THE GAZETTE OF INDIA
(EXTRAORDINARY)
PART II SECTION 3, SUB SECTION (i)
MINISTRY OF HEALTH AND FAMILY WELFARE
(DEPARTMENT OF INDIAN SYSTEM OF MEDICINE AND HOMOEOPATHY)

NOTIFICATION

New Delhi, the 31st January 2003.

G.S.R. 73(E) - Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by section 33 N of the Drugs and Cosmetics Act, 1940 (23 of 1940) in the Gazette of India Extraordinary Part – II, Section 3, Sub-section (i), dated the 12th July 2001 vide No. GSR 492 (E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft will be taken into consideration after the expiry of a period of thirty days from the date on which copies of the Official Gazette containing the notification were made available to the public;

And whereas the said Gazette was made available to the public on 12th July 2001;

And whereas objections and suggestion from the public on the said draft have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 33-N of the said Act, the Central Government, hereby makes the following further amendments in the Drugs and Cosmetics Rules, 1945, namely:-

RULES

1. (1) These rules may be called the Drugs and Cosmetics 2nd (Amendment) Rules, 2003.

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

2. In the Drugs and Cosmetics Rules 1945, -

(a) After Rule 160, the following shall be inserted, namely:-

APPROVAL OF 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.

160 A. Application for grant of approval for testing Ayurvedic, Siddha and Unani drugs. – Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of the said Ayurvedic, Siddha and Unani drugs, shall be made in Form 47 to the Licensing Authority appointed by the State Government for the purposes of Part XVI, XVII or XVIII of these rules, as the case may be, and referred to as the "approving authority" under this Part and shall be accompanied by an inspection fee of six thousand rupees in respect of the Ayurvedic, Siddha, Unani drugs specified in the books prescribed in First Schedule to the Act.

Provided that the applicant shall furnish to the approving authority such additional information as may be required by it in connection with the application in Form 47.

Provided further that if the applicant applies for renewal of approval after its expiry but within six months of such expiry, the inspection fee payable shall be six thousand rupees plus an additional inspection fee at the rate of one thousand rupees per month in the case of testing of Ayurvedic, Siddha and Unani drugs specified in First Schedule to the Act.

Explanation.- For the purpose of this Part, the words “Ayurvedic, Siddha and Unani drugs” shall also mean and include the raw materials used in the manufacture of Ayurvedic, Siddha and Unani drugs, as the case may be.

160 B. Form in which approval to be granted for carrying out tests on Ayurvedic, Siddha and Unani drugs on behalf of licensees for manufacture of Ayurvedic, Siddha and Unani drugs and conditions for grants or renewal of such approval.- (1) Approval for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs shall be granted in Form 48.

(2) Before approval in Form 48 is granted or renewed, the following conditions shall be complied with by the applicants, namely:-

(i) The premises where the tests are carried out shall be well lighted and properly ventilated except where the nature of tests of any Ayurvedic, Siddha and Unani drug warrants otherwise. Wherever necessary, the premises shall be air-conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests and microbiological tests.

(ii) (a) The applicant shall provide adequate space having regard to the nature and number of samples of drugs proposed to be tested:

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate. Provided further that separate section shall be provided for (i) Chemistry, (ii) Pharmacognosy, (iii) Ayurveda, Siddha and Unani, (iv) Microbiology, (v) Sample Room, (vi) Office-cum-Record Room, with proper partitions and minimum required area of 800 square feet.

(b) The applicant shall provide a list of persons who may be employed with him as experts, such as Chemist, Botanist and expert in Ayurveda/ Siddha/Unani or Pharmacist who shall possess a degree in Chemistry, Botany, Atyurved/Siddha/Unani/Bachelor in Pharmacy from a recognized University or equivalent, with experience for 2 years for carrying out tests or analysis as per the Ayurvedic, Siddha and Unani pharmacopoeias.

(c) The applicant shall provide adequate equipments essential for carrying out tests for identity, purity, quality and strength Ayurvedic, Siddha and Unani drugs as per pharamcopoeial standards or other available standards.

“List of equipment recommended is given below:”.

Chemistry Section

1. Alcohol determination apparatus complete set.
2. Volatile oil determination apparatus.

3. Boiling point determination apparatus.
4. Melting point determination apparatus.
5. Refractometer.
6. Polarimeter.
7. Viscometer (ostwalds, Redwood viscometer).
8. Tablet disintegration apparatus.
9. Moisture determination apparatus (IC filtrator).
10. U.V. Spectro-Photometer.
11. Muffle furnace.
12. Electronic Balance.
13. Hot air oven(s) different range of temperature/vacuum oven.
14. Refrigerator.
15. Glass distillation apparatus/plant.
16. Water supply demineralised exchange equipment/Distillation equipment.
17. Air conditioner.
18. LPG Gas Cylinder with burners.
19. Water bath (temperature controlled).
20. Heating mantle (4) or as required.
21. TLC apparatus with all accessories.
22. Sieves 10 to 120 with sieve shaker.
23. Centrifuge machine.
24. Dehumidifier (where necessary).
25. PH meter.
26. G.L.C. with F.I. detector.
27. Silica crucible.

28. Tablet friability tester.

29. Tablet dissolution tester.

30. Other related equipment, reagents, chemicals and glasswares.

Pharmacognosy Section

1. Microscope binocular.

2. Dissecting Microscope

3. Microtome

4. Chemical balance

5. Microslide cabinet.

6. Aluminium slide trays.

7. Hot air oven

8. Occular Micrometer.

9. Stage Micrometer

10. Camera Lucida Prism type and mirror type.

11. Hot plates.

12. Refrigerator.

13. LPG Cylinder with burners.

14. Other related equiments, reagents, glasswares etc.

Note: Instruments like HPLC, HPTLC, Atomic Absorption spectrophotometer could be arranged by tie up with other laboratories.

Microbiology Section

1. Laminar air flow bench (L.A.F)
2. B.O.D. Incubator.
3. Plain incubator.
4. Serological water bath.
5. Oven.
6. Autoclave / Sterilizer.
7. Microscope (high power).
8. Colony counter.
9. Other related equipment and reagents.

(3) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of Ayurvedic, Siddha and Unani drugs intended to be tested which shall be adequate in the opinion of the approving authority.

(4) The testing of Ayurvedic, Siddha and Unani drugs, as the case may be, for identity, purity, quality and strength shall be carried out under the active direction of one of the experts stated in clause (b) of sub-rule (2) who shall be the person-in-charge of testing and shall be held responsible for the reports of test issued by the applicant.

(5) The testing of Ayurvedic, Siddha and Unani drugs, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose

qualifications and experience of testing are adequate as stated in clause (b) of sub-rule (2).

(6) The applicant shall provide books of standard recognized under the provisions of the Act and the rules made thereunder and such books of reference as may be required in connection with the testing of analysis of the products for the testing of which approval is applied for.

(7) The applicant shall provide list of standard Ayurvedic, Siddha and Unani drugs (Reference samples) recognized under the provisions of the Act and rules made thereunder and such reference samples kept in the laboratory may be required in connection with the testing or analysis of the products of which approval is applied for.

160 C. Duration of approval.- An approval granted in Form 47 or renewed in Form 49 unless sooner suspended or withdrawn, shall be valid for a period of three years from the date on which it is granted or renewed:

Provided that if an application for the renewal of an approval in Form 40 is made before its expiry or if the application is made within six months of its expiry after the payment of the additional inspection fee, the approval shall continue to be in force until orders to be contrary are passed on the application and the approval shall be deemed to have expired if the application for renewal is not made within six months of expiry.

160 D. Conditions of approval.- An approval in Form 48 shall be subject to the following conditions, namely:-

I. The Institution granted approval under this Part (hereinafter referred to as the approved laboratory) shall provide and maintain adequate staff and adequate premises and equipment as specified in rule 160 B.

II. The approved laboratory shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

III. The approved laboratory shall maintain records of tests for identity, purity, quality and strength carried out on all samples of Ayurvedic, Siddha and Unani drugs and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which date of expiry date is assigned; for a period of two years from such date of expiry and in the case of other substances, for a period of three years.

IV. The approved laboratory shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried out and to inspect the premises and the equipment used for test and the testing procedures employed. The laboratory shall allow the Inspectors to inspect the registers and records maintained under these rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and rules made thereunder have been observed.

V. The approved laboratory shall from time to time report to the approving authority any changes in the person-in-charge of testing of Ayurvedic, Siddha

and Unani drugs or the expert staff responsible for testing, as the case may be, and any material alterations in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.

VI. The approved laboratory shall furnish reports of the results of tests or analysis in Form 50.

VII. In case any sample of Ayurvedic, Siddha and Unani drug is found on test to be not of standard quality, the approved laboratory shall furnish to the approving authority and the licensing authority of the State where the manufacturer and/or sender of the Ayurvedic, Siddha and Unani drugs is located, a copy of the test report on the sample with the protocols of tests applied.

VIII. The approved laboratory shall comply with the provisions of the Act and rules made thereunder and with such further requirements, if any, as may be, specified in the rules made from time to time under Chapter IV-A of the Act of which the approving authority has given the approved laboratory not less than four months' notice.

IX. The approved laboratory shall maintain an inspection book to enable the Inspector to record his impression or defects notices.

160 E. Inspection before grant of approval.- Before an approval in Form 48 is granted, the approving authority shall cause the laboratory at which the testing of Ayurvedic, Siddha and Unani drugs, as the case may be, is proposed to be carried out to be inspected jointly by the Inspectors appointed or

designated by the Central Government and State Government for this purpose, who shall examine the premises and the equipment intended to be used for testing of drugs and verify into the professional qualifications of the expert staff who are or may be employed by the laboratory.

160 F. Report of inspection.- The Inspectors appointed by the Central Government as stated in rule 160-E shall forward to the approving authority a detailed report of the results of the inspection.

160 G. Procedure of approving authority.- (1) If the approving authority after such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the rules made under the Act have been observed, it shall grant approval in Form 48.

(2) If the approving authority is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which shall be satisfied before approval could be granted.

160 H. Application after rejection.- If within a period of six months from the rejection of an application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of two thousand rupees, the approving authority may, if, after causing a further inspection to be made and after being satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 48.

160 I. Renewal.- On an application being made for renewal, the approving authority shall, after causing an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act have been complied with, shall issue a certificate of renewal in Form 49.

160 J. 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 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 thee approval or with any provision of the Act of 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 Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by the Department of Indian Systems of Medicine and Homoeopathy, Government of India in this behalf and notified in the Official Gazette";

(b) in Schedule A, after Form 46, the following Forms shall be inserted, namely:-

"FORM 47
(See rule 160 A)

Application for grant or renewal of approval for carrying out tests on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs.

(1) *I/We ..... of ..... hereby apply for the grant/renewal of approval for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensee for manufacture for sale of Ayurvedic, Siddha and Unani drugs.

(2) *Categories of Ayurvedic, Siddha and Unani drugs other than those specified in the First Schedule to this Act for which testing will be carried out:

	AYURVEDA AND SIDDHA		**UNANI**
1.	Asava and Arista	1.	Nabeez, Khal (Sirka)
2.	Arka-Tinir	2.	Majoon and its sub-categories:- Itrifal, Jawarish, Khameera, Laooq, Halwa.
3.	Avaleha and Paka-Ilakam	3.	Sufoof, Zuroor, Sunoon.
4.	Kvatha Curna-Kutinir Curanam	4.	Namak, Khar
5.	Guggulu	5.	Raughan
6.	Ghrita-Ney	6.	Zimad
7.	Churna-Curanam	7.	Habb (Pill)
8.	Taila-Tailam	8.	Shiyaf
9.	Dravaka-Tiravakam	9.	Qutoor (drops)
10.	Lavana-Uppu	10.	Kohal (Surama), Kajal
11.	Kshara-Saram	11.	Satt, Usara
12.	Lepa-Pacai	12.	Kushta
13.	Vati, Gutika-Kulikai	13.	Joshanda (Single drugs)
14.	Vartti	14.	Sharbat, Sikanjabeen
15.	Netrabindu(Aschyotan)	15.	Sayyal, Arq (Distillates)
16.	Anjana-Kanmai	16.	Qurs (Tablet)
17.	Sattva-Sattu	17.	Marham, Qairooti
18.	Kupipakva Rasayan-Kuppi Centuram	18.	Humool, Furzaja
19.	Parpati	19.	Bakhoor
20.	Pishti	20.	Nabati Advia
21.	Bhasma-Parpam	21.	Maadni Advia
22.	Mandura-Atai Kutinir	22.	Ajsad Advia
23.	Rasayoga-Centuram	23.	Haiwani Advia
24.	Lauha	24.	Jauhar
25.	Ghana Sattva	25.	Natool
26.	Kvath Pravahi-Kutinir	26.	Nashooq, Naswar
27.	Panak (Syrup)-Manappaku	27.	Shamoom

28.	Tablet-Mattirai	28. Saoot (Nasal drops)
29.	Capsule	29. Mazoogh
30.	Ointment-Kalimapu	30. Tila
31.	Phalavarti	31. Lashooq
32.	Dhoomravarti/Doopan	32. Gulqand
33.	Kshar Sutra/Kshar Varti	33. Fateela
34.	Single drugs: (a) Plant based. (b) Mineral based (c) Metal based (d) Animal based (e) Syntehtic (f) Any other Ayurvedic, Siddha, Unani formulation.	34. Ghaza, Ubtan, Sabhgh
35.	Pushp (Phool)	35. Capsule
36.	Nasya	36. Huqna
37.	Swarasa (Fresh juice)	37. Naurah
38.	Karna Bindu (Ear drops)	38. Latookh
39.	Any other dosage form of Patent and Proprietary and Ayurvedic, Siddha, Unani Drug.	39. Vajoor (Throat pain)
		40. Mazmazah (Mouth washer)

(3) Names, qualifications and experience of experts employed for testing and the person-in-charge of testing.

(4) List of testing equipment provided.

(5) *I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

(6) An inspection fee of rupees ..... has been credited to Government under the head of account .....

Dated.....

Signature .....
Full address of the Applicant

* Delete whichever is not applicable.

FORM 48
(See rule 160 B)

Approval for carrying out tests or analysis on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs.

Number of approval and date of issue:

(1) Approval is hereby granted to ..... for carrying out tests for identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani drugs and the raw materials used in the manufacture thereof on the premises situated at .....

Categories of Ayurvedic, Siddha and Unani drugs.

.....

.....

.....

.....

(2) Name of experts employed for testing and the person-in-charge of testing ..... (experts) and ..... (person in charge).

(3) The approval shall be in force from ..... to .....

(4) The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

Signature .....
Date ..... *Designation* .....
Place ..... *Seal of State Licensing Authority*

Conditions of Approval

(1) This approval and any certificate of renewal in Form 49 shall be displayed in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.

(2) If the applicant wishes to undertake during the currency of the approval the testing of any other category of Ayurvedic, Siddha or Unani drugs it should apply to the approving authority for necessary endorsement as provided in Rule 160-A. This approval will be deemed to extend to the items so endorsed.

(3) Any change in the experts or in the person-in-charge of the testing shall be forthwith reported to the approving authority.

(4) The applicant shall inform the approving authority in writing in the event of any change of the constitution of the laboratory operating under this Form. Where any change in the constitution of the laboratory takes place, the current approval 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 approval has been taken from the approving authority in the name of the laboratory with the changed constitution.

FORM 49
(See rule 160 I)

Certified of renewal for carrying out tests or analysis on Ayurvedic, Siddha or Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha or Unani drugs.

(1) Certified that approval number ..... granted on the ..... day of ..... 2001 for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani drugs and the raw materials used in the manufacture thereof at the premises situated at ..... has been renewed from ..... to ..... (Date).

Categories of Ayurvedic, Siddha or Unani drugs.

.....

.....

(2) Name of experts and the person-in-charge of testing ..... (experts) and ..... (person-in-charge).

Signature .....
Date ..... *Designation* .....
Place ..... *Seal of State Licensing Authority*

FORM 50
[See rule 160 D(f)]

Report of test or analysis by approved Laboratory

(1) Name of manufacturer from whom sample received together with his manufacturing license number under the Act or the rules made thereunder.
.....

(2) Reference number and date of the letter from the manufacturer under which the same was forwarded.
.....

(3) Date of receipt of the sample.
.....

(4) Name of Ayurvedic, Siddha and Unani drug of raw material purporting to be contained in the sample
.....

(5) Details of raw material of final product (in bulk finished pack)* as obtained from the manufacturer:

(a) Original manufacturer's name in the case of raw materials and drugs repacked.....
(b) Batch number .....
(c) Batch size as represented by sample .....
(d) Date of manufacture, if any .....
(e) Date of expiry, if any .....

(6) Results of tests or analysis with protocols of test or analysis applied or as per Ayurvedic, Siddha or Unani Pharmacopoeial standards.

(7) Other specific tests for identity, purity, quality and strength of Patent and Proprietary drugs.

In the opinion of the undersigned, the sample referred to above is of standard *quality/is not of standard quality as defined in the Act or the rules made thereunder for the reasons given below

.....
.....

(Signature of the Person-in-Charge of testing)

Date

(F.No.....)

Place

Name & Designation & Seal.....

Name & Address of the Laboratory .....

License No. .....

Note: Final product includes repacked material.

*Delete whichever is not applicable.

L. PRASAD; Jt. Secretary
[No.K.11020/3/2000-DCC(ISM)]

Foot Note: The Drugs and Cosmetics Rules 1945 as amended upto 1.5.1979 is contained in the publication of the Ministry of Health and Family Welfare (Department of Health containing the Drugs and Cosmetics Act, 1941) and the Rules (PDGHS-61) and last amended vide GSR 648(E) dated 16.9.2002.

[To be published in Gazette of India Part II Section 3, sub-section iii]

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Indian Systems of Medicine and Homoeopathy)

NOTIFICATION

New Delhi, the 7th March 2003.

G.S.R. 198(E)-. Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India Extraordinary Part – II Section 3, sub-section (i) dated 13th August, 2002 vide GSR No. 566(E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft will be taken into consideration after the expiry of 45 days from the date on which copies of the Official Gazette containing the notification were made available to the public;

And whereas the said Gazette Notification was made available to the public on 13.8.2002;

And whereas objections and suggestions from the public on the said draft have been considered by the Central Government. Now, therefore, in exercise of the powers conferred by section 33-N of the said Act, the Central Government, hereby makes the following further amendments in the Drugs and Cosmetics Rules 1945, namely:-

1. These rules may be called the Drug and Cosmetics (3rd Amendment) Rules, 2003.

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

1. In the Drugs and Cosmetics Rule, 1945,

(a) after rule 155-A, the following shall be inserted, namely:-

"155-B Certificate of award of G.M.P. of Ayurveda, Siddha and Unani Drugs:
The certificate of Good Manufacturing Practices (GMP) to manufcturers of Ayurved-Siddha or Unani drugs shall be issued to licensee who comply with the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha and Unani drug as laid down in Schedule T".

(b) in rule 157, after condition (1), the following shall be inserted, namely:

"(1A) For getting a certificate of Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs, the applicant shall make an application on a plain paper, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule "T", issue the certificate within a period of 3 months in Form 26E-I",

(c) after Form 26E, the following form shall be inserted, namely:-

"Form 26E-I
(See rule 155-B)

(Certificate of Good Manufacturing Practices (GMP) to manufacturer of Ayurveda, Siddha or Unani drugs):

Certified that manufacturing unit licensee, namely ....., situated at .....State..... License No. .....comply with the requirements of Good Manufacturing Practices (GMP) of Ayurveda-Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetics Rules, 1945.

This certificate is valid for a period of three years.

Dated: Signature
Designation/
Place: Licensing Authority for Ayurveda/
Siddha/Unani Drugs."

(d) for Schedule "T", the following shall be substituted, namely:-

"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:-

(i) raw materials used in the manufacture of drugs are authentic, of prescribed quality 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 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. However, under IMCC Act 1970 registered Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of Good Manufacturing Practices (GMP).

PART I

GOOD MANUFACTURING PRACTICES

Factory Premises:

The manufacturing plant should have adequate space for:-

(i) receiving and storing raw material;
(ii) manufacturing process areas;
(iii) Quality Control section;
(iv) finished goods store;
(v) office
(vi) rejected goods/drugs store.

1.1 General Requirements:

1.1(A) Location and surroundings:

The factory building for manufacture of Ayurveda, Siddha and Unani medicines shall be so situated and shall have such construction as to avoid contamination from open sewrage, drain, public lavatory or any factory which produces disagreeable or abnoxious odour or fumes or excessive soot, dust or smoke.

1.1(B) Buildings:

The building used for factory shall be such as to permit production 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 of moist. The premises used for manufacturing, processing, packaging and labeling will be in conformity with the provisions of the Factory Act. It shall be located so as to be:

(I) Compatible with other manufacturing operations that may be carried out in the same of adjacent premises.

(II) Adequately provided with working space to allow orderly and logical placement of equipment and materials to avoid the risk of mix up between different drugs or components thereof and control the possibility of cross contamination by other drugs or substances and avoid the risk of omission of any manufacturing or control step.

(III) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and dis-infection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean. The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust of waste products.

(IV) Provided with proper drainage system in the processing area. The sanitary fitting and electrical fixtures in the manufacturing area shall be proper and safe.

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

(VI) There should be fire safety measures and proper exits should be there.

(VII) Drying Space:- There be separate space for drying of raw material, in process medicine or medicines require drying before packing. This space will be protected from flies/insects/dusts etc., by proper flooring, wire-mash window, glass pans or other material.

1.1(C) Water Supply:

The water used in manufacture shall be pure and potable quality. Adequate provision of water for washing the premises shall be made.

1.1(D) 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.

1.1(E) Container's Cleaning:

In factories where operations involving the use of containers such as glass bottles, vials and jars are conducted, there shall be adequate

arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

1.1(F) Stores:

Storage should have proper ventilation and shall be free from dampness. It should provide independent adequate space for storage of different types of material, such as raw material, packaging material and finished products.

1.1(F)(A) Raw Materials:

All raw materials procured for manufacturing will be stored in the raw materials store. The manufacture based on the experience and the characteristics of the particular raw material used in Ayurveda, Siddha and Unani system shall decide the use of appropriate containers which would protect quality of the raw material as well as prevent it from damage due to dampness, microbiological contamination or rodent and insect infestation, etc. If certain raw materials require such controlled environmental conditions, the raw materials stores may be sub-divided with proper enclosures to provide such conditions by suitable cabinization. While designing such containers, cupboard or areas in the raw materials store, care may be taken to handle the following different categories of raw material:-

(1) Raw material of metallic origin.
(2) Raw material of mineral origin.
(3) Raw material from animal source.
(4) Fresh herbs.
(5) Dry herbs or plant parts.
(6) Excipients etc.
(7) Volatile oils/perfumes and flavours.
(8) Plant concentrates/extracts and exudates/resins.

Each containers used for raw material storage shall be properly identified with the label which indicates name of the raw material, source of supply and will also clearly state the status of raw material such as “UNDER TEST” or “APPROVED” or “REJECTED”. The labels shall further indicate the identity of the particular supply in the form of batch no. or lot no. and the date of receipt of the consignment.

All the raw materials shall be sampled and got tested either by the in-house Ayurvedic, Siddha and Unani experts (Quality Control technical person) or by the laboratories approved by the Government and shall be used only on approval after verifying. The rejected raw material should be removed from other raw material store and should be kept in separate room. Procedure of ‘First in first out’ should be adopted for raw materials wherever necessary. Records of the receipt, testing and approval or rejection and use of raw material shall be maintained.

1.1(F)(B) Packaging Materials:

All packaging materials such as bottles, jars, capsules etc., shall be stored properly. All containers and closure shall be adequately cleaned and dried before packing the products.

1.1(F)(C) Finished Goods Stores:

The finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores with an area marked 'Quarantine'. After the quality control laboratory and the experts have checked the correctness of finished goods with reference to its packing/labeling as well as the finished product quality as prescribed, then it will be moved to 'Approved Finished Goods Stock' area. Only approved finished goods shall be dispatched as per marketing requirements. Distribution records shall be maintained as required.

If any Ayurvedic, Siddha and Unani drugs needs special storage conditions, finished goods store shall provide necessary environmental requirements.

1.1(G) Working space:

The manufacturing area shall provide adequate space (manufacture and quality control) for orderly placement of equipment and material used in any of the operations for which these are employed so as to facilitate easy and safe working and to minimize or to eliminate any risk of mix-up between different drugs, raw materials and to prevent the possibility of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises.

1.1(H) Health Clothing, Sanitation and Hygiene or Workers:

All workers employed in the factory shall be free from contagious diseases. The clothing of the workers shall consist of proper uniform suitable to the nature of work and the climate and shall be clean. The uniform shall also include cloth or synthetic covering for hands, feet and head wherever required. Adequate facilities for personal cleanliness such as clean towels, soap and scrubbing brushed shall be provided. Separate provision shall be made for lavatories to be used by men and women, and such lavatories shall be located at places separated from the processing rooms. Workers will also be provided facilities for changing their clothes and to keep their personal belongings.

1.1(I) Medical Services:

The manufacturer shall also provide:-

(a) Adequate facilities for first aid;
(b) Medical examination of workers at the time of employment and periodical check up thereafter by a physician once a year, with particular attention being devoted to freedom from infections. Records thereof shall be maintained.

1.1(J) Machinery and Equipments:

For carrying out manufacturing depending on the size of operation and the nature of product manufactured, suitable equipment either manually operated or operated semi-automatically (Electrical or steam based) or fully automatic machinery shall be made available. These may include machines for use in the process of manufacture such as crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labeling and packing etc. To ensure ease in movement of workers and orderliness in operations a suitably adequate space will be ensure between two machines or rows of machines. These machinery and equipments have to be properly installed and maintained with proper cleaning. List of equipments and machinery recommended is indicated in Part II A.

Proper Standard Operational Procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down.

1.1(K) Batch Manufacturing Records:

The licensee shall maintain batch manufacturing record of each batch of Ayurvedic, Siddha and Unani drugs manufactured irrespective of the type of product manufactured (classical preparation or patent and proprietary medicines). Manufacturing records are required to provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurveda, Siddha and Unani mentioned in the First Schedule of the Drugs and Cosmetics Act, 1940 (23 of 1940). These tests may include in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product. These records shall be duly signed by Production and Quality Control Personnel respectively. Details of transfer of manufactured drug to the finished products store including dates and quantity of drugs transferred along with record of testing of the finished product, if any, and packaging, records shall be maintained. Only after the manufactured drugs have been verified and accepted quality shall be allowed to be cleared for sale.

It should be essential to maintain the record of date, manpower, machine and equipments used and to keep in process record of various shodhana, Bhavana, burning in fire and specific grinding in terms of internal use.

1.1(L) Distribution Records:

Records of sale and distribution of each batch of Ayurveda, Siddha and Unani drugs shall be maintained in order to facilitate prompt and complete recall of the batch, if necessary. The duration of record keeping should be the date of expire of the batch. Certain category of Ayurvedic, Siddha and Unani medicines like Bhasma, Rasa, Kupi-pakva, Parpati, Sindura, Karpu/uppu/puram, kushta, Asava-arista etc. do not have expiry date, in contrast their efficacy increases with the passage of time. Hence, records need to be maintained upto 5 years of the exhausting of stock.

1.1(M) Record of Market Complaints:

Manufacturers shall maintain a register to record all reports of market complaints received regarding the products sold in the market. 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 Licensing Authority. The Register shall also be available for inspection during any inspection of the premises.

Report of any adverse reaction resulting from the use of Ayurvedic, Siddha and Unani drugs shall also be maintained in separate register by each manufacture; the manufacture 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 it is a new observation.

1.1(N) Quality Control:

Every licensee is required to provide facility for quality control section in his own premises or through Government approved testing laboratory. The test shall be as per the Ayurveda, Siddha and Unani pharmacopoeial standard. Where the tests are not available, the test should be performed according to the manufacturer specification or other information available. The quality control section shall verify all the raw materials, monitor in process quality checks and control the quality of finished product being released to finished goods store/ware house. Preferably for such quality control there will be a separate expert. The quality control section shall have the following facilities:

(1) There should be 150 sq. ft. area for quality control section.
(2) For identification of raw drugs, reference books and reference samples should be maintained.
(3) Manufacturing record should be maintained for the various processes.

(4) To verify the finished products, controlled samples of finished products of each batch will be kept for till the expiry date of product.
(5) To supervise and monitor adequacy of conditions under which raw materials, semi-finished products and finished products are stored.
(6) Keep record in establishing shelf life and storage requirements for the drugs.
(7) Manufacturers who are manufacturing Patent Proprietary Ayurveda, Siddha and Unani medicines shall provide their own specification and control reference in respect of such formulated drugs.
(8) The record of specific method and procedure of preparation, that is, 'Bhavana', 'Mardana' and 'Puta' and the record of every process carried out by the manufacturer shall be maintained.
(9) The standards of 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.
(10) All raw materials will be monitored for fungal, bacterial contamination with a view to minimize such contamination.
(11) Quality Control Section will have a minimum of:

(i) One person with Ayurveda/Unani/Siddha qualification recognized under Schedule II of Indian Medicine Central Council Act 1970. Two other persons one each with Bachelor qualification in Botany/Chemistry/Pharmacy could be on part time or on contractual basis.
(ii) The manufacturing unit shall have a quality control section as explained under Section 35 (ii). Alternatively, these quality control provisions will be met by getting testing etc., from a recognized laboratory for Ayurveda, Siddha and Unani drugs; under Rule 160-A of the Drugs and Cosmetics Act. The manufacturing company will maintain all the record of various tests got done from outside recognized laboratory.
(iii) List of equipments recommended is indicated in Part II C.

1.2 Requirement for Sterile Product:

1.2(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 dis-infection. 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 and sterile products.

1.2(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 systems 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 opthalmic 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.

PART - II

A. LIST OF RECOMMENDED MACHINERY, EQUIPMENT AND MINIMUM MANUFACTURING PREMISES REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF AYURVEDIC, SIDDHA SYSTEM OF MEDICINE.

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, could also be shared for these items.

S.N	Category of Medicine	Minimum manufacturing space required.	Machinery/equipment recommended.
(1)	(2)	(3)	(4)
		1200 sq. ft. covered area with separate cabins or partitions for each activity. If Unani medicines are manufactured in same premises an additional area of 400 sq. ft. will be required.	
1.	Anjana/Pisti	100 sq. ft.	Kharal/mechanized/motorized Kharal, End runner/Ball-Mill Sieves/Shifter.
2.	Churna/ Nasya Manjan/ Lepa Kwath Churn	200 sq. ft.	Grinder/Disintegrator/ Pulverisar/Powder mixer/ Sieves/Shifter.
3.	Pills/Vati/ Gutika Matrica and tablets.	100 sq. ft.	Ball Mill, Mass Mixer/Powder mixer, Granulator drier, tablet compressing machine, pill/vati cutting machine, stainless steel trays/container for storage and sugar coating, polishing pan in case of sugar coated tablets, mechanized chattoo, (for mixing of guggulu) where required.
4.	Kupi pakva/ Ksara/ Parpati/	150 sq. ft.	Bhatti, Karahi/stainless steel vessels/Patila flask, Multani Matti/Plaster of Paris, Copper

	Lavana Bhasma Satva/ Sindura Karpu/ Uppu/ Param		Rod, Earthen container, Gaj Put Bhatti, Muffle furnace (electrically operated) End/ Edge Runner, Exhaust Fan, Wooden/S.S. Spatula.
5.	Kajal	100 sq. ft.	Earthern lamps for collection of Kajal, Triple Roller Mill, End Runner, Sieves, S.S. Patila, Filling packing and manufacturing room should be provided with exhaust fan and ultra violet lamps.
6.	Capsules	100 sq. ft.	Air conditioner, De-humidifier, hygrometer, thermometer, capsule filling machine and balance.
7.	Ointment/ Marham Pasai	100 sq. ft.	Tube filling machine, Crimping medicine/Ointment mixer, End Runner/Mill (where required), S.S. Storage container, S.S. Patila.
8.	Pak/Avaleh/ Khand/ Modak/ Lakayam	100 sq. ft.	Bhatti section fitted with exhaust fan and should be fly proof, iron kadahi/S.S. Patila and S.S. Storage container.
9.	Panak, Syrup/ Pravahi Kwath Manapaku.	150 sq. ft.	Tinctum press, exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, Filter press/Gravity filter liquid filling machine, P.P. Copping machine.
10.	Asava/Aristha	200 sq. ft.	Same as mentioned above. Fermentation tanks containers and distillation plant where necessary, Filter Press.
11.	Sura	100 sq. ft.	Same as mentioned above plus distillation plant and transfer pump.
12.	Ark/Tinir	100 sq. ft.	Maceration tank, Distillation plant, Liquid filling tank with tap/Gravity filter/Filter press, Visual inspection box.
13.	Tail/Ghrit/Ney	100 sq. ft.	Bhatti, Kadahi/S.S. Patila S.S. Storage containers, Filtration equipment, filling tank with tap/ Liquid filling machine.

14.	Aschyotan/ Netra-Malham Panir, Karn Bindu Nasabindu.	100 sq. ft.	Hot air oven electrically heated with thermostatic control, kettle gas or electrically heated with suitable mixing arrangement 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.
15.	Each manufacturing unit will have a separate area for Bhatti, furnace, boilers, puta etc. This will have proper ventilation, removal of smoke, prevention of flies, insects, dust etc. The furnace section could have tin roof.	200 sq. ft.	

B. LIST OF MACHINERY, EQUIPMENT AND MINIMUM MANUFACTURING PREMISES REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF 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 could also be shared for these items.

S.N	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
(1)	(2)	(3)	(4)
		1200 sq. ft. covered area with separate cabins, partitions for each activity. If Ayurveda/Siddha medicines are also manufactured in same premises an additional areas of 400 sq. ft. will be required.	
1.	Itrifal Tiryaq/ Majoon/Laooq/ Jawarish/ Khamiras.	100 sq. ft.	Grinder/Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Bhatti and other accessories, plant mixer for Khamiras.
2.	Araq	100 sq. ft.	Distillation plant (garembic) S.S. storage tank, boiling vessel, gravity filter, bottle filling machine, bottle washing machine, bottle drier.
3.	Habb (Pills) and tablets.	100 sq. ft.	Ball Mill, Mass Mixer/Powder mixer, Granulator drier, tablet compressing machine, pill/vati cutting machine, stainless steel trays/ container for storage and sugar coating, polishing pan in case of sugar coated tablets, mechanized chattoo, (for mixing of guggul) where required.

4.	Sufoof (Powder)	200 sq. ft.	Grinder/Pulveriser, Sieves, Trays, scoops, Powder mixer (where required).
5.	Raughan (Oils) (Crushing and Boiling)	100 sq. ft.	Oil expeller, S.S. Patilas oil filter bottle, filling machine, bottle drier, Bhatti.
6.	Shiyaf, Surma, Kajal.	100 sq. ft.	End runner, mixing S.S. vessel.
7.	Marham, Zimad (Ointment)	100 sq. ft.	Kharal, Bhatti, End runner, Grinder, Pulveriser, Triple roller mill (if required).
8.	Qurs (Tab.)	100 sq. ft.	Grinder/Pulveriser, Sieves, power mixer (where needed), Granulator, Drier, Tablet compressing machine, Die punches Trays, O.T. Apparatus, Balance with weights, Scoops, Sugar coating pan, Polishing pan, Heater.
9.	Kushta	100 sq. ft.	Bhatti, Kharal, Sil Batta, Earthen pots.
10.	Murabba	100 sq. ft.	Aluminium vessels 50-100 kgs. Capacity, Gendna, Bhatti.
11.	Capsule	100 sq. ft.	Pulveriser, Powder mixer (where needed), capsule filling machine, Air conditioner, De-humidifier balance with weights, storage containers, glass.
12.	Sharbat and Joshanda	100 sq. ft.	Tinctum press, exhaust fan fitted, bhatti section, bottle washing machine, Filter press gravity filter, Liquid filling tank with tap/liquid filling machine, air oven electrically heated with Thermostatic control, kettle.
13.	Qutoor-e-Chashm and Marham (Eye drops, eye ointment)	100 sq. ft.	Hot air oven electrically heated with Thermostatic control, kettle.
14.	Each manufacturing unit will have a	200 sq. ft.	

	separate area for Bhatti, furnaces, boilers, putta etc. This will have proper ventilation, removal of smoke, prevention of flies, insects, dust etc.		

C. LIST OF EQUIPMENT RECOMMENDED FOR IN HOUSE QUALITY CONTROL SECTION.

(Alternatively unit can get the testing 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.	Microtome
4.	Melting Point Determination Apparatus.	4.	Physical Balance
5.	Refractometer.	5.	Aluminium Slide trays.
6.	Polarimeter.	6.	Stage Micrometer.
7.	Viscometer.	7.	Camera Lucida (Prism and Mirror Type).
8.	Tablet Disintegration Apparatus.	8.	Chemicals, Glass-ware etc.
9.	Moisture Meter		
10.	Muffle Furnace		
11.	Electronic Balance		
12.	Magnetic Stirrer.		
13.	Hot Air Oven		
14.	Refrigerator.		
15.	Glass/Steel Distillation Apparatus		
16.	LPG Gas Cylinders with Burners		
17.	Water Bath (Temperature Controlled).		
18.	Heating Mantles/Hot Plates.		
19.	TLC apparatus with all Accessories (Manual)		
20.	Paper Chromatography apparatus with accessories.		

21.	Sieve size 10 to 120 with Sieve shaker.		
22.	Centrifuge machine		
23.	De-humidifier		
24.	pH Meter.		
25.	Limit Test Apparatus		

Note:

The above requirements of machinery, equipments, space are made subject to the modification at the discretion of the Licensing Authority; if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances in a particular case.

(L. PRASAD)
JOINT SECRETARY
[F.NO.K.11020/5/97-DCC(ISM)]

Footnote: The Principal rules were published in the Official Gazette vide notification No.F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide GSR 648(E) dated 16.9.2002.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Indian System of Medicine and Homoeopathy)

NOTIFICATION

New Delhi, the 3rd February 2003.

G.S.R 76(E) -Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by section 33 N of the Drugs and Cosmetics Act, 1940 (23 of 1940) in the Gazette of India Extraordinary Part II Section 3, sub-section (i), dated the 20th August, 2002 vide No. GSR 607 (E) inviting objections and suggestions from persons likely to be affected thereby and notice was given that the said draft will be taken into consideration after the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the notification were made available to the public;

And whereas the said Gazette was made available to the public on 20th August, 2002;

And whereas objections and suggestion from the public on the said draft have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 33-N of the said Act, the Central Government hereby makes the following further amendments in the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics 1st (Amendment) Rules, 2003.

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

2. In the Drugs and Cosmetics Rules, 1945,

(a) after rule 162, the following shall be inserted, namely:-

"162A-Qualifications for State Drug Licensing Authority for licensing of Ayurveda, Siddha and Unani drugs:

(a) The Ayurvedic/Siddha/Unani qualifications as per Schedule II of CCIM Act 1970/B.Pharma(Ayurveda) of a recognized University.

(b) At least 5 years experience in the Ayurveda/Siddha/Unani drug manufacturing or testing of Ayurvedic, Siddha and Unani drugs or enforcement of provisions of Chapter IV A of the Drugs and Cosmetics Act 1940 and rules made/ thereunder or teaching/research of clinical practice of Ayurveda/Siddha/Unani System".

(L. PRASAD)
JOINT SECRETARY (ISMandH)
[F.NO.K.11024/3/2002-DCC(ISM)]

Footnote:- The Drugs and Cosmetics Rules, 1945 as amended upto 1.5.1979 is contained in the publication of the Ministry of Health and Family Welfare (Department of Health containing the Drugs and Cosmetics Act, 1940) and the Rules (PDGHS-61) and last amended vide GSR No. 648(E) dated 16.9.2002.