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 -

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