lag len Nger mKho sMen gyi sByor dPe Dudtse Bumzang Shug so)	(Khenrab Norbu)	19th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1985	Boti/ Tibetan
16.	(Lag len Ches Rigs bTuespa sMen Kun bChud du sGrub pe Lekyi Choga Kun gSal sNang mZod)	(Deui mer Tenzin Phuntsog)	16th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1978	Boti/ Tibetan
17.	(Rinter sMen yig Ches Tus)	Guru Rinpoche etc. (Compiled by Kongtrul Rinpoche)	8th	Mirigs Printing Press 1997 Tibet	Boti/ Tibetan
18.			17th	T. Sonam Tashigang B.P.O.- sNyimo	Boti/ Tibetan

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	(gSowa Rigpe bTen bChoes sMen layi dGong rGyen rGyud bShiyi gSal je Be du Rya sNon po Mallika Phreng wa Che jawa shug so)	(Desi sans rGyas rGya Tso)		Leh-Ladakh 1973	
19.	ས་སྨན་བསྒྲུབ་གྲུབ་ཆོག་དུས་འཕེན་བདེ་ལགས་བཞུགས་སོ། (sMen bsjor Nuspa chog dus Phen bDhe lags bShed Che jawa Shug so)	ས།། མཁྱེན་རབ་ནོར་བུ། (Khenrab Norbu)	19th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1969	Boti/ Tibetan
20.	ས་བདུད་རྩིའི་སྨན་གྱི་རྣམ་ཡེ་ཤེས་མིང་རྒྱས་པར་བཤད་པ་ཤེལ་གོང་ཤེལ་ཏྲེང་ཞེས་བྱ་བ་བཞུགས་སོ། (bDud Tsi sMen gyi rNam ye Nues Ming rGyes par bShed pa Shel gong Sheltreng she jawa Shug so0	ས།། དེའུ་མར་གཙུག་འཛིན་ཕུན་ཚོགས། (Deui mer Tenzin Phuntsog)	16th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1983	Boti/ Tibetan
21.	རྒྱུད་བཤེས་དེལ་པ་མེས་པོའི་ཟལ་ལུང་ཞེས་བྱ་བ་བཞུགས་སོ། (rGyud bSheyi Del pa Mespo'I Zallung She jawa Shug so0	ས།། ཟུར་མཁར་སློ་གྲོས། (Zurkhar Lo dros)	15th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1985	Boti/ Tibetan
22.	ས།། དངུལ་ཆུ་གྲུབ་ཐིས་བཀྲ་ཤིས། (Ngulchu Drupis Tanchos)	ས།། ཨོན་པ་རིན་ཆེན་དཔལ། (Orgenpa Rinchenpal)	12th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1973	Boti/ Tibetan
23.	ས།། སྨན་རྒྱས་རིན་ཆེན་འབྱུང་གནས། (Menngag Rinchen Jungnas)	ས།། འཇམ་དཔལ་རྡོ་རྗེ། (Jampal Dorje)	18th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1975	Boti/ Tibetan
24.	ས་དྲི་གུང་སྨན་རྩིས་ཕྱོགས་བསྒྲིགས། (Dri gung sMen rTsis Phyogs bsGrigs)	ས།། རིག་འཛིན་ཆོས་གྲགས། (Rigzin Chostag)	14th	T. Sonam Tashigang B.P.O.- sNyimo Leh-Ladakh 1981	Boti/ Tibetan
25.	ས།། བྱིས་པའི་ཉེར་འགྲོ་ཕན་གཉིས་ནོར། (bjispa Nyerjor Drophen sNying Nor)	ས།། བྱམས་པ་ཐུབ་དབང་། (Jampa Thubwang)	19th	Mirigs Printing Press- 1970 Tibet	Boti/ Tibetan
26.	ས་སྨན་དཔྱད་བདུད་རྩི་འབུམ་བཟང་ཞུགས་སོ། (sMen dPyed bDud-rTsi Bum bZang Shug so)	བོ་དོང་པན་ཆེན། Bo Dong Penchen	16th	First Printed in Tibet T.Y Tashigangpa 1986	Boti/ Tibetan
27	ས།།ཀོན་མཆོག་གི་ཀུན་གྱུར་དོན་ཉིད་ཡོངས་རྫོགས་བྱང་ཆུབ་སེམས་དཔའ་ཞུགས་སོ། (gSowa Rigpe gShung rGyud Dhon Nying po dGos Dodh Kun Jung she jaw a Shug so)	ལྷུན་གྲུབ་དུད་རྩི་འབྱུང་མེད། Lhunding Dutsi Gyurmed	15th		Boti/ Tibetan
28	ས།།ཤ་ཚོགས་སྨན་ངག་ཉེར་ལྔ་བྱ་རྒྱ་རྩ་ཆི་མེད་བདུད་རྩི་ཤེལ་དཀར་ཕྲེང་བ་དང་། མཁས་པའི་མགུལ་རྒྱན་ཞེས་བྱ་བ་བཞུགས་སོ། (sNa tsoks Men Ngag Nyer Lnga byGya rTsa chi Medh bDhud rTsi Shelkar Phreng wa mKhes Mang Yong kyi mGul rGyen)	དེའུ་དམར་བཀྲ་ཤིས་འཕུན་ཚོགས། Deumar Tenzin Phuntsok	16th		Boti/ Tibetan

29	(gSorig Yen lag brGyed lDhen chu Ter les gChes bsDhus 'Chi Med Norbu Phrengwa)	Karma Nyeleg Tenzin Thinley Rabgyal	15th	sMen tsee khang , Dharamsala, India, 2000	Boti/ Tibetan
30	(sMen dPyed Nyam yig brgya rtsa Zab rGyes shug so)	Gong smen dKon mCog Phendar	16	sMen tsee khang , Dharamsala, India, 1998	Boti/ Tibetan
31	(Men Ngag Zab mo Kun gyi sNing khu bsDhus pa Dharmo sMen Rampe gDams Ngag bKa rGya ma)	Dar mo sMen Rampa Lobsang Choedak	16th	sMen tsee khang , Dharamsala, India, 2010	Boti/ Tibetan
32	(gSowa Rigpe Men Ngag gChes bTues Dang Lag lend Mar Khrid kyi sKor phenbDe bang m bsDus PhenbDe bang mZod Shug so)	Mipham Namgyal Gyatso	18th		Boti/ Tibetan
33	(gSowa Rigpe gChes bTues Phende sNging po Dang che Med Nor Phreng gyi Shal sKong Men Ngag bDued rTsi Rol mTso She jawa Shug so)	sDege bLa sMen Rinchen Woeser	15th		Boti/ Tibetan
34	(gChes bsDus Rinchen phreng wa she jawa Shug so)	Chagdor mGonpo	14th	sMen tsee khang , Dharamsala, India, 2002	Boti/ Tibetan

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Agenda Item No : 6	Update of Schedule E1 list of drugs and Cosmetics Act 1940 and Rules1945	
S.no	Vernacular name	Botanical Name/Chemical name
Plant Origin		
1	Neeradimuthu	Hydnocarpus pentandrus
Metallic / Non-Metallic origin		
1	Rasam	Mercury
2	Lingam	Cinnabar
3	Rasakarpooram	Mercuric sub chloride
4	Veeram	Mercuric per chloride
5	Thalagam	Arsenic trisulphate
6	Manosilai	Red Orpiment (Arsenic disulphide)
7	Vellaipadanam	White arsenic
8	Thurusu	Copper sulphate
9	Mirutharsirungi	Lead
10	Gowri padanam	Arsenic pentasulfide

(L. Swaminathan) Member - ASUDTAB
20/06/22

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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ **W.P.(C) 321/2019 & CM APPL. 1529/2019**

RECKITT BENCKISER INDIA PRIVATE LIMITED AND ORS.
..... Petitioners

Through: Mr. R. Jawahar Lal, Mr.Siddharth Bawa, Mr.Anuj Garg and Mr. Mohit Sharma, Advocates

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Kirtiman Singh, Ms. Manmeet Kaur Sareen and Ms. Vidhi Jain and Mr. Waize Ali Noor, Advocates

\+ **W.P.(C) 502/2019 & CM APPL. 2375/2019**

MAGNET LABS PVT. LTD. ..... Petitioner

Through: Mr. R. Jawahar Lal, Mr.Siddharth Bawa, Mr.Anuj Garg and Mr. Mohit Sharma, Advocates

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Kirtiman Singh, Ms. Manmeet Kaur Sareen and Ms. Vidhi Jain and Mr. Waize Ali Noor, Advocates

\+ **W.P.(C) 505/2019 & CM APPL. 2385/2019**

MANKIND PHARMA LIMITED & ANR ..... Petitioners

Through: Mr. R. Jawahar Lal, Mr.Siddharth Bawa, Mr.Anuj Garg and Mr. Mohit Sharma, Advocates

versus

UNION OF INDIA & ANR ..... Respondents

Through: Mr. Kirtiman Singh, Ms. Manmeet Kaur Sareen and Ms. Vidhi Jain and Mr. Waize Ali Noor, Advocates

\+ **W.P.(C) 985/2019 & CM APPL. 4412/2019**

ASSOCIATION OF MANUFACTURERS OF AYURVEDIC MEDICINE ..... Petitioner

Through: Mr. R. Jawahar Lal, Mr.Siddharth Bawa, Mr.Anuj Garg and Mr. Mohit Sharma, Advocates

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Kirtiman Singh, Ms. Manmeet Kaur Sareen and Ms. Vidhi Jain and Mr. Waize Ali Noor, Advocates

\+ **W.P.(C) 5755/2020 & CM APPL. 20805/2020**

PERFETTI VAN MELLE INDIA PRIVATE LIMITED..... Petitioner

Through: Mr. R. Jawahar Lal, Mr.Siddharth Bawa, Mr.Anuj Garg and Mr. Mohit Sharma, Advocates

versus

UNION OF INDIA ..... Respondent

Through: Mr. Kirtiman Singh, Ms. Manmeet Kaur Sareen and Ms. Vidhi Jain and Mr. Waize Ali Noor, Advocates

\+ **W.P.(C) 15712/2022 & CM APPL. 48899-48900/2022**

KAMA AYURVEDA PRIVATE LIMITED ..... Petitioner

Through: Mr. R. Jawahar Lal, Mr.Siddharth Bawa, Mr.Anuj Garg and Mr. Mohit Sharma, Advocates

versus

UNION OF INDIA THROUGH THE SECRETARY TO THE GOVERNMENT & ANR. ..... Respondents

Through: Mr. Kirtiman Singh, Ms. Manmeet Kaur Sareen and Ms. Vidhi Jain and Mr. Waize Ali Noor, Advocates

CORAM:
HON'BLE MR. JUSTICE MANMOHAN
HON'BLE MR. JUSTICE SAURABH BANERJEE

ORDER

% **01.05.2023**

1. On 16th February, 2023, Mr. P.Chidambaram, learned senior counsel for the petitioners had stated that the petitioners shall be satisfied in the event Rule 170 and Form 26 E4 were re-examined by the respondents.

2. Today, Mr. Kirtiman Singh, learned counsel for the Union of India on instructions states that the writ petitions of the AYUSH stakeholders regarding Rule 170 of the Drugs and Cosmetics Rules, 1945 will be placed before the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) for reconsideration.

3. The statements made by learned counsel for the parties are accepted by this Court and the parties are held bound by the same.

4. With a view to balance the equities, this Court directs that any decision taken by the Union of India in pursuance to the decision of the ASUDTAB shall not be implemented for a period of four weeks from the date of its communication to the learned counsel for the petitioners. It is clarified that in the interregnum, the interim arrangement made by this Court shall continue.

5. With the aforesaid direction, the present batch of writ petitions stand disposed of. It is clarified that, in the event, the petitioners are aggrieved by

the decision taken by the Union of India and/or ASUDTAB, the petitioners shall be at liberty to challenge the same even on the grounds mentioned in the writ petitions.

MANMOHAN, J

SAURABH BANERJEE, J

MAY 1, 2023
AS

I/66005/2023

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T-11011/8/2021-DCC -Part-(2)
Government of India
Ministry of Ayush
(Drug Policy Section)

NBCC Office Block-III (2nd Floor),
East Kidwai Nagar South Ex-I,
New Delhi-110023
Dated: July, 2023

To,

i. All members of ASUDTAB (as per the list annexed),
ii. All special invitee of ASUDTAB (as per the list annexed).

Subject: Amendment in the minutes of the meeting of Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held on 25.05.2023 (Thursday) at 11.00 AM at Nirman Bhawan, Ministry of Health and Family Welfare, New Delhi -reg.

Sir/ Madam,

In reference to the Ministry of Ayush's O.M. no. T-11011/8/2021-DCC -Part-(1) dated 05.07.2023 regarding the subject mentioned above, it is requested to kindly note the following amendment in the minutes of the meeting of ASUDTAB held on 05.07.2023-

Reference	observation/ recommendation of the board	Amendment
S.no. viii. of table under agenda item no. 2	Vd. Santosh Nevpurkar highlighted that this matter is very important for Ayurveda practitioner. Board recommended that this matter may be taken up between the higher authorities/ officials of Ministry of Ayush and Ministry of Environment, Forest and Climate Changes. An inter-ministerial committee may be constituted in this regard. Further it was suggested that this committee may be chaired by Hon'ble Ministers of both Ministries.	"Vd. Santosh Nevpurkar highlighted that this matter is very important for Ayurveda practitioner. Board recommended that this matter may be taken up by Ministry of Ayush with Ministry of Environment, Forest and Climate Changes."

2. In this regard, revised approved minutes of the aforementioned meeting are attached herewith. **(Copy enclosed)**

3. This issues with the approval of Chairman, ASUDTAB.

I/66005/2023

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Encl. As above

Yours Sincerely,

Kousthubha Upadhyaya

(Dr. Kousthubha Upadhyaya)
Adviser (Ay.) & Secretary-ASUDTAB

Copy to -

1. Sr. PPS to DGHS

Annexure

I. List of ASUDTAB Members

1.	The Drug Controller General of India, New Delhi
2.	The Director, Central Drugs Laboratory, Kolkata.
3.	The Government Analyst, Pharmacopoeia Commission for Indian Medicine & Homoeopathy, Ghaziabad, U.P.
4.	Dr. Neeraj Tandon, Scientist –G and Head, Head Medicinal Plants Divison, Indian Council of Medical Research, New delhi-110029
5.	Dr. Pulok K. Mukherjee, Director, Institute of Bio resources and Sustainable Development ,Manipur and Professor (on lien), Dept. of Pharmaceutical Technology, Jadavpur University, Kolkata - 700032.
6.	Dr. Prakash Hegde, Department of Dravya Guna, Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan Karnataka- 573201, P.O. Box No-164.
7.	Dr. C. K. Katiyar, Chief executive officer, Health Care (Technical) Emami Ltd, 687, Anandpur, Kolkata-700007.
8.	Prof. Tajuddin, Department of Ilmul Advia, Aligarh Muslim University, Aligarh
9.	Dr. G. Veluchamy, 24, Chokkanathar Street, Kartjikeyan Nagar, Maduravoyal,Chennai- 602102.
10.	Dr. Sumit Nathani, Associate Professor, Department of Dravya Guna, National Institute of Ayurveda , Madhav Vilas Palace, Jorawar Singh Gate, Amer Road Jaipur - 302002 (Rajasthan).
11.	Dr. F. S. Shernani, Professor and Dean, Aligarh Muslim University, Aligarh, Uttar Pradesh.
12.	Dr. M. Krishnaveni, Professor, Gunapadam, Government Siddha Medical College, 6, Anna Arch Road, NSK Nagar, Arumbakkam Chennai, Tamil Nadu, 600106.
13.	Shri. Lal Hingorani, Pharmanza Herbal Private Limited, 214, Borsad Tarapur Road, Near vadalda Patia, Kaniya, Dharmaraj, Gujarat, India-388435.
14.	Dr. L. Sivakumar, SKM Siddha and Ayurveda Company Ltd.,Saminathapuram, Erode, Tamilnadu.
15.	Dr. Asad Mueed, Trustee and Governing body member of Hamdard National Foundation (India).

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16.	Vd. Santosh Nepulkar, Deerghayu Ayurved Swasthyalay,Nandigram colony, Garkheda, Aurangabad- 431005.
17.	Dr. P. Selva Shunmugam, President, World Siddha Trust, 3A, 1, Park street, Kilpauk Garden, Chennai- 600017.
18.	Dr. Sabahat Ullah Amoroha , H. No. 134 Qazizada Street Amoroha, Uttar Pradesh.

II. List of special invitee of ASUDTAB

1. Dr. Sangeeta Duggal, Advisor (Homoeopathy), Ministry of Ayush,
2. Dr. Anil Khurana, Chairperson, National Commission of Homoeopathy, New Delhi.
3. Dr. Subhash Kaushik, Director General, Central Council for Research in Homoeopathy, New Delhi.
4. Dr. Padma Gurmeet, Director, National Institute of Sowa-Rigpa, Leh, Ladakh.

III. Other officials attended ASUDTAB meeting

1. Dr. Rachna Paliwal, Assistant Drug Controller (H.), AYUSH Vertical, CDSCO
2. Dr. Ramavtar Sharma, Research Officer (Ay.), Office of DDG Ayush, DGHS
3. Dr. Raman Kaushik, Research Officer(Ay.), Drug Policy Section

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Minutes of the meeting of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held under the Chairmanship of Prof. (Dr.) Atul Goel, Director General of Health Services (DGHS), Government of India on 25th May, 2023. Room no. 445 A, NirmanBhawan, New Delhi.

A meeting of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) was held under the Chairmanship of **Prof. (Dr.) Atul Goel, Director General of Health Services (DGHS), Government of India** on 25thMay, 2023. Room No. 445 A, Nirman Bhawan, New Delhi on hybrid mode.

List of the Participants is placed at **Annexure I.**

At the outset Dr. Kousthubha Upadhyaya, Adviser (Ay.), Ministry of Ayush and Member-Secretary, ASUDTAB welcomed the Chairman, members of the Board, Special invitees & the participants and briefed the mandate & background of the board.

Dr. Anil Khurana highlighted that there is no representative of homoeopathy industry in the present ASUDTAB. In this regard, Member-secretary informed the board that the Homoeopathy and Sowa-Rigpa members were co-opted on regular basis till the tenure of this board with the approval of Chairman and Ministry of Ayush.

Chairman suggested that Ministry of Ayush may consider the representatives of Homoeopathy industry in the board as co-opted members. Further, he pointed out that if any member is absent in the three consecutive meetings of ASUDTAB, he/she may be replaced for the remaining tenure of the board. With the permission of Chairman, agenda-wise items were taken up for discussion.

Agenda-wise discussions and outcomes were as follows:

Agenda Item No. 1	**Approval of the minutes of the last meeting of ASUDTAB held on 27.06.2022.**

A copy of the approved minutes of the last meeting of ASUDTAB held on 27.06.2022 was circulated among the members/ invitee along with the approved agenda. In this regard, Dr. C.K. Katiyar commented that the decision of omitting Rule 170 was taken by ASUDTAB in its meeting of 15th March 2021 after recommendation by an expert committee of the Ministry of Ayush. Therefore, it was not appropriate to negate the previous decision of ASUDTAB in subsequent meeting dated 27.06.2022. Further, it was also not an agenda item in that meeting. The observation of Dr. V. G. Somani was in reference to ongoing discussion of the board. No other members had made their observations/ comments regarding Rule 170. The decision was indeed deferred as it was decided to redraft G.S.R. 437 dated 02.07.2021 in a single chapter in D & C Rules, 1945.

Considering the facts pointed out by the member, Chairman recommended to delete the recommendation "***Omission of Rule 170 is not required***" of ASUDTAB in its meeting held on 27.06.2022. ASUDTAB members unanimously agreed for this.

Agenda Item No. 2	**Action Taken Report (ATR) on the last recommendations of ASUDTAB**

Action taken report on the last recommendation of ASUDTAB meeting held on 26.07.2022 were presented before the Board and followings has been recommended –

S.no.	Recommendations of Board	Action Taken Report	Observation/ recommendation of the board
i.	*GSR No. 473(E) dated 02.07.2021 may be re-drafted as a separate part in Drugs & Cosmetics Rules, 1945 having all provisions related to Homoeopathy and Sowa-Rigpa system of medicine in light of recommendations of ASUDTAB at annexure II. Contents of remaining provisions of the said notification are deemed as approved by the ASUDTAB which will adopt as such.*	The agenda is once again placed as Agenda item -3.	Board observed that the matter may be discussed under Agenda item 3.
ii.	*An expert committee may be constituted by Ministry of Ayush to review or revisit the existing provisions of GMP, which will be placed before ASUDTAB.*	Ministry of Ayush vide O.M. no. T-11011/8/2021-DCC-Part(1) dated 15.09.2022 had constituted an Expert Committee to review or revisit the existing provisions of GMP for ASU&H drugs in Drugs & Cosmetic Act, 1940 and Rules there under. Suggestions from all the members of the committee has been sought. Work is under progress and final recommendation of the said expert committee will be placed before ASUDTAB for consideration.	Board recommended that the expert committee may submit its report within 03 months. Dr. Anil Khurana suggested to co-opt one more representative from industry Govt. PSU like HOMCO Kerala and IMPCL. Chairman recommended to consider the suggestion with consultation with Ministry of Ayush.
iii.	*With regard to submission of information under Schedule TA form, it is suggested that Ministry of Ayush may look into*	Schedule TA form regarding consumption of mercury, *Vijaya* and *Ahiphena* has been sought from the States/ UTs. However, Ministry is yet to receive	Board recommended that such data may directly be sought by Ministry of Ayush from ASU drug manufacturers or through

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	compilation and analysis of data submitted under this provision for developing suitable policy initiatives.	completed data from all States/ UTs.	google form.
iv.	*Order no. T.13011/3/2019-DCC (Ayush) dated 29.07.2019 issued by Ministry of Ayush regarding consideration and acceptance of stability study data for fixing the shelf- life of ASU drugs under Rule 161-B of the Drugs & Cosmetics Rules 1945 for the purpose of grant of license and renewal of license in reference to GSR no. 789 (E) dated 18.08.20216 may be converted into Gazette Notification.*	The amendments in Rule 161 B is already notified under draft notification GSR No. 473(E) dated 02.07.2021 for Amendment in Drugs Rules 1945, published by the Ministry of Ayush. The same is placed for recommendation of ASUDTAB for final notification.	Agreed
v.	*An expert committee may be constituted by Ministry of Ayush to review/ revise the Schedule I Books of the Drugs and Cosmetics Act 1940 and Rules 1945. The committee may directly include books of Sowa-Rigpa recommended by Sub-committee for Sowa-Rigpa drugs under ASUDTAB respectively. The committee will review the existing Schedule-I and prepare a draft regarding the revision of Schedule I. The same will be placed before ASUDTAB.*	Ministry of Ayush vide O.M. no. T-11011/8/2021-DCC-Part(1) dated 22.08.2022 has constituted a expert Committee to review/ revise the Schedule I Books of the Drugs & Cosmetic Act, 1940 and Rules thereunder, with Director, PCIM&H as Member Secretary. Work is under progress and final recommendation of the said expert committee will be placed before ASUDTAB for consideration.	The member-secretary, ASUDTAB conveyed that the work of expert committee is in advance stage. Board recommended that Ministry may proceed with draft notification of the schedule books once recommended by the committee. Thereafter final draft along with the comments of stakeholders may be placed before the board.
vi.	*National Commission for Indian Medicine (NCISM) may be requested to direct all registered Ayush practitioner to clearly mention duration of intake of formulations containing Schedule E (1) drugs.*	NCISM had been requested to direct all registered Ayush practitioner to clearly mention duration of intake of formulations containing schedule E (1) drugs in their medical prescription vide letter no. T-11011/8/2021-DCC dated 17.08.2022.	Noted
vii.	*An expert committee may be constituted by Ministry of Ayush to review/ revise the Schedule E (1) under Rule*	Ministry of Ayush vide O.M. no. T-11011/8/2021-DCC-Part (1)dated 22.08.2022 has constituted an expert committee	The member-secretary, ASUDTAB conveyed that the work of expert committee is in advance stage. Board

	161 (2) of Drugs and Cosmetics Act Rules 1945, with representatives of Ayurveda Siddha Unani system of medicine along with a representative from NCISM. The committee will review the existing Schedule E (1) and prepare a draft regarding the revision of Schedule E (1) drugs. The same will be placed before ASUDTAB.	to review the existing Schedule E(1) and prepare a draft regarding the revision of Schedule E(1) drugs. Work is under progress and final recommendation of the said expert committee will be placed before ASUDTAB for consideration.	recommended that Ministry may proceed with draft notification of the schedule E (1) drugs once recommended by the committee. Thereafter final draft along with the comments of stakeholders may be placed before the board.
viii.	*Ministry of Ayush may once again approach Ministry of Environment, Forest and Climate Change with a request to device a mechanism for providing shed Deer Antler or Deer antler burnt Ash or any other animal products used in ASU industry from zoo/reserved forests through respective State Authorities when collection of such animal products do not cause any harm to the biodiversity.*	Ministry of Ayush vide D.O. letter no. T-13020/8/2020-DCC dated 16.08.2022 had requested to Ministry of Environment, Forest and Climate Changes to devise a mechanism for providing shed Deer Antler or Deer Antler burnt ash or any other animal products used in Ayush industry from zoo/ reserved forests through respective State authorities.	Vd. Santosh Nevpurkar highlighted that this matter is very important for Ayurveda practitioner. Board recommended that this matter may be taken up by Ministry of Ayush with Ministry of Environment, Forest and Climate Changes.
ix.	*Minutes of the ASUDTAB meeting should be posted on the website of Ministry of Ayush like practice followed by CDSCO also, for higher level of transparency.*	The minutes of the meeting of ASUDTAB held on 27.06.2022 has been uploaded on the website of Ministry of Ayush (https://main.ayush.gov.in/ayush-drugs/asudtab).	Board appreciated the efforts made in this regard.

Agenda Item No. 3	**Comments received on draft notification GSR No. 473(E) dated 02.07.2021 for Amendment in Drugs Rules 1945, published by the Ministry of Ayush.**

Member-Secretary, ASUDTAB apprised the board regarding the issues and challenges for making a separate part in Drugs & Cosmetics Rules, 1945 having all provisions related to Homoeopathy and Sowa-Rigpa system of medicine, which are as follows –

i. In the existing Rules, Homoeopathy Medicines are considered a special category of Drug under the broad heading of the definition of 'Drugs'. Accordingly, the provisions of

Homoeopathy Drugs follow the provisions related to Drugs other than Homoeopathy drugs and are mentioned under several headings and Part.

ii. Homoeopathic medicines are mentioned under the following Sections and Rules under the D&C Act and Rules respectively:

a) Standards of Homoeopathic Medicines under Schedule II of the Act.

b) Some Definitions under the Rules

c)Provisions for Import of Homoeopathic medicines the approving authority for which is DCGI

d) Provisions for Licensing of New Homoeopathic medicines the approving authority for which is DCGI

e) Separate Part for Sale of Homoeopathic Medicines.

f) Separate Part for Manufacture for Sale or for distribution of Homoeopathic Medicines

g) Separate Part for labelling and packing of Homoeopathic Medicines

h) Approval of Institutions for carrying out tests of Homoeopathic Medicines.

i) Separate forms for application and approval pertaining to Homoeopathic Medicines and schedule M1 for GMP of Homoeopathic Manufacturing Units.

j) Category under Schedule K for exemptions of Chapter IV of the Act.

iii. the enforcement of Homoeopathic Medicines in the States still lies with the Drug inspectors or controlling authority of the allopathy side for the reason mentioned at point I above and in some states separate licensing authority is notified under PART VI-A Sale or PART VII-A for Manufacture of Homoeopathic Medicines. These persons in place in the States would be required to be re-notified under the new Proposed PART/ Chapter.

iv. Reframing of the chapters etc. may require consultation with MoHFW and DTAB for legal clearance on the matter. Further, consultation may also be needed with the stakeholders like Homoeopathic Drugs Manufacturers/ Drug Controllers/Inspectors/Analysts/Importers/researchers to address the problems faced during testing, inspection and compliance by the manufacturers/importers with regard to Homoeopathic Medicines.

v. Already new Drugs, Medical Devices and Cosmetic Bill, 2023 is in advanced stage wherein homoeopathy and Sowa-Rigpa systems are holistically harmonized under common chapter along with other Ayush systems.

vi. Exercise of making separate part for Homoeopathy and Sowa-Rigpa system may requires comprehensive scrutiny of relevant provisions of D & C Rules, 1945. However, that effort may be avoided at this juncture as Rules are to be framed for the proposed new bill.

The representation of Dr. Pradeep Multani, President, Association of Manufacturers of Ayurvedic Medicines (AMAM) dated 10.04.2023 regarding Repealing Rule 170 of D&C Act was discussed in the meeting.

Dr. C.K. Katiyar informed that the provisions for prohibition of misleading advertisements are also covered under Drugs and Magic Remedies (OA), Act, 1954 and Consumer Protection

Act. Further, Dr. Asad Mueed also submitted that there are no requirements of Rule 170 as proper implementation of Drugs and Magic Remedies (OA), Act, 1954is sufficient and restriction on awareness spreading initiatives of industry will be against governments commitment for propagating Ayush systems.

Dr. Padma Gurmeet raised his concern that even though Sowa-Rigpa system was officially recognized under Ayush in 2010, the inclusion of this system under D & C Act, 1940 and rules thereunder is still pending. Member-Secretary informed all the members/ special invitee that for Sowa-Rigpa system, only definition part has been notified under G.S.R. 473(E) dated 02.07.2021, wherein reference to the First schedule is also mentioned. However, the draft notification with regard to addition of Sowa-Rigpa books in the first schedule is still not done. Therefore, it was opined that Sowa-Rigpa part from GSR No. 473(E) dated 02.07.2021 may be finally notified at later stage together with revised first schedule including Sowa-Rigpa books.

In this regard, following had been recommended by the board –

i. Separate part for Homoeopathy and Sowa-Rigpa system is not required at this juncture.
ii. Ministry of Ayush may finally notify the amendments in respect of Homoeopathy drugs as placed before the Board as Annexure-III of agenda, under concerned sections/ part of existing Drugs & Cosmetics Rules, 1945.
iii. to proceed with final notification for omission of Rule 170 and its related Forms mentioned in D & C Rules, 1945.
iv. For Sowa-Rigpa system, authoritative books may first be notified through draft gazette notification, as per **Annexure-II.** Thereafter, final notification of Sowa-Rigpa part as per G.S.R. No. 473(E) dated 02.07.2021 may be notified together.

The board reviewed the GSR No. 473(E) dated 02.07.2021 based on the its observations in the last meeting and recommended for final notification of already agreed provisions, as per Annexure-III.

Agenda Item No. 4	**Draft notification GSR No. 668(E) and 669(E) dated 23.09.2021 for Amendment in Drugs Rules 1945, published by the Ministry of Ayush**

Member-Secretary informed the board that Ministry of Ayush vide notification GSR No. 668(E) and 669(E) dated 23.09.2021 had notified regarding schedule books of homoeopathy and Import of New Homoeopathic medicines. The board considered the recommendations of committee constituted the Chairmanship of Dr. Sangeeta Duggal, Adviser (H.), Ministry of Ayush on stakeholders' comments.

Dr. Anil Khurana suggested that in the final notification for amendment of Rule 30 AA the subclause (2) point v i.e. "all nosodes and sarcodes unless certified otherwise by licensing authority under rule 21" should be removed as keeping this clause in the definition of new homoeopathic medicine will be self-contradictory to the already licensed nosodes and sarcodes

and those mentioned in authoritative homoeopathic literature. These suggestions were accepted by the Board.

The board recommended to include provision of 669(E) dated 23.09.2021 in final notification as per **Annexure-III** and final notification of schedule books of homoeopathy as per **Annexure-IV**.

Agenda Item No.5	**Representation of Ayush Drug manufacturers/ Industry/ Organizations**

i. Representation of Sri Navjeewan Rasayanshala, Jaipur Regulatory concerns of ASU Industry like availability of Schedule-I Books, Rule-169 of Drugs & Cosmetics Rules, 1945-reg.

With regard to representation of Sri Navjeewan Rasayanshala, Jaipur regarding availability of Schedule-I Books, member-secretary conveyed that the expert committee on first schedule, has already suggesting publication of all Schedule I books on the website. Therefore, this issue will be addressed accordingly. Regarding the matter of applicable list of Permitted Excipients, Dr. C.K. Katiyar observed that the lists of excipients mentioned under Rule 169 of D & C Rules, 1945 are dynamic in nature and these are already available in public domain on the respective websites of IP, FSSAI and BIS. Member Secretary also mentioned regarding the representation of Himalaya Drugs Co. regarding allowing of excipients of US pharmacopoeia for boosting exports. Dr. Rajeev Singh Raghuvanshi, DCG (I) mentioned that almost all excipients of USP are already available under I.P. Further, there is an enabling provisio under I.P. for adopting excipients from any other official pharmacopoeia that can be availed by the industry to include any such excipients.

Chairman suggested to disseminate the concerned provision among stakeholders for better awareness and implementation of the D & C Act and Rules. Further, he suggested that Ministry of Ayush may approach National Medical Library, New Delhi to create a dedicated repository/ section of Ayush related authoritative text books and other reference books.

ii. 2000% exorbitant hike in formulation product approval in the amended rule 153 A and 153 B of Drugs & Cosmetics Rule 1945 vide G.S.R. 716(E) dated 1st October 2021.

The board reviewed the representations of Ayush stakeholders regarding rule **153 A and 153 B** of Drugs & Cosmetics Rule 1945 vide G.S.R. 716(E) dated 1st October, 2021 and recommendation of board are as follows –

- The provisions related to all the systems of Ayush should be similar in respect of license fee. Further, the fees may be automatically revised once in 03 years in accordance with cost-inflation index.
- The fee for homoeopathy medicines as recommended by the expert committee for GSR No. 473(E) dated 02.07.2021 i.e. Rs. 2000/- for an application may be finally notified as per **Annexure III.**

- Advisories issued by the Ministry of Ayush to consider maximum 10 homoeopathy medicines (with all its potencies) per application for license, may be included in the draft notification.
- Fee for ASU medicines under Rule 153 of D&C Rules, 1945, "Rupees two thousand per product" may be replaced with "Rupees two hundred per product", may be included in the draft notification.

iii. Representation of Sh. Ramesh Kadyan, President, Micro & Small Scale Ayurvedic Manufacturers Association of Haryana (MSAMA), Haryana date 20.04.2023 regarding Request to Protect the Future of Micro ASU Industries by waiving off New Approval Fee & Retention Fee.

Representation of the Sh. Ramesh Kadyan for different fee structure for micro and small industries were reviewed by the board and the same was not considered as fee is already proposed to be reduced as Rs. 200/- per product, over and above the first 10 products of P&P ASU products.

iv. Representation of Indian Homoeopathic Drug Manufacturers Forum regarding amendment of schedule K of Drug & Cosmetics Rules, 1945.

Representation of the Indian Homoeopathic Drug Manufacturers Forum regarding amendment under the extent and subject to conditions specified in Schedule K, i.e. for removal of the words 'in Form 20C' and word 'retail' of point (ii), so that allopathy drugs wholesale dealers be also allowed to keep Homoeopathic Medicines for maintaining supply chain of Homoeopathic Medicines in allopathic retail stores. The matter was reviewed by the board and it has been recommended that as the matter involves changing the criteria of exemptions for dealers of medicines licensed under rule 61 in schedule K which is for allopathy drugs, it may be referred to DTAB for their deliberations/consideration.

Agenda Item No. 6	**Restricting name of use of Classical ASU Drugs to the category of ASU category of Drugs only**

The following issue raised by Sh. C.K. Katiyar, Member, ASUDTAB were discussed –

- *Mahabhringaraj Kesh Tail which has been manufactured using mineral oil instead of Til Tail but licensed under cosmetic category. This is an example of using name of a classical product Mahabhringaraj for Cosmetic product with entirely different composition.*
- *Second case is Chyawanprash Gummies, where the word Chyawanprash has been used, which is name of a classical Ayurvedic product. The format is Gummies and product has been licensed under FSSAI.*

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Further, it was informed that in both the above cases names of Classical Ayurvedic products have been used for Non-Ayush Drug categories of Cosmetics or FSSAI. Ministry of Ayush has already banned the use of the name of Classical Ayurvedic products even for the proprietary ASU Drugs with Prefix and Suffix.

Dr. Prakash L Hegde submitted that there should be control over the selling of those medicines having classical names with different ingredients. Even it is observed that three or four classical formulations are combined together and new formulations are being prepared with a new name. This also should be taken very seriously as there may not be any proper research data findings or any other relevant information. Evidence should be produced that there is no interactions among these entirely different combinations.

ASUDTAB recommended that the matter of using name of ASU classical formulations in products licensed by FSSAI and CDSCO may be taken up by Ministry of Ayush with the respective organization.

Agenda Item No. 7	**Amendment in Rule 153 and 153 A of Drugs and Cosmetics Act 1940 and Rules 1945 vide gazette notification G.S.R. 341 (E) dated 24.04.2023**

All board memberswere informed that Ministry of Ayush vide notification G.S.R. 716 (E) dated 01.10.2021 had amended Rule 153 to Rule 156 of Drugs and Cosmetics Act 1940 and Rules 1945. Thereafter, vide gazette notification G.S.R. 341(E) dated 24.04.2023, following amendment has been made–

(a) in rule 153, in the second proviso, for the words "within eighteen months" the words "within twenty four months" shall be substituted;

(b) in Rule 153A, in the second proviso, for the words "within eighteen months", the words "within twenty four months" shall be substituted;

Member-secretary requested ASUDTAB board members for the ratification of G.S.R. 341 (E) dated 24.04.2023. The same has been agreed by all board members unanimously.

Further, Chairman suggested to change the name of the 'e-aushadhi portal' as this name may be confused with online sale of medicines through e-commerce platforms. He suggested to explore terms like "e.lic-ayush" portal for this purpose.

Agenda Item No.8	**Technical Committee on adopting new dosage forms under Ayush stream**

The draft prepared by the technical committee for adopting new dosage form under Ayush stream under the Chairmanship of Prof. S.K. Maulik were discussed in the meeting. Dr.

Rajeev Singh Raghuvanshi, DCG (I) informed that parameters are stringent in nature and may be reviewed.

Dr. Anil Khurana suggested to incorporate Homoeopathy System representative also in the said Committee or get the document framed vetted through circulation amongst Homoeopathic fraternity also.

In this regard, Member Secretary suggested that the guidelines may be notified for stakeholder comments and final view may be taken thereafter. Board recommended for notifying the guidelines for stakeholder consultation.

Agenda Item No.9	**Issue of manufacturing license by lease license owner for Ayurveda, Siddha and Unani drug categories.**

The Board observed that there is no explicit provision for lease licensing under Drugs & Cosmetics Act, 1940 and rules thereunder. Ministry of Ayush may issue an advisory to all State/ UTs to avoid granting of licenses under Form 25-Don the basis of lease agreements. For any eventuality for meeting the demand, there is already provision of loan licensing under Drugs & Cosmetics Act, 1940 and rules thereunder.

Agenda Item No.10	**Any other item with the permission of the Chair**

Member Secretary informed the board that Ministry of Ayush has received various representation demanding clear demarcation of ASU medicines containing non-vegetarian ingredients. The board suggested that this is an essential requirement that should be considered. However, it is difficult to define which is to be considered as vegetarian or non-vegetarian as interpretation depends on various religious, ethical and regional consideration.

The Board recommended Ministry of Ayush may constitute a committee of experts to deliberate and suggest on this issue.

The meeting ended with vote of thanks to the Chairman.

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Annexure I

List of participants of ASUDTAB meeting held on 25.05.2023 -

S. No.	Name of ASUDTAB member
1.	Prof. Dr. Atul Goel, The Director General of Health Services, (Chairman ASUDTAB) NirmanBhawan, New Delhi-110011
2.	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India, FDA Bhawan, Kotla Road, ITO, Delhi-110002
3.	Dr. Kousthubha Upadhyaya, Adv.(Ay.), Ministry of Ayush, Member Secretary-ASUDTAB
4.	Director, Central Drugs Laboratory, 3, Kyd Street Kolkatta-700016
5.	Dr. Raman Mohan Singh, Government Analyst, Director, Pharmacopoeia Commission for Indian Medicine & Homoeopathy, Ghaziabad, U.P.
6.	Dr. Neeraj Tandon, Scientist-G and Head, Divisions of Publications & Information and Medicinal Plants, Indian Council of Medical Research, Ansari Nagar, New Delhi 110029
7.	Prof. Pulok K. Mukherjee, Director, Institute of Bio resources and Sustainable Development Manipur and Professor (on lien), Dept. of Pharmaceutical Technology, Jadavpur University, Kolkata - 700 032.
8.	Dr. Prakash Hegde, Department of Dravya Guna, Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan
9.	Dr. C. K. Katiyar CEO Health Care (Technical) Emami Ltd, 687, Anandpur, EM Bypass, Kolkata-700 007
10.	Dr. Sumit Nathani, Associate Professor, Department of DravyaGuna, National Institute of Ayurveda , Madhav Vilas Palace, Jaipur - 302002 (Rajasthan).
11.	Dr. F. S. Shernani, Professor and Dean, Aligarh Muslim University, Aligarh, Uttar Pradesh.
12.	Dr. M. Krishnaveni, Professor, Gunapadam, Government Siddha Medical College, 6, Anna Arch Road, NSK Nagar, Arumbakkam Chennai, Tamil Nadu, 600106.
13.	Shri. Lal Hingorani, Pharmanza Herbal Private Limited, 214, BorsadTarapur Road, Near vadaldaPatia, Kaniya, Dharmaraj, Gujarat, India-388435.
14.	Dr. L. Sivakumar, SKM Siddha and Ayurveda Company Ltd., Saminathapuram, Erode, Tamilnadu
15.	Dr. Asad Mueed, Trustee and Governing body member of Hamdard National Foundation (India).
16.	Vd. Santosh Nevpurkar, Deerghayu Ayurved Swasthyalay,Nandigram colony, Garkheda, Aurangabad- 431005.
17.	Dr. P. Selva Shunmugam, President, Global Centre for Siddha, 3A, 1, Park street, Kilpauk Garden, Chennai- 600017.
18.	Dr. Sabahat Ullah Amoroha , H. No. 134 Qazizada Street Amoroha, Uttar Pradesh.
Special Invitee (s)	
19.	Dr. Sangeeta A. Duggal, Adv.(H), Ministry of Ayush
20.	Dr. Anil Khurana, Chairperson, NCH

21.	Dr. Subhash Kaushik, DG, CCRH
22.	Dr. Padma Gurmeet, Director, NISR
Other official(s)	
23.	Dr. Rachna Paliwal, Assistant Drug Controller (H.), AYUSH Vertical, CDSCO
24.	Dr. Ramavtar Sharma, Research Officer (Ay.), Office of DDGAyush
25.	Dr. Raman Kaushik, Research Officer(Ay.),, Drug Policy Section
ASUDTAB Members who could not attend the meeting	
1.	Prof. Tajuddin, Department of IlmulAdvia, Aligarh Muslim University, Aligarh
2.	Dr. G. Veluchamy, 24, Chokkanathar Street, Kartjikeyan Nagar, Maduravoyal, Chennai-602102

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Annexure-II

MINISTRY OF AYUSH
NOTIFICATION

New Delhi, the June, 2023

G.S.R. –(E).—The following draft amendment further to amend the Drugs and Cosmetics Act, 1940 (23of 1940), which the Central Government proposes to make amendment in the first schedule of the said act, in exercise of the powers conferred by Section 33-O of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Ayurveda, Siddha, Unani DrugsTechnical Advisory Board, is hereby published for information of all persons likely to be affected thereby and noticeis hereby given that said draft amendment will be taken into consideration on or after the expiry of a period of threemonths from the date on which copies of the Gazette of India containing these draft amendment are made available tothe public.

Objections and suggestions which may be received from any person within the period specified above will beconsidered by the Central Government.

Objections and suggestions, if any, may be addressed to the Secretary, Secretary, Ministry of Ayush, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi – 110023or emailed at dcc-ayush@nic.in.

DRAFT AMENDMENT

1. **Short title, and commencement:-** (1) These amendments may be called the Drugs and Cosmetics Act (.. Amendment), 2023.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the First Schedule to the Drugs and Cosmetics Act, 1940(23 of 1940) (hereinafter referred to as the said Act),after heading "C.— **HOMOEOPATHIC SYSTEM** " and the entries relating thereto, the following heading and entriesshall be inserted, namely,-

"D. —SOWA-RIGPA SYSTEM

Sl.no	*Name of book*
1.	Dud-tsinying-poyan-laggyad-pasangwamanngaggi-gyudzes-ja-wa (Four Tantras)
2.	Yan Lak r GyadpaNyingpobDus pa
3.	Men Ngag Je-wa Ring srel
4.	dPallDenrGyudbShilaSoggSowaRigpebKabsTenMenNgagKunGyigNedbsdusPhenbDeb SilZersPro We DawagSarpa She Jawabshug so
5.	gSowaRigpe Men NgagmTha Dag gyichogchigt'ubsDuesNes Men Ngag Yon Ten rGyud Dang Mipham Thin les rGyud Dag giLhenThab Kyi tsul du bKod pa PhenbDeNorbue

bang mZodChesjawabshug so

6. Tsang Tod Dhar ma mGon Poe rGud lung Men Ngag du me bchudchungsLob Me Dhon Zin thig dang bhu la gDhampa yang thig
7. Zing TigmzesrGyanbDudrtsisMenmZodched jaw a bShug so
8. JorwarGyad pa bShug so
9. JuMiphamsMenYigChestus
10. sManpyad Dawe Gyalpo
11. Cha lag ChogyedChed jaw a Shug so
12. dPalldenPhyagpe Men Ngag Bum Khutsur Shug so
13. Man NgagYontenrGyudkyiLanthabs Zug rNguTsa dung SeiweKatpura Due Mm Chi ShaggChodpeRalGriChejawa Shug so
14. ZintikgChesbTuesbDuedrTsi Thig pa
15. Lag lenNgermKhosMengyisByordPeDudtseBumzang Shug so
16. Lag lenChes Rigs bTuespasMenKunbChud du sGrubpeLekyiChogaKungSalsNangmZod
17. RintersMenyigChes Tus
18. gSowaRigpebTenbChoessMenlayidGongrGyenrGyudbShiyigSal je Be du RyasNonpoMallikaPhrengwaChejawashug so
19. sMenbsjorNuspachogdusPhenbDhe lags bShedChejawa Shug so
20. bDudTsisMengylrNam ye Nues Ming rGyes par bShed pa Shel gong Sheltreng she jawa Shug so0
21. rGyudbSheyi Del pa Mespo'IZallung She jawa Shug so0
22. NgulchuDrupisTanchos
23. MenngagRinchenJungnas
24. Dri gung sMenrTsisPhyogsbsGrigs
25. bjispaNyerjorDrqphensNying Nor
26. sMendPyedbDud-rTsi Bum bZang Shug so
27. gSowaRigpegShungrGyudDhonNying p0 dGosDodhKun Jung she jaw a Shug so
28. sNatsoks Men NgagNyerLngabyGyarTsa chi MedhbDhudrTsiShelkarPhrengwamKhesMang Yong kyimGuirGyen
29. gSorig Yen lag brGyedIDhenchuTer les gChesbsDhus Chi Med NorbuPhrengwa
30. sMendPyedNyamyigbrgyartsaZabrGyesshugso

31. Men NgagZabmoKungyisNingkhubsDhuspaDharmosMenRampegDamsNgagbKarGya ma
32. gSowaRigpe Men NgaggChesbTues Dang Lag lend Mar KhridkyisKorphenbDe bang m bsDusPhenbDe bang mZod Shug so
33. gSowaRigpegChesbTuesPhendesNging p0 Dang clte Med Nor PhrenggyiShalsKong Men NgagbDuedrTsiRolmTso She jawa Shug so
34. gChesbsDusRinchenphrengwa she jawa Shug so

Annexure-III

[To be published in the Gazette of India,
(Extraordinary), Part II, Section 3, Sub-section (i)]

MINISTRY OF AYUSH
NOTIFICATION

New Delhi, the June, 2023

G.S.R. (E).—Whereas the draft of certain rules further to amend the Drugs Rules, 1945 was published as required under section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940) (hereinafter referred to as the said Act), in the Gazette of India, Extraordinary, Part-II Section 3, Sub-section (i), dated the 02nd July, 2021 and 23rd September, 2021 vide notification of the Government of India, in the Ministry of Ayush number vide GSR. 473(E), dated the 02nd July, 2021, and GSR. 669(E), dated the 23rd September, 2021 respectively for inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And Whereas, the said Gazette were made available to the public on 08th July, 2021 and 28th September, 2021 respectively;

And Whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, Therefore, in exercise of the powers conferred by section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Ayurveda, Siddha, Unani Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:-

1. Short title, and commencement: - (1) These rules may be called the Drugs (--- Amendment) Rules, 2023. (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to be as the principal Rules) rule 2 (dd)shall be substituted namely-

"(dd) Homoeopathic medicines include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative literature of Homoeopathy as mentioned in first and second schedule of the Act and which is prepared according to the techniques of the official Homoeopathic Pharmacopoeia

of India and abroad and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route."

3. After rule 2 (ec) of the principal rules, the following rule shall be inserted, namely-

"(ed) "Registered Ayurvedic or Siddha or Sowa-Rigpa or Unani medical practitioner" means a person -

(i) holding a qualification granted by an authority specified or notified in the Schedules to the Indian Medicine Central Council Act, 1970 (48 of 1970); or NCISM Act, 2020 (14 of 2020); or

(ii) registered or eligible for registration in a medical register of a State or National register meant for the registration of persons practicing the Ayurveda or Siddha or Sowa-Rigpa or Unani system of medicine as under NCISM Act, 2020 (14 of 2020);"

4. For rule 30AA of the principal rules, the following rule shall be substituted, namely.-

"30AA. Import of New Homoeopathic medicines.— (1) No New Homoeopathic medicine shall be imported except under and in accordance with the permission in writing by the Licensing Authority as defined in clause (b) of rule 21.

(2) The importer of a New Homoeopathic medicine when applying for permission under sub-rule (1) shall produce before the Licensing Authority such documentary and other evidence as may be required by the Licensing Authority for assessing the safety, therapeutic efficacy of the medicine including the minimum homoeopathic provings carried out with it.

Explanation.- For the purpose of this rule, 'New Homoeopathic Medicine' means,—

(i) a Homoeopathic medicine which is not specified in the Homoeopathic Pharmacopoeia of India or United States of America or of the United Kingdom or the German Homoeopathic Pharmacopoeia or the French Homoeopathic Pharmacopoeia or the European Pharmacopeia; or

(ii) which is not recognized in authoritative Homoeopathic books specified in the First Schedule of the Act, as efficacious under the conditions recommended; or

(iii) a combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) or not recognized in authoritative Homoeopathic books referred to in clause (ii); or

(iv) a combination of two or more Homoeopathic medicines even if individually mentioned in Homoeopathic Pharmacopoeia as in clause (i) or in authoritative Homoeopathic books specified in the First Schedule of the Act, which are now proposed to be combined for the first time in a

fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims; or

(3) A New Homoeopathic Medicine shall continue to be considered as New Homoeopathic Medicine for a period of four years from the date of its first approval.

(4) The Licensing Authority as defined in clause (b) of rule 21 after being satisfied that the drug shall be effective and safe for use in the country, shall issue approval subject to the conditions stated therein:

PROVIDED that the Licensing Authority shall, where the data provided or generated on the New Homoeopathic Medicine is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission could be considered.

PROVIDED further that nothing contained under this rule shall be applicable to such Homoeopathic medicine which has been issued approval for import or license for manufacture for sale in India prior to the date of this notification from the concerned State or Central Authority as the case may be, and if such authority or person provides substantive information that the approval of competent authority has been obtained prior to the date of this notification.

Note: For the purpose of safety, therapeutic efficacy of the medicine including the minimum homoeopathic provings carried out with it shall be in accordance with the guidelines prescribed by Central Council for Research in Homoeopathy from time to time."

5 .In rule 67A of the principal rules,

i. subrule (2) shall be substituted namely.-"(2) Application for the grant of a licence to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines shall be made in Form19-B to the Licensing Authority and shall be accompanied by a fee of rupees two thousand.

PROVIDED that valid licence obtained under Form 20C or 20D prior to the date of commencement of this Amendment Rules, 2023, notwithstanding the period for renewal, shall seek for retention of the licence depositing a license retention fee of rupees one thousand for perpetuity of existing licence within a period of one year from the date of commencement of the Drugs and Cosmetics (2nd Amendment) Rules, 2023. Fresh License in Form 20C and 20D will be issued with lifetime validity to such license holders on the deposition of retention fees.".

ii. following sub-rule shall be inserted namely.-"(4) The application shall be made through portal e-AUSHADHI (www.eaushadhi.gov.in) as per the format provided in the said portal, pertaining to the sale license of Homoeopathic Medicines.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government from time to time, during this period either of online and offline process of license application shall be accepted.".

6. For rule 67C of the principal rules, the following rule shall be substituted, namely.-

"**67C. Forms of licences to sell drugs.**-(1) Subject to the conditions of rule 67F being fulfilled, a licence to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines by retail or by wholesale shall be issued in Form 20C or 20D as the case may be.

(2) The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 20C or 20D issued online as per the format provided in the said portal.

PROVIDED that no license shall be required for exhibiting the drugs for promotional activities in any fair.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government from time to time, during this period either of online and offline process of license application shall be accepted."

7. For rule 67E of the principal rules, the following rule shall be substituted, namely:-.-

"**67E Duration of licences.**(1) A licence issued in Form 20C or 20D shall remain valid perpetually.

PROVIDED that the licencee shall submits a self declaration of adherence to the conditions of license and theprovisions of the Drugs and Cosmetics Act and the Rules, every five years from the date of issue of license in form20C or 20D or from the date of submission of last self declaration as the case may be .

PROVIDED further, that such self declaration should be made within two months of completion of five years from thedate of issue of license in Form 20C or 20D or from the date of submission of last self declaration as the case may,and in the event of non submission of such self declaration, license shall be deemed to have been cancelled. Fresh application under Form 19B is to be made thereafter. "

8. The Rule 67EE of the principal rules,shall be omitted.

9. The sub-rule (6) of rule 67G of the principal rules, shall be omitted.

10. In rule 85B of the principal rules, -

i. under sub-rule (1) the words "or renewal" shall be omitted.

ii. sub-rule (2) shall be substituted namely:-
" (2) An application in Form 24C shall be accompaniedby a fee of rupees two thousands.

Provided,notwithstanding the period for renewal, existing license holders under Form 25C prior to the date of commencement of this Amendment Rules, 2023, shall seek for retention of the license depositing a license retention fee of rupees one thousand, for the perpetuity of existing licence within a period of one year from the date of commencement of the Drugs and Cosmetics (2nd Amendment) Rules, 2023. Fresh License in Form 25C will be issued with perpetual validity to such license holders and having factory premises complying with the requirements and conditions as specified in Schedule M1 on the deposition of retention fees.

Provided further that the application shall be processed online through the portal e-AUSHADHI (www.e-aushadhi.gov.in)forthe purpose. Till the portal shall come to effect as notified by the Central Government from time to time, either of online and offline process of license application shall be accepted.

Explanation-for the purpose of this rule single ingredient Homoeopathic medicineswith all of its potencies will be considered as one product and separate fees potency wise is not required.".

iii. sub-rule (3), (4) and (5) shall be omitted.

11. The rule 85D of the principal rule, shall be substituted, namely:-
"85D. Form of licence to manufacture Homeopathic medicines. — (1) Subject to the conditions of rule 85E being fulfilled, a licence to manufacture for sale of Homeopathic medicines shall be issued in Form 25-C. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert committee in homoeopathic systems of medicine as the case may be, which the State Government may approve in this behalf.

(3) The application shall be processed through the portal e-AUSHADHI (www.e-aushadhi.gov.in)forthe purpose.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government from time to time, during this period either of online and offline process of license application shall be accepted.".

12. In rule 85E of the principal rules, -

i.in the opening remarks the words "or renewal" and "or renewed" shall be omitted.

ii. In clause (a) to sub-rule (1) of rule 85E of the principal rules, after the words "a graduate in Science with Chemistry", the words "or Botany or Zoology" shall be inserted.

iii. the third proviso "PROVIDED that in case potentised preparations are made in a Pharmacy holding licence in Form 20-C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label." shall be omitted.

13. For rule 85EA of the principal rule, the following rule, shall be substituted namely:-
"**85EA. Inspection for grant of license and verification of compliance.**-(1) Before a GMP certificate for License under Form 25C is granted or retained, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more qualified inspectors as mentioned under Rule 167 appointed by the State Government.
(2) The inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs and verify the adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules not less than once in five years or as needed as per risk based approach.

Provided that the inspectors are allotted the inspection duty in a randomized manner ensuring that the same inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than five years duration.

PROVIDED further that if the premises is not inspected within the period of the validity of the GMP certificate or even after submission of retention fee, the GMP certificate shall be deemed to be continued for further term of five years.".

14. For rule 85EB of the principal rules, the following rule shall be substituted,namely.-
"**85EB. Report by Inspector.**– (1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and the Requirements of Plant and Equipments as laid down in Schedule M1.

(2) The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the sub- rule (1), to the Licensing Authority.".

15. For rule 85EC of the principal rules, the following rule shall be substituted, namely.-

"**85EC.- Procedure of Licensing Authority.-**
(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, and after being satisfied that the requirements of the provisions referred to in the rules under the Act have been complied with and that the conditions of the licence shall be observed, shall issue a licence under this Part.
(2) If the Licensing Authority is not satisfied of the requirements under sub-rule(1), shall issue a memorandum of shortcoming, and the conditions which shall be satisfied before a licence is granted and shall supply the applicant a copy of the inspection report.
(3) The applicant within two months of issue of such memorandum under sub-rule (2) shall reply the same.
(4) On non-submission of requirements in sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.
(5) For this purpose, the licensing authority shall intimate the applicant and process the application online through the portal e-AUSHADHI (www.e-aushadhi.gov.in) for the purpose.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government from time to time, during this period either of online and offline process of license application shall be accepted.".

16. For rule 85ED of the principal rules, the following rule shall be substituted, namely.-
"**85ED.-Further application after rejection.** —If the applicant, within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices, as the case may be, informs the Licensing Authority that the conditions laid down have been complied with and deposit an inspection fee of rupees one thousand, the Licensing Authority may, after a further inspection, if any, is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part.".

17. Rule 85F shall be substituted namely.-

"**85F. Duration of licence**—(1) A licenceissued in Form 25C shall remain valid perpetually.

Provided that the licencee shall submits a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every year from the date of issue of license in Form 25 C or from the date of submission of last self declaration as the case may be .

Further, provided that such self declaration should be made within three months, of completion of one year from the date of issue of license in Form 25 C or from the date of submission of last self declaration as the case may be, and in the event of non submission of such self declaration, within the time mentioned, the license of the said product shall be suspended temporarily and if the licensee fails to submit the self declaration within a further period of three months, the license of the said product shall be deemed to have been cancelled."

18. The Rule 85G of the principal rules, shall be omitted.

19. In rule 106A of the principal rules, in sub-rule (A), clause (ii), sub-clause (a), after the words "German Homoeopathic Pharmacopoeia", the following shall be inserted, namely,- "or the French Homoeopathic Pharmacopoeia or the European Pharmacopeia."

20. In rule 157 of the principal rules, clause (2) shall be substituted with following, namely.-
"(2) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole time employee and who possesses the following qualifications, namely: –
(a) A degree in Ayurveda, Siddha or Unani system of Medicine, as the case may be, conferred by a University/ State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central Government or a State Government for this purpose, or
(b) A graduate in Pharmacy (Ayurveda or Siddha or Unani) of a University recognised by the Central Government or a State Government with experience of at least two years in manufacturing of Ayurveda, Siddha, Unani drugs as the case maybe in a licensed manufacturing unit.

Provided that the person already registered with the State Licensing Authority as competent person for the purposes of grant of license in Form 25D/25E prior to the coming into force of the Drugs (Amendment Rules) 2023, shall continue to be considered as competent person for the said purposes.".

21. In subrule (2) of Rule 161B, the words "Real time" shall be substituted with "Real time and accelerated".

22. In table under rule 168, for the words "12%" the words "11.40 %" shall be substituted.

23. The Rule 170 of the principal rules, shall be omitted.

24. In FORM 20C.-

i. under clause 2 the words "to ....." shall be omitted.

ii. before the words "Date" the words "License No....." shall be inserted.

25. In FORM 20D.-

i. under clause 2 the words "to ....." shall be omitted.

ii. before the words "Date" the words "License No....." shall be inserted.

26. FORM 20E shall be omitted.

27. In the principal rules, for FORM 24C, the following FORM shall be substituted, namely:—

"FORM 24C

(See rule 85B)

APPLICATION FOR THE GRANT OF A LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC MEDICINES

1. I / W e ..... of.....hereby apply for the grant of licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised preparations on the premises situated at..... .....

Names of the Homoeopathic preparations..... (each item to be separately specified).

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

3. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date.....

Signature

.....

(applicant)

Note—

The application should be accompanied by a Plan of the premises.".

28. In the principal rules after FORM 24C, the following FORM shall be substituted, namely:-

"FORM 25C

(See rule 85D)

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC MEDICINES

No. of Licence and date of issue.....

1. .... is / are hereby licenced to manufacture the following Homoeopathic medicines on the premises situated at..... under the direction and supervision of the following competent technical staff: —

Name of Homoeopathic preparations.

(Each item to be separately specified)

2. Competent Technical staff (Names).

3. The licence shall be in force from .....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ..... Signature

.....

Designation .....

Conditions of Licence

1. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licencee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.

5. The licence is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Homoeopathic medicines as laid down in Schedule M1 of the Drugs Rules, 1945.".

29. FORM 26C shall be omitted.

30. FORM 26 E4 shall be omitted.

31. FORM 26 E5shall be omitted.

Annexure-IV

[To be published in the Gazette of India,(Extraordinary), Part II, Section 3, Sub-section (i)]

Government of India
Ministry of Ayush

NOTIFICATION

New Delhi, the June, 2023

G.S.R. — (E).- Whereas the draft of certain schedules further to amend in the Drugs and Cosmetics Act, 1940 was published as required under Section 8 and Section 16 and Section 33-O of the Drugs and Cosmetics Act, 1940 (23 of 1940) (hereinafter referred to as the said Act), in the Gazette of India, Extraordinary, Part-II Section 3, Sub-section (i), dated the 23rd September, 2021 vide notification of the Government of India, in the Ministry of AYUSH number *vide* GSR. 668(E), dated the 23rd September, 2021, for inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of ninety days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And Whereas, the said Gazette was made available to the public on 28th September, 2021;

And Whereas, objections and suggestions received from the public on the said draft schedule have been considered by the Central Government;

Now, Therefore, in exercise of the powers conferred by Section 8 and Section 16 and Section 33-O of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Ayurveda, Siddha, Unani Drugs Technical Advisory Board, hereby makes the following amendments to the Drugs and Cosmetics Act, 1940, namely:-

1. **Short title, and commencement:-** (1) These amendments may be called the Drugs and CosmeticsAct (-- Amendment), 2023.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the First Schedule to the Drugs and Cosmetics Act, 1940(23 of 1940) (hereinafter referred to as the said Act), after heading "B.—UNANI TIBB SYSTEM" and the entries relating thereto, the following heading and entries shall be inserted, namely,-

"C.—HOMOEOPATHIC SYSTEM

Serial No.	Name of Book
1.	Hahnemann Samuel. MateriaMedicaPura. Vol. I-II. 3rded. London: Hahnemann Publishing Society; 1830/ reprint ed. 1986.

2. Hahnemann Samuel. The Chronic Diseases Their Peculiar nature and their homoeopathic cure. (Theory & Practice). 1st ed. New York: W Radde; 1845.

3. Hering Constantine. The Guiding Symptoms of Our MateriaMedica. Vol. I-X. 1ST ed. Philadelphia: American Homoeopathic Publishing Society; J.M. Stoddart& Co; 1879. /Reprinted ed. New Delhi: B. Jain Publishers; 1989.

4. Allen TF. The Encyclopaedia of pure MateriaMedica. Vol. I-XII. 1sted. New York, Philadelphia: Boericke&Tafel; 1877. /Reprinted ed. New Delhi: B. Jain Publishers; 1986.

5. Allen HC. The MateriaMedica of Nosodes with proving of X-rays. 1st ed. Philadelphia: Boericke&Tafel; 1910/ New Delhi: Jain Publishing Co; 1977

6. Clarke JH. A Dictionary of Practical MateriaMedica. Vol. I-III. 1sted. London: The Homoeopathic Publishing Company; 1902.

7. Hughes Richard. A Manual of Pharmacodynamics. 5th ed. London: Leath and Ross; 1886.

8. Hughes R, Dake JP. Cyclopaedia of Drug Pathogenesy. 1st ed. London: Gould; 1886.

9. Julian OA. MateriaMedica of Nosodes with Repertory. 1stIndian ed. New Delhi: B. Jain Publishers; 1980/ New Delhi: B. Jain Publishers; 1981

10. Julian OA. MateriaMedica of New Homoeopathic Remedies. French ed. UK: Beaconsfield Publishers Ltd; 1971/ Beaconsfield Bucks UK: Beasconsfield Publishers Ltd; 1979

11. Paterson John. The Bowel Nosodes. 1st ed. Calcutta: Hahnemann Publishing CO. Private Ltd; 1950/Calcutta: Hahnemann Publishing Co. Private Ltd.

12. Ghose SC. Drugs of Hindoostan. ed. Calcutta: Hahnemann Publishing Co. Pvt. Ltd; 1952/ 9th ed. Calcutta: Hahnemann Publishing Co. Pvt. Ltd; 1984.

13.	Anshutz's EP. New, Old and Forgotten Remedies. 1st ed. Philadelphia: Boericke&Tafel; 1900.
14.	Boericke William, Dewey Willis A. The Twelve Tissue Remedies. 1st ed. Philadelphia: Boericke&Tafel: 1888.
15.	Kent JT. Lectures Homoeopathic MateriaMedica. 1th ed. Calcutta: Roy Publishing House: 1904.
16.	Boericke OE. Pocket Manual of Homeopathic MateriaMedica, Boericke& Runyon. 6th ed. New York: Boericke&Tafel; 1916/New Delhi: B. Jain Publishers; 1971.
17.	Stephenson J. Hahnemannian Provings, A Materia Medica and Repertory. New York: Boericke&Tafel; 1963/ New Delhi: B. Jain Publishers; 1986
18.	Homoeopathic Pharmacopeia India (HPI)-all volumes published by Govt. of India
19.	Study of Homoeopathic Medicines through Clinical Verification all Volumes published by Central Council for Research in Homoeopathy, New Delhi.
20.	Homoeopathic Drug Provings- all Volumes published by Central Council for Research in Homoeopathy, New Delhi."

3. In the Second Schedule to the said Act, in item number 4A, under 'Class of drug', -

(a) in sub-item (b), after the words "the German Homoeopathic Pharmacopoeia", the following shall be inserted, namely,-

"or the French Homoeopathic Pharmacopoeia or the European Pharmacopeia."

(b) in sub-item (c), after the words "the German Homoeopathic Pharmacopoeia", the following shall be inserted, namely,-

"or the French Homoeopathic Pharmacopoeia or the European Pharmacopeia."

/67065/2023

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Government of India
Ministry of Ayush

NBCC Office Block-III (2nd Floor),
East Kidwai Nagar South Ex-I,
New Delhi-110023

To,

All State/UT Licensing Authorities and Drug Controllers of AYUSH
(As per list attached)

Subject: Rule 170 of Drugs and Cosmetics Rules, 1945 - reg

Sir,

Please refer to the meeting of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) held on 25th May, 2023, New Delhi wherein it had been recommended to proceed with final notification for omission of Rule 170 and its related provisions mentioned in Drugs &Cosmetics Rules, 1945. Approved minutes of this meeting are enclosed. However, the final notification for omission of Rule 170 and its related provisions mentioned in Drugs & Cosmetics Rules, 1945 will take some time.

2. In this regard and in excercise of powers conferred under Section 33 P Drugs & Cosmetics Act Rules, 1940, all States/ UTs licensing authorities are hereby directed not to initiate/ take any action under Rule 170 of Drugs & Cosmetics Rules, 1945.

3. This issues with the approval of the Competent Authority.

Encl. As Above

Yours faithfully,
Signed by Madan Lal Meena
Date: 29-08-2023 11:01:52
Reason: Approved

(Madan Lal Meena)
Under Secretary to the Government of India

Copy for information to:

i) Director (AYUSH) of all States/UTs.

रजिस्ट्री सं. डी.एल.- 33004/99

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REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

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असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 89] नई दिल्ली, सोमवार, फरवरी 5, 2024/माघ 16, 1945
No. 89] NEW DELHI, MONDAY, FEBRUARY 5, 2024/MAGHA 16, 1945

आयुष मंत्रालय

अधिसूचना

नई दिल्ली, 2 फरवरी, 2024

सा.क.नि. 98(अ).—औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा-ढ द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए और आयुर्वेद, सिद्ध, यूनानी औषधि तकनीकी सलाहकार बोर्ड से परामर्श करनेके बाद, औषधि और प्रसाधन सामग्री नियम, 1945 का और संशोधन करने के लिए, जैसा कि केन्द्र सरकार का प्रस्ताव है,कतिपय नियमों का एक प्रारूप, इसके द्वारा प्रभावित होने की संभावना वाले सभी व्यक्तियों की जानकारी के लिए प्रकाशित किया जाता है, जैसा कि उक्त अधिनियम द्वारा अपेक्षित है,और एतद द्वारा सूचना दी जाती है कि उक्त मसौदा नियमों पर हितधारकों की आपत्तियों अथवा सुझावों पर उस तारीख से तीस दिनों की अवधि समाप्त होने पर या उसके बाद विचार किया जाएगा जिस तारीख को इन प्रारूप नियमों वाले भारत के राजपत्र की प्रतियां जनता को उपलब्ध कराई जाएंगी;

उपर्युक्त निर्दिष्ट अवधि के भीतर किसी भी व्यक्ति से उक्त प्रारूप प्राप्त होने वाली आपत्तियों और सुझावों पर केंद्र सरकार द्वारा विचार किया जाएगा;

आपत्तियां या सुझाव, यदि कोई हों, तो सचिव, आयुष मंत्रालय, आयुष भवन,'बी' ब्लॉक, जीपीओ कॉम्पलेक्स, आईएनए, नई दिल्ली-110023 को अग्रेषित किए जाएं अथवा ई-मेल dcc-ayush@nic.in. पर भेजे जाएं।

उपर्युक्त निर्दिष्ट अवधि के भीतर किसी भी व्यक्ति से प्राप्त होने वाली आपत्तियों और सुझावों पर केंद्र सरकार द्वारा विचार किया जाएगा।

मसौदा नियम

1. संक्षिप्त शीर्षक, और प्रारंभ: - (1) इन नियमों को औषधि (संशोधन) नियम, 2024 कहा जाएगा।(2) येसरकारी राजपत्र में उनके प्रकाशन की तारीख से प्रवृत्त होंगे।

2. औषधि नियम, 1945 (जिसे इसमें इसके पश्चात्मूल नियम कहा गया है) में, भाग XVI, XVIA, XVII, XVIII और XIX में, "आयुर्वेदिक, सिद्ध और यूनानी औषधियां" शब्द या "आयुर्वेदिक (सिद्ध सहित) या यूनानी औषधियां" शब्द जहां भी परिलक्षित हों, उनके स्थान पर "आयुर्वेद, सिद्ध, सोवा-रिग्पा और यूनानी औषधियां" शब्द रखे जाएंगे।

3. नियम 2 (घघ)के स्थान पर निम्नलिखित रखा जाएगा, अर्थात-

"(घघ) होम्योपैथिक औषधियों के अंतर्गत कोई भी ऐसी औषधि शामिल है जो होम्योपैथिक प्रमाणों में दर्ज है या जिनकी चिकित्सीय प्रभावकारिता लंबे नैदानिक अनुभव के माध्यम से स्थापित की गई है जैसा कि अधिनियम की पहली और दूसरी अनुसूची में उल्लिखित होम्योपैथी के प्रामाणिक साहित्य में दर्ज है और जिसे भारत और विदेशों के आधिकारिक होम्योपैथिक भेषजसंहिता की तकनीकों के अनुसार तैयार किया गया है और जो ऐसी होम्योपैथिक औषधियों के अवयवों का योग है लेकिन इसके अंतर्गत ऐसी औषधि नहीं है जो आन्त्रेतर मार्ग से दी जाती है।

4. नियम 2 (ङ्ख) के स्थान पर निम्नलिखित रखा जाएगा, अर्थात-

"(ङ्ख) "पंजीकृत होम्योपैथी चिकित्साभ्यासी" से अभिप्रेत है ऐसा व्यक्ति-

(i) जो होम्योपैथी केंद्रीय परिषद अधिनियम, 1973 (1973 का 59); या राष्ट्रीय होम्योपैथी आयोग (एनसीएच) अधिनियम, 2020 (2020 का 15) की अनुसूचियों मेंनिर्दिष्ट या अधिसूचित किसी प्राधिकरण द्वारा प्रदत्त की गई योग्यता रखता हो; या

(ii) जोराष्ट्रीय होम्योपैथी आयोग (एनसीएच) अधिनियम, 2020 (2020 का 15) के तहत होम्योपैथी चिकित्सा पद्धति का अभ्यास करने वाले व्यक्तियों के पंजीकरण हेतुराज्य या राष्ट्रीय पंजिका की चिकित्सा पंजिका में पंजीकृत होया पंजीकरण के लिए पात्र हो;"

5. मूलनियमों के नियम 2 (ङ्ग) के बाद, निम्नलिखित नियम अंत:स्थापित किया जाएगा, अर्थात्-

"(ङ्घ) "पंजीकृत आयुर्वेद या सिद्ध या सोवा-रिग्पा या यूनानी चिकित्साभ्यासी" से अभिप्रेत है ऐसा व्यक्ति -

(i) जो भारतीय चिकित्सा केंद्रीय परिषद अधिनियम, 1970 (1970 का 48); या भारतीय चिकित्सा पद्धतिराष्ट्रीय आयोग (एनसीआईएसएम) अधिनियम, 2020 (2020 का 14) की अनुसूचियों में निर्दिष्ट या अधिसूचित किसी प्राधिकारी द्वारा प्रदत्त की गई योग्यता रखता हो; या

(ii) जोभारतीय चिकित्सा पद्धति राष्ट्रीय आयोग (एनसीआईएसएम) अधिनियम, 2020 (2020 का 14) के तहत आयुर्वेद या सिद्ध या सोवा-रिग्पा या यूनानी चिकित्सा पद्धति का अभ्यास करने वाले व्यक्तियों के पंजीकरण हेतुराज्य या राष्ट्रीय पंजिका की चिकित्सा पंजिका में पंजीकृत है या पंजीकरण के लिए पात्र है;

6. मूल नियमों के नियम 2 (ज) के बाद, निम्नलिखित नियम अंत:स्थापित किया जाएगा, अर्थात्-

"(जज) सोवा-रिग्पा औषधियां— सोवा-रिग्पा औषधियों के अंतर्गत वे सभी औषधियां हैं जो मनुष्यों या पशुओं में रोग या विकार के निदान, उपचार, शमन या निवारण के लिए अथवाबाह्यउपयोग के लिए आशयित हैं, और जो औषधि और प्रसाधन सामग्री अधिनियम,1940 की प्रथम अनुसूची में विनिर्दिष्ट सोवा-रिग्पा चिकित्सा पद्धतियों की प्रामाणिक पुस्तकों में वर्णित फार्मूलों के अनुसार अनन्य रूप से विनिर्मित हैं।

(जझ) सोवा-रिग्पा सांपत्तिक औषधि- सोवा-रिग्पा चिकित्सा पद्धतियों के संबंध में वे सब योग अभिप्रेत हैं जिनमें केवल ऐसे संघटक अन्तर्विष्ट हैं जो प्रथम अनुसूची में विनिर्दिष्ट सोवा-रिग्पा चिकित्सा पद्धतियों की प्रामाणिक पुस्तकों में वर्णित फार्मूलों में उल्लिखित हैं, किंतु इसके अंतर्गत ऐसी औषधि नहीं है जो आन्त्रेतर मार्ग से दी जाती है और ऐसा योग भी नहीं है जो खंड (जज) में यथा विनिर्दिष्ट प्रामाणिक पुस्तकों में सम्मिलितहै।"

7. मूल नियमों के नियम 30-कक के लिए, निम्नलिखित नियम प्रतिस्थापित किया जाएगा, अर्थात्.-

"30-कक. नई होम्योपैथिक औषधियोंका आयात.— (1) नियम 21 के खंड (ख) में यथा परिभाषित अनुज्ञप्ति प्राधिकारी द्वारा लिखित अनुमति के अलावा कोई नई होम्योपैथिक औषधि का आयात नहीं किया जाएगा।

(2) उप-नियम (1) के तहत अनुमति के लिए आवेदन करते समय नई होम्योपैथिक औषधि का आयातकर्ता, अनुज्ञप्ति प्राधिकारी के समक्ष ऐसे दस्तावेजी और अन्य साक्ष्य प्रस्तुत करेगा जो अनुज्ञप्ति प्राधिकारी द्वारा औषधि की सुरक्षा, चिकित्सीय प्रभावकारिता का आकलन करने के लिए अपेक्षित हो, जिसमें वे न्यूनतम होम्योपैथिक प्रमाण भी हैं जो इसमें किए गए हों।

स्पष्टीकरण-इस नियम के प्रयोजनार्थ 'नई होम्योपैथिक औषधि'से अभिप्रेत है,—

(i) ऐसी होम्योपैथिक औषधि जो भारत या संयुक्त राज्य अमेरिका या यूनाइटेड किंगडम की आधिकारिक होम्योपैथिक भेषजसंहिता या जर्मन होम्योपैथिक भेषजसंहिता या फ्रेंच होम्योपैथिक भेषजसंहिता या यूरोपीय भेषजसंहिता में विनिर्दिष्ट नहीं है; या

(ii) जिसे अधिनियम की प्रथम अनुसूची में विनिर्दिष्ट प्रामाणिक होम्योपैथिक पुस्तकों मेंअनुशंसित शर्तों के तहत प्रभावोत्पादक के रूप में मान्यता प्राप्त नहीं है; या

(iii) जो एक या एक से अधिक ऐसी होम्योपैथिक औषधियों का योग है जो खंड (i) में वर्णित किसी भी भेषजसंहिता में विनिर्दिष्ट नहीं है या खंड (ii) में वर्णित प्रामाणिक होम्योपैथिक पुस्तकों में मान्यता प्राप्त नहीं है; या

(iv) जो दो या दो से अधिक होम्योपैथिक औषधियों का योग है, भले ही उनका आधिकारिक होम्योपैथिक भेषजसंहिता में खंड (i) या अधिनियम की पहली अनुसूची में विनिर्दिष्ट प्रामाणिक होम्योपैथिक पुस्तकों में अलग-अलग उल्लेखहो, औरजिन्हें अब पहली बार एक निश्चित अनुपात में संयोजित करने का प्रस्ताव हो, या पहले से ही विपणन संयोजन में अवयवों के अनुपात को कुछ दावों के साथ बदलने का प्रस्ताव हो; या

(3) एक नई होम्योपैथिक औषधि को इसके पहले अनुमोदन की तारीख से चार वर्ष की अवधि के लिए नई होम्योपैथिक औषधि के रूप में माना जाता रहेगा।

(4) नियम 21 के खंड (ख) में परिभाषित अनुज्ञप्ति प्राधिकारी इस बात से संतुष्ट होने के बाद कि औषधि देश में उपयोग के लिए प्रभावी और सुरक्षित होगी, इसमें उल्लिखित शर्तों के अधीन अनुमोदन जारी करेगा।

परंतु अनुज्ञप्ति प्राधिकारी, जहां नई होम्योपैथी औषधि पर उपलब्ध कराए गए या उत्पन्न आंकड़े अपर्याप्त हैं, वहां आवेदक को लिखित रूप में सूचित करेगा, और अनुमति पर विचार किए जाने से पहले शर्तों को पूरा किया जाना होगा।

परन्तु इस नियम के अधीन निहित कोई भी बात ऐसी होम्योपैथिक औषधि पर लागू नहीं होगी जिसे संबंधित राज्य या केन्द्रीय प्राधिकारी, जैसा भी मामला हो, से इस अधिसूचना की तिथि से पूर्व भारत में बिक्री के लिए विनिर्माण हेतु आयात या अनुज्ञप्ति हेतु अनुमोदन जारी किया गया हो, और यदि ऐसा प्राधिकारी या व्यक्ति पर्याप्त सूचना प्रदान करता हो कि इस अधिसूचना की तारीख से पहले सक्षम प्राधिकारी का अनुमोदन प्राप्त कर लिया गया है।

नोट: सुरक्षा के उद्देश्य से, औषधि की चिकित्सीय प्रभावकारिता जिसमें इसके साथ किए गए न्यूनतम होम्योपैथिक प्रमाण शामिल हैं, समय-समय पर केंद्रीय होम्योपैथी अनुसंधान परिषद द्वारा निर्धारित दिशानिर्देशों के अनुसार होगा।"

8.मूलनियमों के नियम 67-क में,

i.उपनियम (2) को प्रतिस्थापित किया जाएगा, अर्थात्.-"(2) होम्योपैथिक औषधियों की बिक्री, भंडारण या प्रदर्शन या बिक्री या वितरण की पेशकश हेतु अनुज्ञप्ति प्रदान करने के लिए आवेदन अनुज्ञप्ति प्राधिकारीको प्रपत्र 19-ख में किया जाएगा और इसके साथ दो हजार रुपये का शुल्क भी देना होगा।

ii.निम्नलिखित उप-नियम अंत:स्थापित किया जाएगा, अर्थात्.-"(4) आवेदन, ई-औषधि पोर्टल (www.eaushadhi.gov.in) के माध्यम से पोर्टलमें दिए गए होम्योपैथिक औषधियों की बिक्री अनुज्ञप्तिसे संबंधित प्रारूप के अनुसार किया जाएगा।

परंतु यह भी कि केंद्रीय सरकार की अधिसूचना द्वाराई-औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक,अनुज्ञप्ति हेतु आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी।"

9.मूलनियमों के नियम 67-ग के लिए, निम्नलिखित नियम प्रतिस्थापित किया जाएगा, अर्थात्.-

"**67-ग.औषधियों की बिक्री हेतु अनुज्ञप्तियों के प्रारूप-**(1)नियम 67-च की शर्तों को पूरा किए जाने के अधीन, खुदरा या थोक द्वारा होम्योपैथिक औषधियों को बेचने, स्टॉक करने या प्रदर्शित करने या बिक्री की पेशकश या वितरित करने हेतुअनुज्ञप्ति,प्रपत्र20-ग या 20-घ,जैसा भी मामला हो, में जारी की जाएगी।

(2) अनुज्ञप्ति, आवेदन की प्राप्ति की तारीख से दो महीने की अवधि के भीतर या अनुज्ञप्ति प्राधिकारी द्वारा उजागर की गई खामियों को आवेदक द्वारा पूरा किए जाने की तारीख से जारी की जाएगी।

(3) आवेदन पर, ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से कार्रवाई की जाएगी और उक्त पोर्टल में दिए गए प्रारूप के अनुसार प्रपत्र 20-ग या 20-घ में अनुज्ञप्ति ऑनलाइन जारी की जाएगी।

परंतु किसी भी मेले में प्रचार गतिविधियों के लिए औषधियों के प्रदर्शन के लिए किसी अनुज्ञप्ति की आवश्यकता नहीं होगी।

परंतु यह भी कि केंद्रीय सरकार की अधिसूचना द्वारा ई-औषधिपोर्टल(www.e-aushadhi.gov.in) केलागू होने तक,अनुज्ञप्ति हेतु आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी।"

10.मूल नियमों के नियम 67-ङ के लिए, निम्नलिखित नियम प्रति स्थापित किया जाएगा, अर्थात्:-.

"67-ङ अनुज्ञप्तियों की अवधि-(1)प्रपत्र 20-ग या 20-घ में जारी अनुज्ञप्ति अविरत तक विधिमान्यबनी रहेगी।

परंतु, अनुज्ञप्ति-धारी, अनुज्ञप्ति की शर्तों और औषधि एवं प्रसाधन सामग्री अधिनियम के उपबंधों और उसके तहत बनाए गए नियमों के अनुपालन की स्वत:घोषणा, प्रपत्र 20-ग या 20-घ में अनुज्ञप्ति जारी होने की तारीख से या स्वत:घोषणा की प्रस्तुति की तारीख से, जो भी यथास्थिति हो, प्रत्येक पांचवर्ष में प्रस्तुत करेगा।

(2) अनुज्ञप्ति प्राधिकारी, अनुज्ञप्ति-धारी को स्वत:घोषणा प्रस्तुत करने के लिए अनुज्ञप्ति जारी करने की तारीख से प्रत्येक पांच वर्ष के अंतराल के पूरा होने की तारीख से पहले या ऐसा अनुस्मारक जारी करने की तारीख से, जो भी यथास्थिति हो, देय पावती और ईमेल के साथ पंजीकृत डाक/स्पीड पोस्ट मेल: महीने में और तीन महीने में दो अनुस्मारक जारी करेगा।

बशर्ते कि ऐसी स्वत:घोषणा, प्रपत्र 20-ग या 20-घ में अनुज्ञप्ति जारी करने की तारीख से पांच साल पूरे होने के तीन महीने के भीतर या अंतिम स्वत:घोषणा प्रस्तुत करने की तारीख से, जो भी यथास्थिति हो, की जानी चाहिए और ऐसी स्वत:घोषणा प्रस्तुत नहीं करने की स्थिति में, अनुज्ञप्ति रद्द मानी जाएगी।इसके बाद प्रपत्र 19-ख मेंनया आवेदन किया जाना होगा।"

11.मूल नियमों के नियम 67-ङङ को विलोपित किया जाएगा।

12.मूल नियमों के नियम 67-छ के उप-नियम (6) को विलोपित किया जाएगा।

13.मूल नियमों के नियम 85-ख में, -

i.खंड (1) के तहत "या नवीकरण" शब्द विलोपित किया जाएगा।

ii.खंड (2) को निम्नलिखित से प्रतिस्थापित किया जाएगा, अर्थात्:-

"(2) प्रपत्र-24-ग में आवेदन के साथ -

(क) नियम 2के खंड (घघ) में परिभाषित किसी भी एकल अवयव वाली होम्योपैथिक औषधियों के लिए दो हजार रुपये का शुल्क भेजा जाएगा।

(ख) नियम 2के खंड (घघ) में परिभाषित होम्योपैथिक औषधियों के अवयवों के संयोजन के लिए दो हजार रुपये का शुल्क भेजा जाएगा।

परंतु नवीकरण की अवधि के बावजूद, औषधि नियम, 2024 के लागू होने की तारीख से पहले प्रपत्र-25-गमेंमौजूदा अनुज्ञप्ति-धारी, जिसके पास अनुसूची ङ-1 के अनुसार उत्तमविनिर्माण पद्धति कावैध प्रमाण पत्र हो, औषधि नियम,2024 के लागू होने की तारीख से एक वर्ष की अवधि के भीतर मौजूदा अनुज्ञप्ति की निरंतरता की मांग करेंगे, औरइसके लिएइसनियम के खंड (क) के तहत आने वाली मौजूदा अनुज्ञप्ति प्राप्त औषधियों के लिए एक हजार रुपये का एकमुश्त अनुज्ञप्ति प्रतिधारण शुल्क जमा करेंगे; और इस नियम के खंड (ख) के अंतर्गत आने वाली मौजूदा अनुज्ञप्तिप्राप्त औषधियों के लिए होम्योपैथिक औषधियोंकेअवयवोंके संयोजन के लिए एक सौ रुपये प्रति उत्पाद की दर से जमा करेंगे।

परंतु यह भी कि औषधि नियम, 2024 के शुरू होने के छ: महीने के भीतर केंद्रीय सरकार की अधिसूचना द्वारा ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक अनुज्ञप्ति के लिए आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगीऔर इस अवधि के दौरानअनुज्ञप्ति हेतुआवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी]

परंतु यह भी कि केंद्रीय सरकार की अधिसूचना द्वारा ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक अनुज्ञप्ति के लिए आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी".

स्पष्टीकरण- इस नियम के खंड (क) के प्रयोजनहेतुएकल अवयव वाली होम्योपैथिक औषधियों को इसकी सभी क्षमताओं के साथ एक उत्पाद के रूप में माना जाएगा और प्रत्येक क्षमता के लिए अलग-अलग शुल्क की आवश्यकता नहीं है।

iii.खंड (3), (4), (5) को विलोपित किया जाएगा।

14.नियम 85-ख के बाद, निम्नलिखित नियम अंत:स्थापित किया जाएगा, अर्थात्.-

"85-खक. होम्योपैथिक औषधियोंके विनिर्माण के लिए ऋण अनुज्ञप्ति हेतु आवेदन- (1) होम्योपैथिक औषधियों की बिक्री या वितरण के लिए ऋण अनुज्ञप्ति प्रदान करने के लिए आवेदन, इस भाग के प्रयोजन के लिए राज्य सरकार द्वारा नियुक्त अनुज्ञप्ति प्राधिकारी को किया जाएगा और यहप्रपत्र-24 ग1 में किया जाएगा।

(2) प्रपत्र-24-ग1 में आवेदन के साथ -

(क) नियम 2 के खंड (घघ) में परिभाषित किसी भी एकल अवयववालीहोम्योपैथिक औषधियों के लिए दो हजार रुपये का शुल्क भेजा जाएगा।

(ख) नियम 2 के खंड (घघ) में परिभाषित होम्योपैथिक औषधियों के अवयवों के संयोजन के लिए प्रति उत्पाद दो सौ रुपये का शुल्क भेजा जाएगा।

परंतु यह भी कि केंद्रीय सरकार की अधिसूचना द्वारा ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक अनुज्ञप्ति के लिए आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी"

स्पष्टीकरण- इस नियम के खंड (क) के प्रयोजनहेतुएकल अवयव वाली होम्योपैथिक औषधियों को इसकी सभी क्षमताओं के साथ एक उत्पाद के रूप में माना जाएगा और प्रत्येक क्षमता के लिए अलग-अलग शुल्क की आवश्यकता नहीं है।

स्पष्टीकरण- इस नियम के प्रयोजनों के लिए, "ऋण अनुज्ञप्ति" का अभिप्राय है अनुज्ञप्ति प्राधिकारी द्वारा ऐसे आवेदक को जारी की गई अनुज्ञप्ति, जिसके पास विनिर्माण हेतु अपनी व्यवस्था नहीं है, लेकिनप्रपत्र-25-ग में अनुज्ञप्तिधारी के स्वामित्व वाली विनिर्माण सुविधाओं का वह स्वयं लाभ उठाना चाहता है।

85-खख. होम्योपैथिक औषधियों की विनिर्माण इकाई के लिए उत्तम विनिर्माण पद्धतियों के प्रमाण पत्र हेतु आवेदन- (1) होम्योपैथिक औषधियों की विनिर्माण इकाई के लिए उत्तम विनिर्माण पद्धतियों का प्रमाण पत्र प्रदान करने के लिए आवेदन, अनुज्ञप्ति प्राधिकारी को प्रपत्र-24-ग2 में पांच हजार रुपये के शुल्क के साथ किया जाएगा।

(2) प्रपत्र-24-ग2 में प्रत्येक आवेदन ऐसीइकाई के लिए किया जाएगा जिसके पास अनुसूची ड1 के तहत निर्धारित परिसर और अन्य अपेक्षाएं हैं।

परंतु यह भी कि केंद्रीय सरकार की अधिसूचना द्वारा ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक अनुज्ञप्ति के लिए आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी"

15.मूल नियम के नियम 85-घ को प्रतिस्थापित किया जाएगा, अर्थात्:-

"85-घ.होम्योपैथिक औषधियों के विनिर्माण हेतु अनुज्ञप्ति का प्रपत्र— (1) नियम 85-ङ की शर्तों को पूरा किए जाने के अध्यधीन, होम्योपैथिक औषधियोंकी बिक्री के लिए विनिर्माण कीअनुज्ञप्ति,प्रपत्र-25-ग मेंजारी की जाएगी और होम्योपैथिक औषधियों की बिक्री के लिए विनिर्माण हेतुऋण अनुज्ञप्ति,प्रपत्र-25-ग-1 में जारी की जाएगी।अनुज्ञप्ति, आवेदन की प्राप्ति की तारीख से दो महीने की अवधि के भीतर या अनुज्ञप्ति प्राधिकारी द्वारा उजागर की गई किसी कमी को आवेदक द्वारा पूरा कर लेने की तारीख से जारी की जाएगी।

(2) इस नियम के तहत अनुज्ञप्ति प्राधिकारी द्वारा अनुज्ञप्ति,होम्योपैथिक चिकित्सा पद्धतियों की ऐसी विशेषज्ञ समिति,जिसे राज्य सरकार इस संबंध में अनुमोदित करे,से परामर्श करने के बाद प्रदान की जाएगी।

(3) इस प्रयोजनार्थ, आवेदन पर, ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से कार्रवाई की जाएगी।

परंतु यह भी कि केंद्रीय सरकार की अधिसूचना द्वारा ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक अनुज्ञप्ति के लिए आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी।"

16.मूल नियमों के नियम 85ङ में, -

i. शुरुआती टिप्पणी में "या नवीकरण" और "या नवीनीकृत" शब्दों को विलोपित किया जाएगा।

ii.मूल नियमों के नियम 85ङ के उप-नियम (1) के खंड (क) में, "रसायन विज्ञान के साथ विज्ञान में स्नातक" शब्दों के बाद, "या वनस्पति विज्ञान या जीव-विज्ञान" शब्दों को अंत:स्थापित किया जाएगा।

iii.खंड (ग) को प्रतिस्थापित किया जाएगा, अर्थात्.-

"(ग) राष्ट्रीय होम्योपैथी आयोग (एनसीएच) अधिनियम, 2020 (2020 का 15) की अनुसूची के तहत परिभाषित योग्यता रखता हो और होम्योपैथिक औषधियों के विनिर्माण में 18 महीने का अनुभव हो।"

iv.नियम 85ङ (2क) के तहत परंतुक को प्रतिस्थापित किया जाएगा, अर्थात् - "उत्तम विनिर्माण पद्धति का प्रमाण पत्र":होम्योपैथिक औषधियों के विनिर्माताओं को,जो अनुसूची ड-1 में विनिर्दिष्ट आवश्यकताओं का अनुपालन करते हैं, उत्तम विनिर्माण पद्धतियों का प्रमाण पत्र, प्रपत्र-26 ग-1 में जारी किया जाएगा।

v. तीसरा परंतुक "किंतु यदि प्रपत्र-20-ग में अनुज्ञप्ति रखने वाली फार्मेसी में शक्तियुक्त संपाक तैयार किए जाते हैं, तो शर्त (2) और (3) लागू नहीं होंगी।अनुज्ञप्ति धारक, अनुज्ञप्ति प्राधिकारी की संतुष्टि के लिए यह सुनिश्चित करेगा कि उसके द्वारा विनिर्मित उत्पाद, लेबल पर किए गए दावों के अनुरूप हैं।" को विलोपित किया जाएगा।

17. मूलनियम के नियम 85-ङक के स्थान पर निम्नलिखित नियम प्रतिस्थापित किया जाएगा, अर्थात्:-

"85-ङक.अनुज्ञप्ति प्रदान करने और अनुपालन के सत्यापन के लिए निरीक्षण-(1) प्रपत्र-25-ग अथवा प्रपत्र-25-ग-1 मेंअनुज्ञप्ति के लिए जीएमपी प्रमाण पत्र प्रदान करने या प्रतिधारित करने से पहले, अनुज्ञप्ति प्राधिकारीउस प्रतिष्ठान का कारण जानेगा जिसमें औषधियों का विनिर्माण किया जाना प्रस्तावित है या किया जा रहा है या जिनका निरीक्षण नियम 167 के तहत केंद्र या राज्य सरकार द्वारा नियुक्त एक या अधिक योग्यता प्राप्त निरीक्षकों द्वारा किया जाना है।

(2) एक या अधिक निरीक्षक औषधियों के विनिर्माण के लिए उपयोग किए जाने वाले या उपयोग किए जा रहे प्रतिष्ठान की जांच करेंगेऔर अनुज्ञप्तिकी शर्तों और औषधि एवं प्रसाधन सामग्री अधिनियम के प्रावधानों तथा औषधि नियमों की अनुपालना का *पांच साल में कम से कम एक बार या जोखिम आधारित दृष्टिकोण के अनुसार जैसा जरूरी हो,* सत्यापन करेंगे।

परंतु औषधि निरीक्षकों को निरीक्षण ड्यूटी एक यादृच्छिक तरीके से यह सुनिश्चित करते हुए सौंपी जाती है कि उस औषध निरीक्षक को किसी विशेष स्थापना का निरीक्षण का कार्य कम से कम पांच वर्ष की अवधि में लगातार दो बार से अधिक नहीं सौंपा गया हो।

परंतु यह भी कि यदि उत्तम विनिर्माण पद्धतियों के प्रमाण पत्र की विधिमान्यता की अवधि के भीतर या प्रतिधारण शुल्क जमा करने के बाद भी परिसर का निरीक्षण नहीं किया जाता है, तो उत्तम विनिर्माण पद्धतियों के प्रमाण पत्र को पांच वर्ष की अगली अवधि के लिए जारी समझा जाएगा।"

18.मूल नियमों के नियम 85-ङख के लिए, निम्नलिखित नियम प्रतिस्थापित किया जाएगा, अर्थात्.-

"85-ङख.निरीक्षक द्वारा रिपोर्ट-(1) निरीक्षक अथवा निरीक्षकों द्वारा सभी परिसरों, संयंत्र और उपकरणों के लिए सभी क्षेत्रों की जांच की जाएगी और विनिर्माण में प्रयुक्त की जाने वाली या प्रयुक्त की जा रही प्रक्रिया का, साथ ही विनिर्माण की जा रही औषधियों या विनिर्माण की जाने वाली औषधियों के मानकीकरण तथा परीक्षण के लिए प्रयुक्त किए जाने वाले या प्रयुक्त किए जा रहे साधनों का निरीक्षण किया जाएगा और नियोजित किए जाने वाले तकनीकी कर्मचारीवृंद की व्यावसायवृतिअर्हताओं की भी जांच की जाएगी। वह आवेदन में दिए गए कथनों की सत्यता, और सक्षम तकनीकी कर्मचारीवृंद की आवश्यकता को पूरा करने के लिए आवेदक की क्षमता, विनिर्माण संयंत्रों, परीक्षण उपकरणों और उत्तम विनिर्माण पद्धतियों की अपेक्षाओं तथा अनुसूची 'ड-1' में अधिकथित संयंत्र और उपकरणों की अपेक्षाओं की जांच और सत्यापन भी करेगा।

(2) निरीक्षक, अनुज्ञप्ति प्राधिकारी को उप नियम (1) के अनुसार अपने निरीक्षण को पूरा कर लिए जाने पर अपनी अनुशंसाओं के साथ निरीक्षण के प्रत्येक पहलू पर अपने निष्कर्ष देते हुए विस्तृत विवरणात्मक रिपोर्ट प्रस्तुत करेगा।"

19.मूल नियमों के नियम 85-ङग के लिए, निम्नलिखित नियम प्रतिस्थापित किया जाएगा, अर्थात्.-

"85-ङग-अनुज्ञापन प्राधिकारीकी प्रक्रिया-

(1) यदि अनुज्ञप्ति प्राधिकारी ऐसी किसी और जांच, यदि कोई हो, जैसा भी वह आवश्यक समझे, के पश्चात संतुष्ट है कि अधिनियम के तहत नियमों का अनुपालन किया गया है और यह भी कि अनुज्ञप्ति की शर्तों तथा अधिनियम के अधीन नियमों का पालन किया जाएगा, तो वह इस भाग के तहत एक अनुज्ञप्ति जारी करेगा।

(2) यदि अनुज्ञप्तिप्राधिकारी उप-नियम(1) के तहत अपेक्षाओं से संतुष्ट नहीं है तो वह कमियों पर एक ज्ञापन जारी करेगा और अनुज्ञप्ति प्रदान करने से पूर्व उन शर्तों को पूरा किया जाना आवश्यक होगा तथा निरीक्षण रिपोर्ट की प्रति आवेदक को भेजेगा।

(3) आवेदक द्वारा उप-नियम (2) के तहत ऐसे ज्ञापन के जारी होने के दो माह के भीतर उसका उत्तर देना अपेक्षित होगा।

(4) उप–नियम (2) में अपेक्षित जवाब प्रस्तुत नहीं करने पर अनुज्ञप्ति प्राधिकारी द्वारा आवेदन रद्द कर दिया जाएगा और आवेदक को रद्द करने के कारणों के बारे में सूचित किया जाएगा।

(5) इस प्रयोजन के लिए अनुज्ञप्ति प्राधिकारी ई-औषधि (www.e-aushadhi.gov.in) पोर्टल के माध्यम से आवेदन प्रक्रिया के बारे में आवेदक को सूचित करेगा।

परंतु यह भी कि केंद्रीय सरकार द्वारा यथा अधिसूचित औषधि पोर्टल (www.e-aushadhi.gov.in) के लागू होने तक अनुज्ञप्ति के लिए आवेदन की ऑनलाइन और ऑफलाइन प्रक्रिया स्वीकार की जाएगी।"

20.प्रमुख नियमों के नियम 85-ङघ के लिए, निम्नलिखित नियम प्रतिस्थापित किया जाएगा, अर्थात्.-

"85-ङघ-रद्द होने के पश्चात पुन: आवेदन– यदि आवेदक अनुज्ञप्ति अथवा उत्तम विनिर्माण पद्धतियों के लिए प्रमाण-पत्र, जो भी यथास्थिति हो, के लिए किसी आवेदन के रद्द होने के छह माह की अवधि के भीतर अनुज्ञप्ति प्राधिकारी को सूचित करता है कि निर्धारित शर्तें पूरी कर ली गई हैं और एक हजार रुपए का निरीक्षण शुल्क जमा करदेता है, तब अनुज्ञप्ति प्राधिकारी द्वारा पुन: निरीक्षण, यदि कोई हो, करलिए जाने पर वह इससे संतुष्ट होता है कि अनुज्ञप्ति अथवा प्रमाण पत्र प्रदान करने की शर्तों को पूरा कर लिया गया है तो वह इस भाग के तहत अनुज्ञप्ति अथवा प्रमाणपत्र जारी करेगा।"

21.नियम 85-च को निम्निलिखित से प्रतिस्थापित किया जाएगा, अर्थात्.-

"85-च-अनुज्ञप्ति की अवधि—(1)प्रपत्र-25-ग या प्रपत्र-25-ग1 में जारी अनुज्ञप्तितबतक अविरत विधिमान्य बनी रहेगी जब तक इसे निलंबित या रद्द नहीं किया जाता।

परंतु, अनुज्ञप्ति-धारी, उसकेद्वारा उपयोग की जाने वाली विनिर्माण सुविधाओं की उत्तम विनिर्माण पद्धतियों के प्रमाण पत्र की वैधता सुनिश्चित करेगा।

22.नियम 85-च के पश्चात्निम्नलिखित नियम अंत:स्थापित किया जाएगा, अर्थात्.-

"85-चक-होम्योपैथिक औषधियों की विनिर्माण इकाइयों के लिए उत्तम विनिर्माण पद्धतियों के प्रमाण पत्र की अवधि— प्रपत्र-26-ग1 में जारी प्रमाण पत्र तब तक विधिमान्य बना रहेगा जब तक कि अनुज्ञप्तिप्राधिकारी द्वारा इसे रद्द नहीं कर दिया जाता है, किंतु अनुज्ञप्ति-धारी द्वारा इसके जारी होने की तारीख से हर पांच वर्ष की अवधि के समाप्त होने से पहले एक हजार रुपये का प्रमाण पत्र प्रतिधारण शुल्क जमा किया जाता हो।

(2) यदि अनुज्ञप्ति-धारी उप-नियम (1) में उल्लेख के अनुसार नियत तारीख पर या उससे पहले प्रमाण पत्र प्रतिधारण शुल्कका भुगतान करने में विफल रहता है, तो उसे प्रमाण पत्र प्रतिधारण शुल्क के साथ हर महीने या उसके छह महीने तक के हिस्से के लिए प्रमाण पत्र प्रतिधारण शुल्क के दो प्रतिशत की दर से विलंब शुल्क का भुगतान करना होगा, और इस प्रकार के शुल्क का भुगतान न करने की स्थिति में, प्रमाण पत्र को रद्द समझा जाएगा।"

23.मूलनियमों के नियम 85-छको विलोपित किया जाएगा।

24.मूलनियमों के नियम 85-जमें-

i.खंड (ख) के अधीन "अधिनियम के तहत नियुक्त निरीक्षक" शब्दों के स्थान पर "केन्द्र या राज्य सरकार द्वारा नियुक्त नियम 167 के अधीन यथा उल्लिखित योग्य निरीक्षक" शब्दों को प्रतिस्थापित किया जाएगा।

ii.खंड (घ) को विलोपित किया जाएगा।

iii.खंड (च) के बाद निम्नलिखित परंतुक "परंतु यह भी कि नियम और अनुसूची-ङ1 के तहत उल्लिखित विवरणों का ऑनलाइन रिकॉर्ड रखने वाले विनिर्माताओं को भी स्वीकार किया जाएगा" को अंत:स्थापित किया जाएगा।

25. मूल नियमों के नियम 106-क में, उप-नियम (क), खंड (ii), उपखंड (क) में "जर्मन होम्योपैथिक फार्माकोपिया" शब्दों के पश्चात् निम्नलिखित अंत:स्थापित किया जाएगा, अर्थात् - या फ्रेंच होम्योपैथिक फार्माकोपिया या यूरोपीय फार्माकोपिया।"

26.मूलनियमों के नियम 153 में,

(i) खंड (ख) को प्रतिस्थापित किया जाएगा, अर्थात्.-

"(ख) प्रपत्र-24घ मेंप्रति उत्पाद दो सौ रुपये के शुल्क के साथअनुज्ञप्ति प्राधिकारी को ई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से इसमें दिए गए आयुर्वेद, सिद्ध या यूनानी औषधियों की बिक्री के लिए विनिर्माण के अनुज्ञप्ति से संबंधित प्रारूपके अनुसार,जैसा कि अधिनियम की धारा 3 के खंड (ज) के उपखंड (i) में यथापरिभाषित है।"

(ii) पहला परंतुक निम्नलिखित से प्रतिस्थापित किया जाएगा अर्थात्.-

"परंतु नवीकरण की अवधि के बावजूद, औषधि नियम, 2024 के लागू होने की तारीख से पहले प्रपत्र-25घके तहत मौजूदा अनुज्ञप्ति-धारी और अनुसूची-नके अनुसार उत्तम विनिर्माण पद्धतियों का वैध प्रमाण पत्र रखने वाले ऐसे अनुज्ञप्ति-धारी को औषधि नियम लागू होने की तारीख से एक वर्ष की अवधि के भीतर मौजूदा अनुज्ञप्ति की निरंतरता के लिए अनुमति लेनी होगी, और अधिनियम की धारा 3 के खंड (क) के तहत आने वाली मौजूदा अनुज्ञप्ति-प्राप्त औषधियों के लिए एक हजार रुपये का एकबारगी अनुज्ञप्ति प्रतिधारण शुल्क जमा करना होगा; और अधिनियम की धारा 3 के खंड (ज) के उप-खंड (i) के तहत आने वाली मौजूदा अनुज्ञप्ति-प्राप्त औषधियों के लिए प्रति उत्पाद एक सौ रुपये की दर सेशुल्क जमा करना होगा।"

27. मूलनियमों के नियम 153-कमें,

(i)खंड (ख) को निम्निलिखित से प्रतिस्थापित किया जाएगा, अर्थात्.-

"(ख) जैसा अधिनियम की धारा 3 के खंड (ज) के उपखंड (i) में परिभाषित है,अनुज्ञप्ति प्राधिकारी को प्रपत्र-24ङ मेंई-औषधि पोर्टल (www.e-aushadhi.gov.in) के माध्यम से इसमें दिए गए आयुर्वेद, सिद्ध या यूनानी औषधियों की बिक्री हेतुऋणकी अनुज्ञप्ति से संबंधित प्रारूपके अनुसार प्रति उत्पाद दो सौ रुपये के शुल्क के साथ।"

(ii) पहला परंतुक निम्नलिखित से प्रतिस्थापित किया जाएगा अर्थात्

"परंतु नवीकरण की अवधि के बावजूद, औषधि नियम, 2024 के लागू होने की तारीख से पहले प्रपत्र-25ङके तहत मौजूदा अनुज्ञप्ति-धारी और अनुसूची-नके अनुसार उत्तम विनिर्माण पद्धतियों का वैध प्रमाण पत्र रखने वाले ऐसे अनुज्ञप्ति-धारी को औषधि नियम लागू होने की तारीख से एक वर्ष की अवधि के भीतर मौजूदा अनुज्ञप्ति की निरंतरता के लिए अनुमति लेनी होगी, और अधिनियम की धारा 3 के खंड (क) के तहत आने वाली मौजूदा अनुज्ञप्ति-प्राप्त औषधियों के लिए एक हजार रुपये का एक बारगी अनुज्ञप्ति प्रतिधारण शुल्क जमा करना होगा; और अधिनियम की धारा 3 के खंड (ज) के उप-खंड (i) के तहत आने वाली मौजूदा अनुज्ञप्ति-प्राप्त औषधियों के लिए प्रति उत्पाद एक सौ रुपये की दर सेशुल्क जमा करना होगा।"

28. मूलनियम के नियम 156-ग में, उपनियम (1) को निम्नलिखित से प्रतिस्थापित किया जाएगा, अर्थात्:-

"(1) प्रपत्र-26ङ-1 में प्रमाण पत्र देने से पहले, अनुज्ञप्तिप्राधिकारी उस प्रतिष्ठान का कारण जानेगाजिसमें औषधियों का विनिर्माण किया जाना प्रस्तावित है या किया जा रहा है और जिसका इस अधिनियम के अंतर्गत,नियम 167 के तहत निरीक्षण केंद्र या राज्य सरकार द्वारा नियुक्त एक या अधिक योग्य निरीक्षकों द्वारा किया जाना प्रस्तावित है, एक या अधिक निरीक्षक औषधियों के विनिर्माण के लिए उपयोग किए जाने वाले या उपयोग किए जा रहे प्रतिष्ठान की जांच करेंगे।

29. मूलनियमों के नियम 157 में, खंड (2) को निम्नलिखित सेप्रतिस्थापित किया जाएगा, अर्थात्.-

"(2) आयुर्वेद, सिद्ध, सोवा-रिग्पा या यूनानी औषधियों का विनिर्माण सक्षम तकनीकी कर्मचारियों के निर्देशन और पर्यवेक्षण के तहत किया जाएगा, जिसमें कम से कम एक व्यक्ति ऐसा होगा, जो पूर्णकालिक कर्मचारी हो और जिसके पास निम्नलिखित योग्यताएं हों, अर्थात्: –

(क) किसी विश्वविद्यालय/राज्य सरकार या सांविधिक संकायों, भारतीय चिकित्सा पद्धति परिषदों और बोर्डों,जिन्हें इस प्रयोजन हेतु केंद्र सरकार या किसीराज्य सरकार से मान्यता मिली हो,द्वारा प्रदान की आयुर्वेद, सिद्ध, सोवा-रिग्पा या यूनानी चिकित्सा पद्धति,जैसा भी मामला हो,में डिग्री, अथवा

(ख)केंद्र सरकार या राज्य सरकार द्वारा मान्यता प्राप्त विश्वविद्यालय से फार्मेसी (आयुर्वेद या सिद्ध या सोवा-रिग्पा या यूनानी) में स्नातक के साथ अनुज्ञप्तिप्राप्त विनिर्माण इकाई में आयुर्वेद, सिद्ध, सोवा-रिग्पा या यूनानी औषधियों, जैसा भी मामला हो,के विनिर्माण में कम से कम दो साल का अनुभव।

परंतु औषधि (संशोधन नियम) 2024 के लागू होने से पहले प्रपत्र-25घ/25ङमें अनुज्ञप्ति देने के प्रयोजनों के लिए सक्षम व्यक्ति के रूप में राज्य अनुज्ञप्ति प्राधिकरण मेंपहले से ही पंजीकृत व्यक्ति को उक्त प्रयोजनों के लिए सक्षम व्यक्ति माना जाता रहेगा।"

30.नियम 161-खके उपनियम (2) में, "वास्तविक समय" शब्दों को "वास्तविक समय और त्वरित" सेप्रतिस्थापित किया जाएगा।

31.नियम 162-क में खंड (क) को निम्नलिखित से प्रतिस्थापित किया जाएगा, अर्थात्–

"(क) भारतीय चिकित्सा पद्धति राष्ट्रीय परिषद (एनसीआईएसएम) अधिनियम, 2020 (2020 का 14)की अनुसूचियोंके अनुसार आयुर्वेद/सिद्ध/सोवा-रिग्पा/यूनानी योग्यताएं/किसी मान्यता प्राप्त विश्वविद्यालय से बी. फार्मा (आयुर्वेद)।"

32.नियम 168 के तहत तालिका में, "12%" शब्दों के लिए "11.40%" शब्द प्रतिस्थापित किए जाएंगे।

33.मूल नियमों के नियम 170 को विलोपित किया जाएगा।

34. प्रपत्र-ग में-

i. खंड 2 के तहत शब्द"को ....." विलोपित किया जाएगा।

ii. "दिनांक" शब्दों से पहले "अनुज्ञप्ति संख्या" शब्द....." प्रतिस्थापित किए जाएंगे।

35.प्रपत्र-20घ में-

i. खंड 2 के तहत शब्द "को ....." विलोपित किया जाएगा।

ii. "दिनांक" शब्दों से पहले "अनुज्ञप्ति संख्या" शब्द ....." प्रतिस्थापित किए जाएंगे।

36.प्रपत्र-20ङ को विलोपित किया जाएगा।

37.मूलनियमों में, प्रपत्र-24गके लिए, निम्नलिखित प्रपत्र प्रतिस्थापित किया जाएगा, अर्थात्:—

"प्रपत्र-24ग

(नियम 85-खदेखें)

होम्योपैथिक औषधियों की बिक्री या वितरण हेतु विनिर्माण के लिए अनुज्ञप्ति प्रदान करने के लिए आवेदन

1.मैं/हम.....निवासी.....एतद्वारा.....

.....में स्थित परिसर में निम्नलिखित होम्योपैथिक मदर टिंक्चर्स/शक्तियुक्त संपाकों के विनिर्माण हेतु अनुज्ञप्ति प्रदान करने के लिए आवेदन करता हूँ/करते हैं।

होम्योपैथिक संपाकों के नाम .....(प्रत्येक मद का अलग-अलग उल्लेख करें)।

2.होम्योपैथिकऔषधियोंके विनिर्माण और परीक्षण के लिए नियोजित तकनीकी कर्मचारीवृंद के नाम, अर्हताएं और अनुभव .....

3..... रुपए का शुल्क ..... लेखा शीर्ष के तहत सरकार के खाते में जमा कर दिया गया है और संबंधित ट्रेजरी चालान/ऑनलाइन लेन-देन संबंधी स्लिप इसके साथ संलग्न है।

तारीख..... हस्ताक्षर.....

(आवेदक)

टिप्पण-आवेदन के साथ परिसरों के नक्शे की प्रति संलग्न होनी चाहिए।

38.मूल नियमों में प्रपत्र-24ग के बाद, निम्नलिखित प्रपत्र अंत:स्थापित किया जाएगा, अर्थात्:-

"प्रपत्र-24ग1

(नियम85खक देखें)

होम्योपैथिक औषधियों के विक्रयार्थ विनिर्माण के लिए उधार अनुज्ञप्ति प्रदान किए जाने के लिए आवेदन

1.मैं/हम*.....निवासी**.....एतद्वारा

.....स्थित परिसर में निम्नलिखित होम्योपैथिक मदर टिंक्चर्स/ शक्तियुक्त संपाकों के विनिर्माण हेतु मार्फत*.....उधार अनुज्ञप्ति प्रदान करने के लिए आवेदन करता हूँ/करते हैं।

होम्योपैथिक संपाकों के नाम.....(प्रत्येक मद का अलग-अलग उल्लेख करें)।

2. विनिर्माण परिसरों में होम्योपैथिक औषधियों के विनिर्माण और परीक्षण मे वास्तविक रूप से जुड़े तकनीकी कर्मचारीवृंद के नाम, अर्हताएं और अनुभव।

3. मैं/हम*निम्नलिखित संलग्न करते हैं,

(क) विनिर्माण कंपनी के लिए मेरे/हमारे पत्र की एक सत्य प्रति जिसकी विनिर्माण क्षमता का मैं/हम उपयोग करना चाहता हूं/चाहते हैं।

(ख) विनिर्माण कंपनी से पत्र की एक सत्य प्रति कि वे मेरे/हमारे द्वारा अपेक्षित प्रत्येक मद के विनिर्माण हेतु अपने सक्षम तकनीकी कर्मचारीवृंद, उपकरण और परिसर की सेवाएं देने के लिए सहमत हैं और वे इस संबंध में कच्ची सामग्री और तैयार उत्पादों के लिए पृथक रूप से रजिस्टर बना कर रखेंगे।

(ग) विनिर्माण किए जाने के लिए प्रस्तावित औषधों के डिब्बों के नमूने।

4.....लेखा शीर्ष के तहत ..... रूपए का शुल्क सरकार के खाते में जमा कर दिया गया है और संबंधित ट्रेजरी चालान/ऑनलाइन संव्यवहार संबंधी स्लिप संलग्न है।

तारीख..... हस्ताक्षर .....

(आवेदक)"

* यहां यथास्थिति मालिक, भागीदार या प्रबंध निदेशकका नाम दर्ज करें।

**यहां आवेदक फर्म का नाम और कारोबार का पता या प्रमुख स्थान दर्ज करें।

यहां विनिर्माण कंपनी, जहां वास्तविक रूप से विनिर्माण किया जाएगा, का नाम और पता तथा अनुज्ञप्ति संख्या जिसके तहत विनिर्माण किया जाएगा दर्ज करें।

प्रपत्र-24-ग-2

(नियम 85खख देखें)

होम्योपैथिक औषधियों की विनिर्माण इकाइयों के लिए उत्तम विनिर्माण पद्धतियों के प्रमाण पत्र हेतु आवेदन

1. मैं/हम*.....निवासी**.....एतद्वारा

.....स्थित परिसर में होम्योपैथिक औषधियों के विनिर्माण हेतु मार्फत#.....उत्तम विनिर्माण पद्धतियों का प्रमाण-पत्र प्रदान करने के लिए आवेदन करता हूँ/करते हैं।

2. ..... रुपए का शुल्क ..... लेखा शीर्ष के तहत सरकार के खाते में जमा कर दिया गया है और संबंधित ट्रेजरी चालान/ऑनलाइन लेन-देन संबंधी स्लिप इसके साथ संलग्न है।

तारीख..... हस्ताक्षर.....

(आवेदक)

टिप्पण-आवेदन के साथ परिसरों के नक्शे की प्रति संलग्न होनी चाहिए।

39.मूल नियमों में प्रपत्र-25गके लिए, निम्नलिखित प्रपत्र अंत:स्थापित किया जाएगा, अर्थात्:-

"प्रपत्र-25ग

(नियम 85घ देखें)

होम्योपैथिक औषधियों की बिक्री या वितरण हेतुविनिर्माण का लाइसेंस

अनुज्ञप्ति की संख्या और जारी करने की
तारीख.....

1. .....को..... स्थित परिसर में निम्नलिखित होम्योपैथिकऔषधियों के विनिर्माण के लिए अनुज्ञप्त किया जाता हैजोनिम्नलिखित सक्षम तकनीकी कर्मचारीवृंद के निर्देशन और पर्यवेक्षणके तहत होगी:-

होम्योपैथिक संपाकों के नाम:

(प्रत्येक मद पृथक रूप से स्पष्ट की जाए)

2.सक्षम तकनीकी कर्मचारीवृंद (नाम):

3. अनुज्ञप्ति..... से प्रवृत्त होगी।

4. अनुज्ञप्ति, नीचे दी गई शर्तों तथा ऐसी अन्य शर्तों, जो औषधि और प्रसाधन सामग्री अधिनियम, 1940 के तत्समय प्रवृत्त नियमों में विनिर्दिष्ट की जाएं, के अधीन है।

तारीख..... हस्ताक्षर .....

पदनाम .....

अनुज्ञप्ति की शर्तें

1. अनुज्ञप्ति में नामित तकनीकी कर्मचारीवृंद में कोई भी परिवर्तन अनुज्ञप्ति प्राधिकारी कोसूचित किया जाएगा।

2. इस अनुज्ञप्ति को ऐसी अतिरिक्त वस्तुओं तक विस्तारित करने के लिए समझा जाएगा, जैसाकि अनुज्ञप्ति-धारक समय-समय पर अनुज्ञप्तिप्राधिकारी को सूचित कर सकता है, और जैसा कि अनुज्ञप्ति प्राधिकारी द्वारा समर्थन किया जा सकता है।

3. अनुज्ञप्ति-धारक, अनुज्ञप्ति के तहत काम कर रही फर्म के गठन में किसी भी बदलाव की स्थिति में लिखित रूप में अनुज्ञप्ति प्राधिकारी को सूचित करेगा। जहां फर्म के गठन में कोई भी बदलाव होता है, वर्तमान अनुज्ञप्ति परिवर्तन की तारीख से अधिकतम तीन महीने के लिए विधिमान्य मानी जाएगी, जब तक कि इस बीच पुनर्गठन के साथ फर्म के नाम पर अनुज्ञप्ति प्राधिकारी से नई अनुज्ञप्ति नहीं ली गई हो।

4. अनुज्ञप्ति जब तक निलंबित या रद्द नहीं की जाती है, स्थायी रूप से विधिमान्य रहेगी। तथापि, अनुज्ञप्ति की शर्तों और औषधि एवं प्रसाधन सामग्री अधिनियम 1940 (1940का 23) और औषधि नियम, 1945के उपबंधों के अनुपालन कोपांच वर्ष में कम से कम एक बार या जोखिम आधारित दृष्टिकोण के अनुसार आवश्यकतानुसार निर्धारित किया जाएगा।

5. औषधि नियम, 1945की अनुसूची-ड-1 में यथानिर्धारित होम्योपैथिक औषधियों की उत्तम विनिर्माण पद्धतियों (जीएमपी)की अपेक्षाओं को पूरा करने के बाद ही अनुज्ञप्ति जारी की जाती है।

40. मूल नियमों में प्रपत्र-25-ग के बाद, निम्नलिखित प्रपत्रअंत:स्थापित किया जाएगा, अर्थात्:-

"प्रपत्र-25-ग-1

(नियम 85घ देखें)

होम्योपैथिक औषधियों की बिक्री या वितरण हेतु विनिर्माण के लिए उधार अनुज्ञप्ति

1.अनुज्ञप्ति की संख्या और जारी करने की
तारीख.....

2.....के.....को.....स्थित परिसर में निम्नलिखित होम्योपैथिक औषधियों की बिक्री या वितरण हेतु विनिर्माण के लिए मार्फत.....उधार अनुज्ञप्ति प्रदान की जाती हैजो निम्नलिखित विशेषज्ञ तकनीकी कर्मचारियों के निर्देश और पर्यवेक्षण के तहत होगी:-

(क) विशेषज्ञ तकनीकी कर्मचारीवृंद (नाम):

(ख) होम्योपैथिक संपाकों के नाम:

(प्रत्येक मद पृथक रूप से स्पष्ट की जाए)

3. अनुज्ञप्ति..... से प्रवृत्त होगी।

4. अनुज्ञप्ति, नीचे दी गई शर्तों तथा ऐसी अन्य शर्तों, जो औषधि और प्रसाधन सामग्री अधिनियम, 1940 के तत्समय प्रवृत्त नियमों में विनिर्दिष्ट की जाएं, के अधीन है।

तारीख..... हस्ताक्षर .....

पदनाम .....

अनुज्ञप्ति की शर्तें

1.अनुज्ञप्ति में नामित तकनीकी कर्मचारीवृंद में कोई भी परिवर्तन अनुज्ञप्ति प्राधिकारी कोसूचित किया जाएगा।

2.इस अनुज्ञप्ति को ऐसी अतिरिक्त वस्तुओं तक विस्तारित करने के लिए समझा जाएगा, जैसाकि अनुज्ञप्ति-धारक समय-समय पर अनुज्ञप्तिप्राधिकारी को सूचित कर सकता है, और जैसा कि अनुज्ञप्ति प्राधिकारी द्वारा समर्थन किया जा सकता है।

3. अनुज्ञप्ति-धारक, अनुज्ञप्ति के तहत काम कर रही फर्म के गठन में किसी भी बदलाव की स्थिति में लिखित रूप में अनुज्ञप्ति प्राधिकारी को सूचित करेगा। जहां फर्म के गठन में कोई भी बदलाव होता है, वर्तमान अनुज्ञप्ति परिवर्तन की तारीख से अधिकतम तीन महीने के लिए विधिमान्य मानी जाएगी, जब तक कि इस बीच पुनर्गठन के साथ फर्म के नाम पर अनुज्ञप्ति प्राधिकारी से नई अनुज्ञप्ति नहीं ली गई हो।

4.अनुज्ञप्ति जब तक निलंबित या रद्द नहीं की जाती है, स्थायी रूप से विधिमान्य रहेगी। तथापि, अनुज्ञप्ति की शर्तों और औषधि एवं प्रसाधन सामग्री अधिनियम 1940 (1940का 23) और औषधि नियम, 1945के उपबंधों के अनुपालन को पांच वर्ष में कम से कम एक बार या जोखिम आधारित दृष्टिकोण के अनुसार आवश्यकतानुसार निर्धारित किया जाएगा।"

41. प्रपत्र-26-गविलोपित किया जाएगा।

42. मूल नियमों मेंप्रपत्र-26-घ से पहले, निम्नलिखित प्रपत्र अंत:स्थापित किया जाएगा, अर्थात्:-

"प्रपत्र-26-ग-1

(नियम 85ङदेखें)

होम्योपैथिक औषधियों के विनिर्माता को उत्तम विनिर्माण पद्धतियों का प्रमाण पत्र (जीएमपी)

यहप्रमाणित किया जाता है कि विनिर्माण इकाई अनुज्ञप्ति-धारी, अर्थात्..... .....
जो.....में स्थित है और जिसके पास राज्य .....की अनुज्ञप्ति संख्या.....है, औषधि एवं प्रसाधन सामग्री नियम, 1945 की अनुसूची-ड1 में यथा निर्धारित होम्योपैथिक औषधियों की उत्तम विनिर्माण पद्धतियों की अपेक्षाओं का अनुपालन करती है।

यह प्रमाण पत्र पांच वर्ष की अवधि के लिए विधिमान्य है और उत्तम विनिर्माण पद्धतियां(जीएमपी) निम्नलिखित विभिन्न खुराकोंके लिए विधिमान्य हैं:-

तारीख:.....हस्ताक्षर.....

स्थान: .....पदनाम.....

होम्योपैथिक औषधियों के लिए अनुज्ञप्ति प्राधिकारी

43.प्रपत्र-26-ङ-4 को विलोपित किया जाएगा।

44. प्रपत्र-26-ङ-5को विलोपित किया जाएगा।.

[फा. सं. टी-11011/05/2019-डीसीसी(आयुष)]

कविता गर्ग, संयुक्त सचिव

टिप्पण : मूल नियम, भारत के राजपत्र में अधिसूचना संख्या एफ.28-10/45-एच(1), तारीख 21 दिसंबर, 1945 द्वारा प्रकाशित किएगए थे और अधिसूचना संख्या सा.का.नि. ....., तारीख.....द्वारा अंतिम बार संशोधित किए गए थे।

MINISTRY OF AYUSH

NOTIFICATION

New Delhi, the 2nd February, 2024

G.S.R. 98(E).—The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940) and after consultation with Ayurveda, Siddha, Unani Drug Technical Advisory Board, is hereby published as required by the said section, for the information of all persons likely to be affected thereby; and notice is hereby given that the objections or suggestions of the stakeholders on the said draft rules will be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Any objection or suggestion, which may be received from any person with respect to the said draft rules within the period specified above, will be taken into consideration by the Central Government;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of Ayush, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi – 110023 or emailed at dcc-ayush@nic.in.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

DRAFT RULES

1. Short title, and commencement: - (1) These rules may be called the Drugs (Amendment) Rules, 2024. (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs Rules, 1945 (hereinafter referred to be as the principal Rules), in part XVI, XVIA, XVII, XVIII and XIX, the words "Ayurvedic, Siddha and Unani Drugs" or the words "Ayurvedic (including siddha) or Unani drugs" wherever appearing shall be substituted with the words "Ayurveda, Siddha, Sowa-Rigpa and Unani Drugs".

3. Rule 2 (dd) shall be substituted namely-

"(dd) Homoeopathic medicines include any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative literature of Homoeopathy as mentioned in first and second schedule of the Act and which is prepared according to the techniques of the official Homoeopathic Pharmacopoeia of India and abroad and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route."

4. Rule 2 (eb) shall be substituted namely-

"(eb) "Registered Homoeopathy medical practitioner" means a person -

(i) holding a qualification granted by an authority specified or notified in the Schedules to the Homoeopathy Central Council Act, 1973 (59 of 1973); or The National Commission for Homoeopathy (NCH) Act, 2020 (15 of 2020); or

(ii) registered or eligible for registration in a medical register of a State or National register meant for the registration of persons practicing the Homoeopathy system of medicine as under National Commission for Homoeopathy (NCH) Act, 2020 (15 of 2020);"

5. After rule 2 (ec) of the principal rules, the following rule shall be inserted, namely-

"(ed) "Registered Ayurveda or Siddha or Sowa-Rigpa or Unani medical practitioner" means a person -

(i) holding a qualification granted by an authority specified or notified in the Schedules to the Indian Medicine Central Council Act, 1970 (48 of 1970); or National Commission for Indian System of Medicine (NCISM) Act, 2020 (14 of 2020); or

(ii) registered or eligible for registration in a medical register of a State or National register meant for the registration of persons practicing the Ayurveda or Siddha or Sowa-Rigpa or Unani system of medicine as under National Commission for Indian System of Medicine (NCISM)Act, 2020 (14 of 2020);"

6. After rule 2 (h) of the principal rules, the following rule shall be inserted, namely-

"(hh) Sowa-Rigpa drugs — Sowa-Rigpa drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Sowa-Rigpa systems of medicine, specified in the First Schedule of the Drugs and Cosmetic Act, 1940.

(hi) Sowa-Rigpa Proprietary medicine.- In relation to Sowa-Rigpa systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Sowa-Rigpa systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (hh)."

7. For rule 30AA of the principal rules, the following rule shall be substituted, namely.-

"30AA. Import of New Homoeopathic medicines.— (1) No New Homoeopathic medicine shall be imported except under and in accordance with the permission in writing by the Licensing Authority as defined in clause (b) of rule 21.

(2) The importer of a New Homoeopathic medicine when applying for permission under sub-rule (1) shall produce before the Licensing Authority such documentary and other evidence as may be required by the Licensing Authority for assessing the safety, therapeutic efficacy of the medicine including the minimum homoeopathic provings carried out with it.

Explanation.- For the purpose of this rule, 'New Homoeopathic Medicine' means,—

(i) a Homoeopathic medicine which is not specified in the official Homoeopathic Pharmacopoeia of India or United States of America or of the United Kingdom or the German Homoeopathic Pharmacopoeia or the French Homoeopathic Pharmacopoeia or the European Pharmacopeia; or

(ii) which is not recognized in authoritative Homoeopathic books specified in the First Schedule of the Act, as efficacious under the conditions recommended; or

(iii) a combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) or not recognized in authoritative Homoeopathic books referred to in clause (ii); or

(iv) a combination of two or more Homoeopathic medicines even if individually mentioned in the official Homoeopathic Pharmacopoeia as in clause (i) or in authoritative Homoeopathic books specified in the First Schedule of the Act, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims; or

(3) A New Homoeopathic Medicine shall continue to be considered as New Homoeopathic Medicine for a period of four years from the date of its first approval.

(4) The Licensing Authority as defined in clause (b) of rule 21 after being satisfied that the drug shall be effective and safe for use in the country, shall issue approval subject to the conditions stated therein.

PROVIDED that the Licensing Authority shall, where the data provided or generated on the New Homoeopathic Medicine is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission could be considered.

PROVIDED further that nothing contained under this rule shall be applicable to such Homoeopathic medicine which has been issued approval for import or license for manufacture for sale in India prior to the date of this notification from the concerned State or Central Authority as the case may be, and if such authority or person provides substantive information that the approval of competent authority has been obtained prior to the date of this notification.

Note: For the purpose of safety, therapeutic efficacy of the medicine including the minimum homoeopathic provings carried out with it shall be in accordance with the guidelines prescribed by Central Council for Research in Homoeopathy from time to time."

8. In rule 67A of the principal rules,

i. subrule (2) shall be substituted namely.-"(2) Application for the grant of a licence to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines shall be made in Form19-B to the Licensing Authority and shall be accompanied by a fee of rupees two thousand.

ii. following sub-rule shall be inserted namely.-"(4) The application shall be made through portal e-AUSHADHI (www.eaushadhi.gov.in) as per the format provided in the said portal, pertaining to the sale license of Homoeopathic Medicines.

PROVIDED that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted." .

9. For rule 67C of the principal rules, the following rule shall be substituted, namely.-

"**67C. Forms of licences to sell drugs.**-(1) Subject to the conditions of rule 67F being fulfilled, a licence to sell, stock or exhibit or offer for sale or distribute Homoeopathic medicines by retail or by wholesale shall be issued in Form 20C or 20D as the case may be.

(2) The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and license in Form 20C or 20D issued online as per the format provided in the said portal.

PROVIDED that no license shall be required for exhibiting the drugs for promotional activities in any fair.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted.".

10. For rule 67E of the principal rules, the following rule shall be substituted, namely:-.-

"67E Duration of licences.(1) A licence issued in Form 20C or 20D shall remain valid perpetually.

PROVIDED that the licencee shall submit a self declaration of adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Rules, every five years from the date of issue of license in Form 20C or 20D or from the date of submission of last self declaration as the case may be .

(2) The licensing authority shall issue two reminders to licensee for submission of self declaration, six months and three months by Registered Post/ Speed post with Acknowledgement Due and email, before the date of completion of every five years interval from the date of issue of license or from the date of issuance of such reminder, as the case may be.

PROVIDED further, that such self declaration should be made within three months of completion of five years from the date of issue of license in Form 20C or 20D or from the date of submission of last self declaration as the case may be, and in the event of non submission of such self declaration, license shall be deemed to have been cancelled. Fresh application under Form 19B is to be made thereafter."

11. The Rule 67EE of the principal rules, shall be omitted.

12. The sub-rule(6) of rule 67G of the principal rules, shall be omitted.

13. In rule 85B of the principal rules, -

i. under clause (1) the words "or renewal" shall be omitted.

ii. clause (2) shall be substituted namely:-

"(2) The application in Form 24C shall be accompanied-

(a) by a fee of rupees two thousand for any number of single ingredient Homoeopathic medicines as defined in clause (dd) of Rule 2.

(b) by a fee of rupees two hundred per product for combination of ingredients of Homoeopathic medicines as defined in clause (dd) of Rule 2.

PROVIDED, notwithstanding the period for renewal, existing license holders under Form 25C prior to the date of commencement of the Drugs Rules, 2024, and having a valid Good Manufacturing Practices Certificate as per Schedule M1, shall seek for the perpetuity of existing licence within a period of one year from the date of commencement of the Drugs Rules, 2024, by depositing a onetime licence retention fee of rupees one thousand for existing licenced drugs falling under clause (a) of this rule; and at the rate of rupees one hundred per product for combination of ingredients of Homoeopathic medicines for existing licenced drugs falling under clause (b) of this rule.

Provided further that either of online and offline process of licence application shall be accepted till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect within six months of the commencement of the Drugs Rules, 2024 and during this period either of online and offline process of licence application shall be accepted.]

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted.".

Explanation-for the purpose of clause (a) of this rule single ingredient Homoeopathic medicines with all of its potencies will be considered as one product and separate fees potency wise is not required.".

iii. Clause (3), (4), (5) shall be omitted.

14. After Rule 85B, the following rule shall be inserted, namely.-

"85BA. Application for loan licence to manufacture Homoeopathic Medicines.-(1)Application for grant of loan license to manufacture for sale or for distribution of Homoeopathic medicines shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part and shall be made in Form 24 C1.

(2) The application in Form 24C1 shall be accompanied-

(a) by a fee of rupees two thousand for any number of single ingredient Homoeopathic medicines as defined in clause (dd) of Rule 2.

(b) by a fee of rupees two hundred per product for combination of ingredients of Homoeopathic medicines as defined in clause (dd) of Rule 2.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted.".

Explanation-for the purpose of clause (a) of this rule, single ingredient Homoeopathic medicines with all of its potencies will be considered as one product and separate fees potency wise is not required.

Explanation—For the purposes of this rule, a "loan licence" means a licence issued by the Licensing Authority to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licencee in Form 25C.

85BB. Application for Certificate of Good Manufacturing Practices for Homoeopathic medicines manufacturing unit-(1) An application for the grant of a Certificate of Good Manufacturing Practices for Homoeopathic medicines manufacturing unit shall be made in Form 24C2 to the licensing authority along with a fee of rupees five thousand.

(2) Every application in Form 24C2 shall be made for a unit having premises and other requirements as prescribed under Schedule M1.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted.".

15. The rule 85D of the principal rule, shall be substituted, namely:-

"85D. Form of licence to manufacture Homeopathic medicines. — (1) Subject to the conditions of rule 85E being fulfilled, a licence to manufacture for sale of Homeopathic medicines shall be issued in Form 25-C and loan licence to manufacture for sale of Homeopathic medicines shall be issued in Form 25-C-1. The licence shall be issued within a period of two months from the date of receipt of the application or from the date of fulfillment by the applicant of any shortcomings highlighted by the licensing authority as the case maybe.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert committee in homoeopathic systems of medicine, which the State Government may approve in this behalf.

(3) The application shall be processed through the portal e-AUSHADHI (www.e-aushadhi.gov.in) for the purpose.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted.".

16. In rule 85E of the principal rules, -

i. In the opening remarks the words "or renewal" and "or renewed" shall be omitted.

ii. In clause (a) to sub-rule (1) of rule 85E of the principal rules, after the words "a graduate in Science with Chemistry", the words "or Botany or Zoology" shall be inserted.

iii. clause (c) shall be substituted, namely.-

"(c) holds qualification as defined under schedules of The National Commission for Homoeopathy (NCH) Act, 2020 (15 of 2020)with 18 months of experience in the manufacture of Homoeopathic medicines:"

iv. the proviso under rule 85E (2A) shall be substituted, namely.- "Certificate of Good Manufacturing Practice: The certificate of Good Manufacturing Practices to manufacturers of Homoeopathic Medicines, who comply with the requirements as specified in schedule M-I, shall be issued in Form 26C-1.

v. the third proviso "PROVIDED that in case potentised preparations are made in a Pharmacy holding licence in Form 20-C, the conditions (2) and (3) shall not apply. The licensee shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label." shall be omitted.

17. For rule 85EA of the principal rule, the following rule, shall be substituted namely:-

"85EA. Inspection for grant of license and verification of compliance.-(1) Before a GMP certificate for License under Form 25Cor Form 25C1 is granted or retained, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more qualified inspectors as mentioned under Rule 167 appointed by the Central or State Government.

(2) The inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs and verify the adherence to the conditions of license and the provisions of the Drugs and Cosmetics Act and the Drugs Rules not less than once in five years or as needed as per risk based approach.

PROVIDED that the inspectors are allotted the inspection duty in a randomized manner ensuring that the same inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than five years duration.

PROVIDED further that if the premises is not inspected within the period of the validity of the GMP certificate or even after submission of retention fee, the GMP certificate shall be deemed to be continued for further term of five years.".

18. For rule 85EB of the principal rules, the following rule shall be substituted, namely.-

"**85EB. Report by Inspector.**– (1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and the Requirements of Plant and Equipments as laid down in Schedule M1.

(2) The Inspector shall forward a detailed descriptive report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the sub- rule (1), to the Licensing Authority.".

19. For rule 85EC of the principal rules, the following rule shall be substituted, namely.-

"**85EC.-Procedure of Licensing Authority.-**

(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, and after being satisfied that the requirements of the provisions referred to in the rules under the Act have been complied with and that the conditions of the licence shall be observed, shall issue a licence under this Part.

(2) If the Licensing Authority is not satisfied of the requirements under sub-rule(1), shall issue a memorandum of shortcoming, and the conditions which shall be satisfied before a licence is granted and shall supply the applicant a copy of the inspection report.

(3) The applicant within two months of issue of such memorandum under sub-rule (2) shall reply the same.

(4) On non-submission of requirements in sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.

(5) For this purpose, the licensing authority shall intimate the applicant and process the application online through the portal e-AUSHADHI (www.e-aushadhi.gov.in) for the purpose.

PROVIDED further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect as notified by the Central Government, till such time, either of online and offline process of license application shall be accepted.".

20. For rule 85ED of the principal rules, the following rule shall be substituted, namely.-

"**85ED.-Further application after rejection.** —If the applicant, within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices, as the case may be, informs the Licensing Authority that the conditions laid down have been complied with and deposit an inspection fee of rupees one thousand, the Licensing Authority may, after a further inspection, if any, is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part.".

21. Rule 85F shall be substituted namely.-

"**85F. Duration of licence**—(1) A licence issued in Form 25Cor Form 25C1unless it is sooner suspended or cancelled shall remain valid perpetually.

PROVIDED that the licencee shall ensure validity of Good Manufacturing Practices certificate of the manufacturing facilities used by the licencee.

22. After rule 85F the following Rule shall be inserted namely.-

"**85FA. Duration of Certificate of Good Manufacturing Practices for Homoeopathic medicines manufacturing units**—(1) A certificate issued in Form 26C1 shall remain valid unless it is cancelled by the Licensing authority subject to deposit of a certificate retention fee of rupees one thousand before the expiry of a period of every succeeding five years from the date of its issue.

(2) If the licencee fails to pay certificate retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay certificate retention fee along with a late fee calculated at the rate of two per cent of the certificate retention fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the certificate shall be deemed to have been cancelled."

23. The rule 85G of the principal rules, shall be omitted.

24. In rule 85H of the principal rules.-

i. under clause (b) for the words "Inspector appointed under the Act" the words "qualified inspectors as mentioned under Rule 167 appointed by the Central or State Government" shall be substituted.

ii. clause (d) shall be omitted.

iii. after clause (f) the following proviso " PROVIDED further that manufacturers maintaining online records of details mentioned under the rule and Schedule M1 shall also be accepted." shall be inserted.

25. In rule 106A of the principal rules, in sub-rule (A), clause (ii), sub-clause (a), after the words "German Homoeopathic Pharmacopoeia", the following shall be inserted, namely,- "or the French Homoeopathic Pharmacopoeia or the European Pharmacopeia."

26. In rule 153 of the principal rules,

(i) clause (b) shall be substituted namely.-

" (b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24D to the licensing authority along with a fee of rupees two hundred per product, through the portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the licence for manufacture for sale of Ayurveda, Siddha or Unani drugs.".

(ii) first proviso shall be substituted namely.-

"Provided, notwithstanding the period for renewal, existing license holders under Form 25D prior to the date of commencement of the Drugs Rules, 2024 and such licence holder having a valid Good Manufacturing Practices Certificate as per Schedule T shall for the perpetuity of existing licence within a period of one year from the date of commencement of the Drugs Rules, 2024, by depositing a onetime licence retention fee of rupees one thousand for existing licenced drugs falling under clause (a) of section 3 of the Act; and at the rate of rupees one hundred per product for existing licenced drugs falling under sub-clause (i) of clause (h) of section 3 of the Act.".

27. In rule 153 A of the principal rules,

(i) clause (b) shall be substituted namely.-

"(b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24E to the licensing authority along with a fee of rupees two hundred per product, through the portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the loan licence for manufacture for sale of Ayurveda, Siddha or Unani drugs.".

(ii) first proviso shall be substituted namely.-

"Provided, notwithstanding the period for renewal, existing license holders under Form 25E prior to the date of commencement of the Drugs Rules, 2024 and such licence holder having a valid Good Manufacturing Practices Certificate as per Schedule T shall seek for the perpetuity of existing licence within a period of one year from the date of commencement of the Drugs Rules, 2024, by depositing a onetime licence retention fee of rupees one thousand for existing licenced drugs falling under clause (a) of section 3 of the Act; and at the rate of rupees one hundred per product for existing licenced drugs falling under sub-clause (i) of clause (h) of section 3 of the Act."

28. In rule 156C of the principal rule, sub-rule (1) shall be substituted namely:-

"(1) Before a certificate in Form 26E-1 is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more qualified inspectors mentioned under Rule 167 appointed by the Central or State Government under this Act, the inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs."

29. In rule 157 of the principal rules, clause (2) shall be substituted with following, namely.-

"(2) The manufacture of Ayurveda, Siddha, Sowa-Rigpa or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole time employee and who possesses the following qualifications, namely: –

(a) A degree in Ayurveda, Siddha, Sowa-Rigpa or Unani system of Medicine, as the case may be, conferred by a University/ State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognised by the Central Government or a State Government for this purpose, or

(b) A graduate in Pharmacy (Ayurveda or Siddha or Sowa-Rigpa or Unani) of a University recognised by the Central Government or a State Government with experience of at least two years in manufacturing of Ayurveda, Siddha, Sowa-Rigpa or Unani drugs as the case maybe in a licensed manufacturing unit.

Provided that the person already registered with the State Licensing Authority as competent person for the purposes of grant of license in Form 25D/25E prior to the coming into force of the Drugs (Amendment Rules) 2024, shall continue to be considered as competent person for the said purposes.".

30. In subrule (2) of Rule 161B, the words "Real time" shall be substituted with "Real time and accelerated".

31. In rule 162 A, clause (a) shall be substituted, namely –

" (a) The Ayurveda/Siddha/ Sowa-Rigpa/Unani qualifications as per Schedules of National Council for Indian System of Medicine (NCISM) Act, 2020 (14 of 2020)/B. Pharma (Ayurveda) of a recognized University."

32. In table under rule 168, for the words "12%" the words "11.40 %" shall be substituted.

33. The Rule 170 of the principal rules, shall be omitted.

34. In FORM 20C.-

i. under clause 2 the words "to ....." shall be omitted.

ii. before the words "Date" the words "License No....." shall be inserted.

35. In FORM 20D.-

i. under clause 2 the words "to ....." shall be omitted.

ii. before the words "Date" the words "License No....." shall be inserted.

36. FORM 20E shall be omitted.

37. In the principal rules, for FORM 24C, the following FORM shall be substituted, namely:—

"FORM 24C

(See rule 85B)

APPLICATION FOR THE GRANT OF A LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC MEDICINES

1. I / We ..... of.....hereby apply for the grant of licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised preparations on the premises situated at..... .....

Names of the Homoeopathic preparations..... (each item to be separately specified).

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

3. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date.....

Signature .....

(applicant)

Note—

The application should be accompanied by a Plan of the premises.".

38. In the principal rules after FORM 24C, the following FORM shall be inserted, namely:-

"**FORM 24C1**

(See rule 85BA)

APPLICATION FOR THE GRANT OF A LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC MEDICINES

1. I / W e* ..... of**.....hereby apply for the grant of loan licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised preparations on the premises situated at..... ..... Under the C/o#.....

Names of the Homoeopathic preparations..... (each item to be separately specified).

2. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Homoeopathic medicines in the manufacturing premises.

3. I / We* enclose,

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me / us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.

(c) Specimen of labels, cartons of the drugs proposed to be manufactured.

4. A fee of Rs ..... has been credited to Government under the head of account ..... and the relevant Treasury Challan/online transaction slip is enclosed herewith.

Date ..... Signature ....

*Enter here the name of the proprietor, partners or Managing Director, as the case may be.

** Enter here the name of the applicant firm and the address or the principal place of business.

Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates.

FORM 24-C-2

(See rule 85BB)

APPLICATION FOR THE CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR HOMOEOPATHIC MEDICINES MANUFACTURING UNITS.

1. I / We ..... of.....hereby apply for the grant of a Certificate of Good Manufacturing Practices for Homoeopathic medicines manufacturing on the premises situated at..... .....

2. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date..... Signature .....

(applicant)

Note—The application should be accompanied by a Plan of the premises.".

39. In the principal rules for FORM 25C, the following FORM shall be substituted, namely:-

"FORM 25C

(See rule 85D)

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC MEDICINES

No. of Licence and date of issue.....

1. ..... is / are hereby licenced to manufacture the following Homoeopathic medicines on the premises situated at..... under the direction and supervision of the following competent technical staff: —

Name of Homoeopathic preparations.

(Each item to be separately specified)

2. Competent Technical staff (Names).

3. The licence shall be in force from .....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date .....

Signature .....

Designation .....

Conditions of Licence

1. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licencee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.

5. The licence is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Homoeopathic medicines as laid down in Schedule M1 of the Drugs Rules, 1945."

40. In the principal rules after FORM 25C, the following FORM shall be inserted, namely:-

"FORM 25-C-1

(See rule 85D)

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF HOMOEOPATHIC MEDICINES

1. Number of Licence.....date of issue.....

2 ..... of. ..... is hereby granted a loan licence to manufacture for sale or distribution of Homoeopathic medicines, on the premises situated at ..... C/o.....under the direction and supervision of the following expert technical staff:

(a) Expert Technical staff (Names).....
(b) Name of Homoeopathic preparations.

(Each item to be separately specified)

3. The licence shall be in force from .....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date .....

Signature .....

Designation .....

Conditions of Licence

1. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licencee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.".

41. FORM 26C shall be omitted.

42. In the principal rules before FORM 26-D, the following FORM shall be inserted, namely:-

"FORM 26C-1

(See rule 85E)

CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP) TO MANUFACTURER OF HOMOEOPATHIC MEDICINES

Certified that manufacturing unit licensee, namely .....situated at .....

State ..... Licence No ..... comply with the requirements of Good

Manufacturing Practices of homoeopathic medicines as laid down in Schedule M1 of the

Drugs and Cosmetics Rules, 1945.

This certificate is valid for a period of five years and the Good Manufactruing Practices (GMP) is valid for the various dosage forms as follows:

Date :..... Signature.....

Place : . . . . Designation.....

Licensing Authority for homoeopathic medicines

43. FORM 26 E4 shall be omitted.

44. FORM 26 E5shall be omitted.

[F. No. T-11011/05/2019-DCC(AYUSH)]

KAVITA GARG, Jt. Secy.

Note : The principal rules were published in the Gazette of India, *vide*, notification No. F. 28-10/45-H(1), dated the 21st December, 1945 and last amended, *vide*, notification number G.S.R. -, dated the -

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.