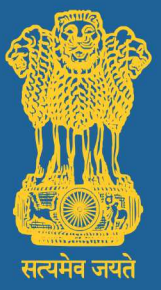

Guidelines For Inspection of GMP Compliance

by Ayurveda, Siddha and Unani Drug Industry

Department of AYUSH

Ministry of Health and Family Welfare
Government of India
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GUIDELINES FOR

INSPECTION OF GMP COMPLIANCE

BY ASU DRUG INDUSTRY

Department of AYUSH,

(Drug Control Cell)

Ministry of Health and Family Welfare,

Government of India.

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Disclaimer: This manual has been prepared on the basis of provisions in the Drugs and Cosmetics Rules, 1945 for inspectors and ASU drug manufacturing units aimed at providing orientation and training about various aspects related to Inspection of Ayurveda, Siddha and Unani drug manufacturing units. The contributors and reviewers have taken due care to ensure correctness of the contents before publication and cannot be held responsible for any omission or inadvertent errors, nor can they warrant that all aspects of the subject have been covered. The manual is a guiding tool and does not have any connotation of legal binding.

Users of this manual are welcome to provide their feedback and suggestions for any improvement to Drug Control Cell, Department of AYUSH, 'B' Block, GPO Complex, INA, New Delhi-110023 by mail or by email at dcc-ayush@nic.in

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CONTENTS AT A GLANCE

INTRODUCTION

Drugs and Cosmetics Act 1940 and Rules thereunder provide for appointment of Inspectors of Ayurveda, Siddha & Unani (ASU) systems of medicines who play significant role in implementation of Drugs & Cosmetics (D&C) Act 1940 and Rules thereunder. One of the important tasks of Inspectors working under the State Licensing Authority of ASU systems is inspection of ASU Drug manufacturing Units before issuing license to manufacture ASU drugs under the provisions of the D&C Act and Rules thereunder.

Training level and experience of Inspectors for the purpose of regulatory implementation varies because qualifications prescribed for Drug Inspectors of ASU drugs vary. The Inspector may be a graduate in Pharmacy/ Pharmaceutical Chemistry/ Medicine (with specialization in Clinical pharmacology or Microbiology) having undergone practical training in the manufacture of ASU drugs or having a Degree/Diploma in A/S/U systems of medicines or possessing Degree in Ayurveda Pharmacy as per the provisions of the Act and Rules thereunder. Under such circumstances when the qualifications and experience levels of inspectors vary, it is important to impart comprehensive knowledge of the D&C Act and Rules thereunder to the inspectors for facilitating uniform implementation of the Act. This is all more important as there is no induction training when the person with requisite qualification is assigned the job of an inspector. In many of the States, due to lack of dedicated manpower for enforcement of provisions of Drugs & Cosmetics Act, ASU doctors working in the Hospitals/ Dispensaries are designated as inspectors usually without any additional capacity building training specifically on analytical aspects. In such a situation this manual becomes even more essential.

This inspection manual covering various aspects about the qualifications, duties and responsibilities of inspectors will be a much needed helpful guide for orientation of ASU inspectors for proper discharge of their duties under D&C Act and Rules thereunder. The Guidelines for Inspection of GMP compliance by ASU drug industry are especially explained in detail for development of insight of the inspectors regarding interpretation and implementation of the Rules. This manual is expected to assist State Licensing Authorities to augment the regulatory capacities of inspectors and develop master trainers as well.

Chapter I

GMP: An Overview

1. *GMP*

Good Manufacturing Practice (**GMP**) is a production and testing practice that helps to ensure a quality product. GMP guidelines are not prescriptive instructions on how to manufacture products. These are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process.

The Good Manufacturing Practices for ASU Drugs as described in Rule 157 of Drugs & Cosmetics Rules 1945 with conditions as specified in Schedule T / GMP are to ensure that:

(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 of acceptable quality

(V) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. 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 Practice (GMP)

2. *Importance of GMP*

Unlike conventional pharmaceutical products, which are usually produced from synthetic materials by means of reproducible manufacturing techniques and procedures, ASU medicines are mainly prepared from materials of herbal origin, which are often obtained from varied geographical and/or commercial sources. As a result it may not always be possible to ascertain

the conditions to which they may have been subjected. In addition, they may vary in composition and properties. Furthermore, the procedures and techniques used in the manufacture and quality control of ASU medicines are often substantially different from those employed for conventional pharmaceutical products.

Because of the inherent complexity of naturally grown medicinal plants and the often variable nature of cultivated ones, the examples of contamination with toxic medicinal plants and/ or plant parts and the number and small quantity of defined active ingredients, the production and primary processing has a direct influence on the quality of ASU medicines. For this reason, application of GMPs in the manufacture of ASU medicines is an essential tool to assure their quality.

3. Basic Principles of GMP

Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation. Basic concepts of all of these guidelines remain more or less similar to the ultimate goals of safeguarding the health of the patient as well as producing good quality medicine.

Although there are a number of them, all guidelines follow a few basic principles:

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.

- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.

- Instructions and procedures are written in clear and unambiguous language.

- Operators are trained to carry out and document procedures.

- Records are made manually or by instruments during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented.

- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.

- A system is available for recalling any batch of drug from sale or supply.

- Complaints about marketed drugs are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective drugs and to prevent recurrence.

There may be many ways for a company to fulfil the GMP requirements while setting up its quality program and manufacturing process. It is the company's responsibility to determine the most effective and efficient quality process.

4. Legal provisions for GMP

The legal provisions related to GMP are described under Drugs and Cosmetics Rules 1945, particularly Rule 151 to 160 and Schedule T.

5. Roles and responsibilities of Inspectors conducting GMP inspection

The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations, or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed in Drugs & Cosmetics Act 1940 and Rules thereunder.

In relation to Ayurvedic, Siddha or Unani drug, an inspector appointed by the Central Government or a State Government under section 33G of Drugs & Cosmetics Act 1940 is called as Inspector.

A person with any of the following qualifications can be appointed as an Inspector:

(a) Degree in Pharmacy/ Pharmaceutical Sciences/ Medicine with specialization in Clinical pharmacology or Microbiology from a University established in India by law and shall have undergone practical training in the manufacture of Ayurvedic (including Siddha) or Unani drug, as the case may be; or

(b) Degree in Ayurvedic or Siddha or Unani System or a degree in Ayurveda Pharmacy, as the case may be, conferred by a University or State Government or a Statutory Faculty, Council or Board of Indian Systems of Medicine recognized by the Central Government or the State Government for this purpose; or

(c) Diploma in Ayurveda, Siddha or Unani Systems, as the case may be, granted by a State Government or an Institution recognized by the Central Government or a State Government for this purpose.

Drugs & Cosmetics Rule 167and 49 may be seen for details.

Any person having any financial interest in the manufacture or sale of any drug cannot be appointed as Inspector in spite of meeting above requirements.

Duties regarding regulation of manufacture for sale of ASU drugs

Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed—

- Inspect,

(i) any premises wherein any ASU drugs is being manufactured and the means employed for standardizing and testing the ASU drugs;

(ii) any premises wherein any ASU drugs is being sold, or stocked or exhibited or offered for sale, or distributed .

- Take samples of any ASU drug,

(i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

(ii) from any person who is in the course of conveying, delivering or preparing to deliver such ASU drugs to a purchaser or a consignee.

- At all reasonable times, with such assistance, if any, as he considers necessary,

(i) search any person, who, he has reason to believe, has secreted about his person, any ASU drugs in respect of which an offence under Chapter IV-A of D&C Act has been, or is being, committed; or

(ii) enter and search any place in which he has reason to believe that an offence under Chapter IV-A of D&C Act has been, or is being committed; or

(iii) stop and search any vehicle, vessel, or other conveyance which, he has reason to believe, is being used for carrying any ASU drug in respect of which an offence under Chapter IV-A of D&C Act has been, or is being, committed, and order in writing the person in possession of the ASU drugs in respect of which the offence has been, or is being, committed, not to dispose of any stock of such ASU drugs for a specified period

not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the ASU drugs, seize the stock of such ASU drugs and any substance or article by means of which the offence has been ,or is being, committed or which may be employed for the commission of such offence. **(Clause c of Section 22 of D&C Act 1940)**

- Examine any record, register, document or any other material object found with any person, or in place, vehicle, vessel or other conveyance referred as above and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the Rules made thereunder.

- A receipt by an Inspector for the stock of any ASU drugs or any record, register, document or any other material object seized by him shall be in Form 16 of Drugs & Cosmetics Rules 1945.

- Require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any ASU drugs in respect of which he has reason to believe that an offence under Chapter IV-A of D&C Act has been, or is being, committed.

- Exercise such other powers as may be necessary for carrying out the purposes of Chapter IV-A of D&C Act or any rules made there under.

- The provisions of the Code of Criminal Procedure, 1973 shall, so far as may be, apply to any search or seizure under Chapter IV-A of D&C Act as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code.

- Every record, register or other document seized or produced as above shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts there from certified by that person, in such manner as may be prescribed, have been taken.

- If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under Chapter IV-A of D&C Act or refuses to produce any record, register or other document when so required as mentioned above, he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorized to inspect the manufacture of Ayurvedic (including Siddha) or Unani drugs—

(i) to inspect not less than twice a year, all premises licensed for manufacture of Ayurvedic (including Siddha) or Unani drugs within the area allotted to him and to satisfy himself that the conditions of the license and the provisions of the Act and the Rules made thereunder are being observed;

(ii) to send forth with to the controlling authority after each inspection a detailed report indicating whether or not the conditions of the license and the provisions of the Act and rules made thereunder are being observed;

(iii) to take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these Rules;

(iv) to institute prosecutions in respect of violation of the Act and the Rules made thereunder.

Every inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian penal Code and shall be officially sub-ordinate to such authority as the Government appointing him may specify in this behalf.

The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it think fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

Standard procedure for drug sample collection by a Drug Inspector

- Where an Inspector takes any sample of an ASU drugs under Chapter IV-A of D&C Act, he shall tender the fair price thereof and may require a written acknowledgement therefor.

- Where the price tendered is refused, or where the Inspector seizes the stock of any ASU drugs, he shall tender a receipt therefore in the Form 17A of Drugs & Cosmetics Rules 1945.

- Where an Inspector takes a sample of a ASU drugs for the purpose of test or analysis, he shall intimate such purpose in writing in the Form 17 of Drugs & Cosmetics Rules 1945, to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively

seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the ASU drug is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the ASU drugs is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the ASU drugs be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

- The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis.

(The Sample for test or analysis to be sent to the Government Analyst shall be sent by registered post or by hand in a sealed package, enclosed together with a memorandum in Form 18-A of Drugs & Cosmetics Rules 1945, in an outer addressed to the Government Analyst. The package as well as the outer cover shall be marked with a distinguishing number. A copy of the memorandum and a specimen impression of the seal used to seal the package shall be sent by registered post or by hand to the Government Analyst. On the receipt of the package from an Inspector, the Government Analyst or an Officer authorized by him in writing in his behalf shall open the package and shall also record the conditions of the seals on the package).

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the ASU drugs;

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

(Section 18A – "Every person, not being the manufacturer of a ASU drugs or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.")

- Where an Inspector takes any action under clause *(c)* of section 22,

(i) he shall use all despatch in ascertaining whether or not the ASU drugs contravenes any of the provisions of the section 33EEC and, if it is ascertained that the ASU drugs does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be take , such action as may be necessary for the return of the stock seized;

(ii) if he seizes the stock of the ASU drugs, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof;

(iii) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the ASU drugs, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

- Where an Inspector seizes any record, register, document or any other material object, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

Duties Regarding Joint Inspection for Approval of Drug Testing laboratories under Rule 160A-J

- 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.

- 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.

- The approved laboratory shall allow the Inspector appointed under the Act to enter with or without prior notice the premises where 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.

6. Role of the Licensing Authority regarding GMP certification

The licensing authority notified by the State Government is responsible for enforcing all the provisions of D&C Rules 1945 related to issue of GMP certification. The detailed provisions will follow in next few pages.

Chapter II

Legal provisions for GMP certification

Rules as in Drugs & Cosmetics Rules 1945 regarding

Manufacture for Sale of Ayurvedic (including Siddha) or Unani Drugs

(Part XVI of D&C Rules 1945)

151. Manufacture on more than one set of premises

If Ayurvedic (including Siddha) or Unani drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

152. Licensing Authorities

For this purpose of this Part the State Government shall appoint such Licensing Authorities and for such areas as may be specified in this behalf by notification in the Official Gazette.

153. Application for licence to manufacture Ayurvedic (including Siddha) or Unani drugs.

(1) An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24-D to the Licensing Authority along with a fee of rupees one thousand:

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case the fee payable for renewal of such licence shall be rupees one thousand and two hundred plus an additional fee of rupees six hundred..

(2) A fee of rupees three hundred shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

153-A Loan Licence

(i) An application for the grant or renewal of a loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24-E to the Licensing Authority along with a fee of rupees six hundred.

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

PROVIDED that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

PROVIDED further that the applicant may apply for renewal after the expiry of one month, but within three months of such expiry in which case the fee payable for renewal of such licence shall be rupees six hundred plus an additional fee of rupees three hundred.

(ii) A fee of rupees one hundred and fifty shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

154. Form of licence to manufacture Ayurvedic (including Siddha) or Unani drugs

(1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-D. The licence shall be issued within a period of three months from the date of receipt of the application.

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

154-A Form of loan licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs

(i) A loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25E.

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

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

155. Certificate of renewal

The certificate of renewal of a licence in Form 25-D shall be issued in Form 26-D.

155-A *Certificate of renewal of a loan licence*

The certificate of renewal of a loan licence in Form 25-E shall be issued in Form 26-E.

155-B Certificate of award of G.M.P. of Ayurveda, Siddha and Unani Drugs

(i) The certificate of Good Manufacturing Practices to manufacturers of Ayurveda, Siddha or Unani drugs shall be issued for a period of five years to licensees who comply with the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha and Unani drugs as laid down in Schedule T.

(ii) The certificate referred to in sub rule (1) shall be issued for a period of five years from the date of issuance of the license.

156. Duration of licence

An original licence in Form 25-D or a renewed license in Form 26-D, unless sooner suspended or cancelled shall be valid for a period of five years from the date of its issue or renewed.

PROVIDED that if the application for the renewal of a licence is made before its expiry or within one month of its expiry, or if the application is made within three months of its expiry after payment of the additional fee of rupees five hundred, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if the application for its renewal is not made within three months of its expiry.

156-A Duration of loan licence

An original loan licence in Form 25-E or a renewed loan licence in Form 26-E, unless sooner suspended or cancelled, shall be valid for a period of five years from the date of its issue or renewed:

PROVIDED that if the application for the renewal of a loan licence is made in accordance with rule 153-A, the loan licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if the application for its renewal is not made within three months of its expiry.

157. Conditions for the grant or renewal of a licence in Form 25-D

Before a licence in Form 25-D is granted or renewed in Form 26-D the following conditions shall be complied with by the applicant, namely —

(1) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.

(a) For issuing of the certificate of Good Manufacturing Practices, the Licensing Authority shall verify the requirements as per Schedule T and issue the Good Manufacturing Practices certificate in Form 26 E-I, simultaneously along with grant or renewal of License in Form 25-D.

(2) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least one person, who is a whole time employee and who possesses the following qualifications, namely —

(a) A degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory

Faculties, Councils and Boards of Indian Systems of medicines recognized by the Central Government or a State Government for this purpose, or

(b) A diploma in Ayurveda, Siddha or Unani system of medicine granted by a State Government or an Institution recognised by the Central Government for this purpose, or

(c) A graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany of a University recognized by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani systems of medicines, or

(d) A Vaid or Hakim registered in a State Register of Practitioners of indigenous systems of medicines having experience of at least four years in the manufacture of Ayurvedic or Siddha or Unani drugs, or

(e) A qualification as Pharmacist in Ayurvedic (including Siddha) or Unani systems of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani drugs as may be recognized by the Central Government.

(3) The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda and the competent technical staff to direct and supervise the manufacture if Siddha drugs and Unani drugs shall have qualification in Siddha or Unani, as the case may be.

157-A Maintaining of records of raw material used by licensed manufacturing unit of Ayurveda, Siddha and Unani drugs in the preceding financial year

Each licensed manufacturing unit of Ayurveda or Siddha or Unani drugs shall keep a record of raw material used by each licensed manufacturing unit of Ayurveda, Siddha or Unani drugs, as the case may be in the proforma given in Schedule TA in respect of all raw materials utilized by that unit in the manufacture of Ayurveda or Siddha or Unani drugs in the preceding financial year, and shall submit the same by the 30th day of June of the succeeding financial year to the State Drug Licensing Authority of Ayurveda, Siddha and Unani drugs and to the National Medicinal Plants Board or any agency nominated by the National Medicinal Plants Board for this purpose.

158. *Conditions of licence*

A licence in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely —

(a) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw material and finished products.

(b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw material as well as finished products, and to inspect the records maintained under these rules.

(c) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

158-A Conditions of loan licence

A licence in Form 25-E shall be subject to the following further conditions, namely:

(i) The licence in Form 25-E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

(ii) The licensee shall comply with the provisions of the Act and of the Rules and with such further requirements if any, as may be specified in any Rules subsequently made under Chapter IV-A of the Act, provided that where such further, requirements are specified in the Rules; these would come into force four months after publication in the Official Gazette.

(iii) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or any other person on his behalf, of the raw materials and finished products.

(iv) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules have been observed.

(v) The licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed.

158-B Guidelines for issue of license with respect to Ayurveda, Siddha or Unani drugs

I. (A) Ayurveda, Siddha Unani Medicines under section 3 (a):-

Ayurveda, Siddha or Unani drugs 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 Ayurvedic, Siddha and Unani Tibb system of medicine, as specific in the First Schedule;

(B). Patent or Proprietary medicine under section 3(h);

(i) In relation to Ayurvedic, Siddha and Unani Tibb system of medicine of all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb system of medicines specified in the First Schedule, but does not include a medicine which is administrated by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

(ii) Balya/Poshak/Muqawi/Unavuporutkal/positive health promoter formulations having ingredients mentioned in books of First Schedule of the Drugs and Cosmetics Act and recommended for promotional and preventive health.

(iii) Saundarya Prasadak (Husane afza)/Azhag-sadhan formulations having ingredients mentioned in Books of First Schedule of the Drugs and Cosmetics Act and recommended for oral,skin, hair and body care.

(iv) Aushadh Ghana (medicinal Plant extracts – dry/wet) extract obtained from plant mentioned in books of First Schedule of the Act including Aqueous or hydro-alcohol.

II. (A) For issue of license to the medicine with respect to Ayurvedic, Siddha or Unani, the conditions relating to safety study and the experience or evidence of effectiveness shall be such as specified in columns (5) and (6) of the Table given below:-

S. No.	Category	Ingredient(S)	Indication(S)	Safety study	Experience/Evidence of Effectiveness	
					Published Literature	Proof of Effectiveness
1.	(A) Ayurveda, Siddha And Unani drugs. Given in 158-B as referred in 3(a)	As per text	As per text	Not Required	Required	Not Required
2.	(B) Any change in dosage form of Ayurveda, Siddha and Unani drugs as described in section 3(a) of the Drugs and Cosmetics Act, 1940	As per text	As per text	Not Required	Required	Not Required
3.	(C) Ayurveda, Siddha And Unani drugs referred in 3(a) to be used for new indication	As per text	New	Not Required	If Required	Required

II. B For issue of license with respect to Patent or Proprietary medicine. The condition relating to Safety studies and experience or evidence of effectiveness specified as follows:-

S. No.	Category	Ingredient(S)	Indication(S)	Safety study	Experience/Evidence of Effectiveness	
1.	Patent or Proprietary medicine	As per text	Textual rationale	Not Required	Of Ingredients	*Pilot study as per relevant protocol for Ayurveda, Siddha and Unani drugs.
2.	Ayurveda, Siddha and Unani drug with any of the ingredients of Schedule E (1) of The Drugs and Cosmetics Act, 1940.	As per text	Existing	Required	Required	Required

(III) For issue of license with respect to Balya and Poshak medicines the person who applies for license is required to submit the following:

(i) Photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st Schedule;

(ii) Conduct safety studies in case the product contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda, Siddha and Unani Drugs formulations;

(iii) For textual indications the safety and effectiveness study is not required.

(IV) For issue of license with respect to Saundarya Prasadak (Husane afza/Azhagu Sodhan) the person who applied for license required to:-

(i) Submit photo copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st schedule;

(ii) Conduct safety studies, in case the formulation contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda, Siddha and Unani formulation;

(iii) For textual indications the safety and effectiveness study is not required.

(V) For issue of license with respect to medicine Ausadh Ghana [extract of/medicinal plant (dry or wet).

S. No.	Category	Ingredient (S)	Indication (s)	Safety study	Experience/Evidence of Effectiveness	
					Published Literature	Proof of Effectiveness
1.	(A) Aqueous	As per Text	As per Text	Not Required	Not Required	Not Required
2.	(A1). Aqueous	As per Text	New indication	Not Required	Not Required	Required
3.	(B) Hydro-Alcohol	As per Text	As per Text	Not Required	If Required	Not Required
4.	(B1) Hydro-Alcohol	As specified	New Indication**	Required	If Required	Required
5.	Other than Hydro/ Hydro-Alcohol	As specified	As specified	Required Acute, Chronic, Mutagenicity and Teratogenicity	If Required	Required

*The standard protocol will also include concept of Anupan, Prakriti & Tridosh etc. published by Central Research Councils Ayurveda, Siddha, Unani and other Government/ Research Bodies.

**New indication means which is other than mentioned in 1st schedule books of Drugs and Cosmetics Act 1940.

159. *Cancellation suspension of licences*

(1) The Licensing Authority may, after giving the licensee an opportunity to show cause within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the drugs to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act and the Rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

160. *Identification of raw materials*

Raw materials used in the preparation of Ayurvedic (including Siddha) or Unani drugs shall be identified and tested, wherever test are available for their genuineness, and records of such tests as are carried out for the purpose and the methods thereof shall be maintained.

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 toensure that:

(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 of acceptable quality.

(v) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. 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 G.M.P.

PART-I

Good manufactring 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 sewerage, drain, public lavatory or any factory which produces disagreeable or obnoxious 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 or moist. The premises used for manufacturing, processing, packaging and labelling 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 or 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 disinfection. 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 or waste products.

(iv) Provided with proper drainage system in the processing area. The sanitary fittings 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 should be separate space for drying of raw material, in process medicine or medicines which 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 of potable quality. Adequate provision of water for washing the premises shall be made.

1.1(D) **Disposal of Waste-** From the manufacturing sections and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off after suitable treatment as per guidelines of pollution control authorities to render them harmless.

1.1(E) **Containers' Cleaning-** In factories where operations involving the use of containers such as glass bottles, vials and jars are conducted, there shall be adequate arrangement 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 the 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, cabins or areas in the raw materials store, care may be taken to handle the following different categories of raw materials:-

(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 & flavours.

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

Each container 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 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 Government and shall be used only on approval after verifying. The rejected raw material should be removed from other raw materials store and should be kept in a 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 closures 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 within an area marked "Quarantine". After the quality control laboratory and the experts have checked the correctness of finished goods with reference to its packing/labelling 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 drug 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 of 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 brushes 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:-

(i) Adequate facilities for first aid;

(ii) Medical examination of workers at the time of employment and periodical checkup 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 team 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, labelling and packing, etc. To ensure ease in movement of workers and orderliness in operations a suitably adequate space will be ensured between two machines or rows of machines. These machinery and 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 and 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 any 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 grindings 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 expiry of the batch, Certain categories 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 up to 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 such complaints to the Licensing Authority. The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha andUnani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or 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's 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/warehouse. Preferably for such quality control there will be a separate expert. The quality control section shall have the following facilities:

(a) There should be 150 sq feet area for quality control section.

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

(c) Manufacturing record should be maintained for the various processes.

(d) To verify the finished products, controlled samples of finished products of each batch will be kept till the expiry date of product.

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

(f) Keep record in establishing shelf life and storage requirements for the drugs.

(g) Manufacturers who are manufacturing patent proprietary Ayurveda, Siddha and Unani medicines shall provide their own specification and control references in respect of such formulated drugs.

(h) 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.

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

(j) All raw materials will be monitored for fungal, bacterial contamination with a view to minimize such contamination.

(k) Quality control section will have a minimum of-

(i) (a) Expert in Ayurveda or Siddha or Unani who possess a degree qualification recognized under Schedule II of Indian Medicine Central Council Act, 1970.

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

(c) A Botanist (Pharmacognosist) who shall possess at least a Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University.

(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 equipment recommended is indicated in Part II-C.

1.2 Requirement for Sterile Product:

(A) Manufacturing Areas– For the manufacture of sterile Ayurvedic, Unani and Siddha drugs, separate enclosed areas specifically designed for the purpose shall be provided. These areas shall be provided with air locks for entry and shall be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas. The filters shall be checked for performance on installation and periodically thereafter the record of checks shall be maintained. All the surfaces in sterile manufacturing areas shall be designed to facilitate cleaning and disinfection. For sterile manufacturing routine microbial counts of all Ayurvedic, Siddha and Unani drug manufacturing areas shall be carried out during operations. Results of such count shall be checked against established in-house standards and record maintained. Access to manufacturing areas shall be restricted to minimum number of authorized personnel. Special procedure to be followed for entering and leaving the manufacturing areas shall be written down and displayed. For the manufacturing of Ayurvedic, Siddha and Unani drug that can be sterilized in their final containers, the design of the areas shall preclude the

possibility of the products intended for sterilization being mixed with or taken to be products already sterilized. In case of terminally sterilized products, the design of the areas shall preclude the possibility of mix-up between non-sterile products.

(B) **Precautions against contamination and mix:**

a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated enclosure within the building,

(b) Using appropriate pressure differential in the process area.

Providing a suitable exhaust system.

(d) Designing laminar flow sterile air system for sterile products.

(e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.

(f) Individual containers of liquids and ophthalmic solutions shall be examined against black-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.

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

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

PART-II

A. List of recommended machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of ayurvedic, siddha system of Medicines

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

S. No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
		1200 Square feet covered area with separate cabins or partitions for each activity. If Unani medicines are manufactured in same premises an additional area of 400 sq. feet will be required.	
1.	Anjana/Pisti	100 sq. feet.	Kharal/mechanized/ motorized Kharal, End runner/ Ball – mill, Sieves/ Shifter.
2.	Churna / Nasya/ Manjan/Lepa/ Kwath Churn	200 sq feet	Grinder/Disintegrator/Pulveriser/ Powder mixer/Sieves/Shifter.
3.	Pills/Vati /Gutika Matirai and tablets	100 sq. feet	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, mechanised chattoo (for mixing guggulu) where required.
4.	Kupi pakava/Ksara/ Parpati/LavanaBhasma Satva/Sindura Karpu/ Uppu / Param	150 sq. feet	Bhatti, Karahi/Stainless steel Vessels/ Patila, Flask, Multani Matti/Plaster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, Mufflefurnace(Electrically operated), End/Edge Runner, Exhaust Fan, Wooden/ S.S.Spatula.
5.	Kajal	100 sq. feet	Earthen 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. feet	Air Conditioner, De-humidifier, hygrometer, thermometer, Capsule filling machine and balance.
7.	Ointment/Marham Pasai	100sq. feet	Tube filling machine, Crimping Machine, Ointment Mixer, End Runner/ Mill (Where required), S.S. Storage Container S.S.Patila.
8.	Pak/Avaleh/Khand/ Modak/Lakayam	100 sq. feet	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, feet	Tincture press, exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, filter press / Gravity filter, liquid filling machine, P.P. Capping Machine.
10.	Asava / Arishta	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 plusDistillation 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/Nasa- bindu	100 sq. ft	Hot air oven electrically heated with thermostatic control, kettle gas or electrically heated with suitable mixing arrangements, collation mill, or ointment mill, tube filling
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, insets, 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. No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
		1200 square feet covered area with separate cabins, partitions for each activity. If Ayurveda / Siddha Medicines are also manufactured in same premises an additional area of 400 square feet will be required.	
1.	Itrifal Tirya/majoon/ Laooq/Jawarish Khamiras	100 sq. feet	Grinder/ Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Bhatti and other accessories, plant mixer for Khamiras.
2.	Arq.	100 sq. feet	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. feet	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
4.	Sufoof (Powder)	200 sq. feet	Grinder / pulveriser, Sieves, Trays, Scoops, Powder mixer (where required).
5.	Raughan (oils) (Crushing and boiling)	100 sq. feet	Oil Expeller, S.S. Patilas, Oil filter bottle, Filling machine, Bottle drier, Bhatti.
6.	Shiyaf, Surma, Kajal	100 sq. feet	End runner, mixing S.S. Vessel.
7.	Marham, Zimad (Ointment)	100 sq. feet	Kharal, Bhatti, End runner, Grinder, Pulveriser, Triple Roller Mill (if required).
8.	Qurs (Tab.)	100 sq. feet	Grinder/Pulveriser, Sieves, Powder 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. feet	Bhatti, Kharal, Sil Batta, Earthen pots.
10.	Murabba	100 sq. feet	Aluminium Vessels 50-100 kgs. Capacity, Gendna, Bhatti.
11.	Capsule	100 sq. feet	Pulveriser, Powder mixer (where needed), capsule filling machine, Air conditioner, De-humidifier, Balance with weights, storage containers, glass.
12.	Sharbat and Joshanda	100 sq. feet	Tinctum Press, exhaust fan fitted, Bhatti section, Bottle washing machine, Filter Press Gravity filter, Liquid filling tank with tap/liquid filling machine, hot air oven electrically heated with thermostatic control, kettle.
13.	Qutoor-e- Chashm and Marham (Eye drops, eye ointment)	100 sq. feet	Hot air oven electrically heated with thermostatic control, kettle.
14.	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, insets, dust etc.	200 sq. ft	

C. List of equipment recommended for in-house quality control section

(Alternatively, unit can get testing done from the Government approved laboratory).

(A)	CHEMISTRY SECTION	(B)	PHARMACOGNOSY SECTION
1.	Alcohol Determination Apparatus (complete set)	1.	Microscope Binoculor.
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, Glassware 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 to120 with Sieve shaker.		
22.	Centrifuge Machine.		
23.	Dehumidifier.		
24.	pH Meter.		
25.	Limit Test Apparatus.		

D. Supplementary guidelines for manufacturing of rasaushadhies or rasamaraunthukul and kushtajat (herb-mineral-metallic compound) of ayurveda, siddha and unani medicines.

These guidelines are intended to complement those provide above and should be read in conjunction with the parent guidelines. The supplementary guidelines are to provide general and minimum technical requirements for quality assurance and control in manufacturing rasaushadhies or rasamaraunthukul and kushtajat (Herb-mineral-metallic formulations). These supplementary guidelines deal with Bhasmas, satwa(of Metals and Minerals origin) Druti parpam, karpu and kushta etc. used in Ayurveda, Siddha and Unani Medicines.

The supplementary GMP guidelines for Rasaushadhies or Rasamaraunthukul and Kushtajat are needed to establish the authenticity of raw drug minerals and metals, in

process validation quality control parameters to ensure that these formulations are processed and prepared in accordance with classical texts and for which safety measures are complied. Only those manufacturing units which have Good Manufacturing Practices for ASU Drugs and supplementary certificate for Rasaushadhies or Rasamaraunthukul and Kushtajat formulations shall be allowed to manufacture the same. Supplementary Good Manufacturing Practices certificate for Rasaushadhies shall be issued by the State Licensing Authority only after thorough inspection by an expert team including Rasashastra experts nominated by the Department of AYUSH.

2. *Manufacturing Process Areas*

For the Manufacturing of Bhasma and Kupipakawa and Rasaaushadhi preparations made from metals and minerals the following specific areas shall be provided, which should be completely segregated from the production areas used for preparations of plants and animals by product based formulations to avoid cross contamination. The following exclusive areas are required for Rasaushadhies or Rasamaraunthukul and Kushtajat.

2.2 (a) Bhatti or Heating Devise Section for Bhasma and Rasaaushadhi:- 100 sq. feet for heating, burning, putta and any heat related work with proper ventilation, exhaust and chimney. This could be tin shed also.

(b) Grinding, Drying and Processing Section for Bhasma and Rasaaushadhi:- 10sq. feet (Manual or mechanical, oven etc.). Drying may be done in a space which is covered by glass or other transparent material to allow entry of sunrays on the material to keep for the purpose. If drying is being in oven the temperature of the same may be selected specific temperature.

(c) Rasaushadhis Related Store:- 100 sq. ft.

The size and Dimensions of each Bhatti section would be so designed ti suit the batch size or quantity of materials to be processed, keeping in mind the processed, keeping in mind the processing is done as per the conditions of Drugs and Cosmetics Act mentioned unde Schedule I official books.

In additions to the fuel prescribed in the schedule books namely coal, fire woods, cow dung cakes etc., use of other heating devices e.g. electrical heating, oil or gas fired furnace and other may be employed so as to provide the required temperature as per the nature of material and object of heating. Depending on the formulation being manufactured, manufacturers may adopt aerobic or anaerobic process. Properly baked and clean earthen pots of other crucibles and glass containers or appropriate design shall be used.

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

Since processing of Rasaaushadhi may introduce heavy metal contamination and cross contamination etc., therefore, cleaning of equipment is particularly important after every process by using appropriate cleaning agent which should not react with material of equipment and must be free unwanted properties e.g. corrosiveness.

2.3 Records shall be maintained specially for temperatures attained during the entire process of Bhasmikaran, while employing different kinds of classical puta, furnace using oil, gas or electricity. Appropriate temperature measuring instrument should be employed such as pyrometer and, pyrograph for manual reading or recording by heat sensors, connected to computer, as the case may be.

In order to handle large quantities, appropriate technology like use of hand operated extruders for making chakrikas or pellets may be adopted. However, such equipment made of aluminium or its alloys should not be used.

Access to manufacturing areas shall be restricted to minimum number of authorised personal only.

3. Quality Control

A. In Process Quality Control

The registers as indicated below should exclusively be maintained for ready reference:-

(a) Shodhan Register with following details:

(1) Sl. No.

(2) Batch no. and Size

(3) Date, time and duration

(4) Name of the Raw-material with Quality reference and quantity

(5) Quantity of Shodhana Dravya

(6) Book reference followed

(7) Methodology

(b) Bhavana and Putta Register with following details:

(1) Sl. No.

(2) Batch no. and Size

(3) Date, time and duration

(4) Name of the material with Quantity of starting materials

(5) Quantity of nirvapya Dravya

(6) Quantity of Bhavana Dravya

(7) Date and Time of Starting and completion of Bhavana or Mardana and duration

(8) Type and Number of Puttas

(9) Time and Date of completion Puttas

(10) Colour and texture of the products or standards

(11) In process tests followed (Bhasma Pariksha and any other tests)

(12) In case heating at a particular temperature is required, record of attainment of that temperature.

(c) Grinding Records Register: (Finished Products/Intermediate Procedure)

(1) Sl. No.

(2) Batch no. and Size

(3) Date, time and duration

(4) Name of the material with Quantity

(5) Name of the equipment (SS/granite)

(6) Duration of grinding

(7) Repeat the grinding if required (number of repetition)

(d) Packing details:

(1) Name of Rasaushadhi

(2) Type of Dosage Form (e.g. Powder, pill tablet etc.)

(3) Weight of Rasaushadhis in each unit.

B. Product Quality Control

The specifications for finished Rasaushadhi are primarily intended to define the quality rather than to establish full characterization, and should focus on those characteristics found to be useful in ensuring the quality. Consistent quality for Rasaushadhi can only be assured if the starting material-metals and minerals are used of pharmacopoeial standards. In some cases more detailed information may be needed on aspects of their process. The manufacture will ensure in-house standards for the uniform quality of products.

Quality testing will be carried out as per official Pharmacopoeia or Schedule books for texts namely, colour, taste, varitaratwa, Rekhapurnatwa, Laghutva, Nirudhumatwa, Dntagree kachakacha, Niruttha, Apunarbhava and Nischandratwa.

The Particle size of products should be tested adopting microscopic fitted with micrometre of particle size analyser or any appropriate other techniques. Required physio-chemical characterization of the product should be undertaken by appropriate analytical equipment. The Standard Manufacturing Process of the product should be evolved/follow up. The disintegration time of pills-vati and tablets should also be recorded.

4. Product recalls

Literature inserted inside the products package should indicate the name, address of the manufacturing unit or email or telephone number for reporting of any adverse drug reaction by physicians or patients. On receipt of such Adverse Drug Reaction report, it will be the responsibility of the manufacturer to ensure the recall the product from the market.

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

5. *Medical Examination of the employees*

Employees engaged in manufacturing should be medically examined periodically at least once a year for any adverse effect of the drug during manufacturing process fir which necessary investigations may be carried out for ensuring that there is no effect of material on the vital organs of the employees. Annual examination reports of the employees shall be made available to statuary inspectors during Good Manufacturing Practices inspections

6. *Self- Inspection*

The release of Rasaushadhis should be under the control of a person who has been trained in the specific features of the processing and quality assurance of Rasaushadhis Personnel dealing with the production and quality assurance of Rasaushadhis manufacturing section should have an adequate training in the specific subject of Rasaushadhis manufacturing. He will be at least a degree holder in Ayurveda/Siddha/ Unani medicine or B. Pharma degree holder in Ayurveda/Siddha/ Unani medicine.

7. *Dosage form of Rasaushadhis*

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

8. *Area Specification/requirement for an applicant companies only to have GMP of Rasaushadhies or Rasamaraunthukul and Kushtajat (Herbo-mineral-metallic compounds) of Ayurveda, Siddha and Unani Medicines:*

S. No.	Category of Medicine/ Manufacturing area	Minimum Manufacturing space required (1500 sq. ft.)	Machinery equipment recommended
1	Pisti/ Grinding area for Bhasma. Phisti, Kushtajat.	100 sq. ft.	Kharal/mechanized/motorized Kharal, End runner/Ball-Mill Sieves/Shifter
2	Powdering area for raw drugs of plant origin giving in Rasaushadhies (Herbo-metallic formulations)	200 sq. ft.	Grinder/ Disintegrator/Pulverisar/Powder mixer/ sieves/ Shifter
3	Pills/Vati/Gutika Matrica and tablets/Habb making area.	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 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/ Lavana Bhasma Satva/Sindura Karpu/Uppu Param/Qushta/ Jawhar	150sq. ft.	Bhatti, Karahi/stainless steel vessels/patila flask, Multani Matti/ palster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, muffle furnace (electrically operated) End/ Edge Runner, Exhaust Fan, Wooden, S.S. Sapatula.
5	Receiving and storing raw material	200 sq. ft.	
6	Quality Control Section	150 sq. ft.	
7	Quarantine/observation	50 sq. ft.	
8	Finished goods store	150 sq. ft.	
9	Rejected Good Store	50 sq. ft.	
10	Bhatti-Putta Area	200 sq. ft.	
11	Area for water and washing etc.	50 sq. ft.	
12	Office	100 sq. ft.	
	Total	1500 sq. ft.	

Note:- The above requirements of machinery, equipment's, 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 (he may do so after recording reasons in writing)

SCHEDULE-TA

(See Rule 157-A)

Form for record of utilization of raw material by Ayurveda or Siddha or Unani Licensed manufacturing units during the financial year.

Identification particulars

Manufacturing License no……..

Issued By ……..……

Name:……..

Address:…….

State:…… Pin Code:…….....……

Telephone:…….. Fax:…….....……

Email:……..

1. Quantity of Medicinal Plants/Extracts/Essential Oils/ Metals/ Animal By-Products/ minerals used During 1st April, to 31st March, of the preceding year (For Productions at the identified facility)

(a) Herbs Used

Common names as in AFI/API	Plant's Botanical name	Quantity Used/ per annum (in kg's)	Sources of Supply					Part Used			
			Traders/ Manufacturers	Forest Collectors	Cultivators	Imported	Total	Whole plant	Root	Leaf	Others

Format of various forms used by Inspectors and other Regulatory Officers.

FORM 1A

Memorandum to the pharmacopoeial laboratory for indian medicine (plim)

From …….

(Full name, Designation and Postal Address of the sender)

Serial No……

To,

The Director, Pharmacopoeial Laboratory for Indian Medicine,

I send herewith under the provisions of section 11(2)/ section 25(4) and section 33-H of the Drugs and Cosmetics Act, 1940, sample(s) of a drug purporting to be …….. for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

1. The distinguishing number on the packet is……..

3. Particular of offence alleged……..

3. Matter on which opinion is required……..

4. A fee of Rs…….. has been deposited in court.

Date …… ..... ……..

Magistrate/ Authorised Signatory

FORM 2A

Certificate of test or analysis from the pharmacopoeial laboratory for indian medicine or government analyst

Certified that the samples, bearing number…….. purporting to be a sample of …….. received on …… with memorandum No. …… dated ……. From …….. has been tested / analysed and that the result of such test / analysis is as stated below.

2. The conditions of the seals on the packet on receipt were as follows:-

*3. In the opinion of the undersigned the sample is of standard quality as defined in the Drugs and Cosmetics Act, 1940 or rules thereunder for the reasons given below.

OR

In the opinion of the undersigned the sample is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 or rules thereunder for the reasons given below.

Note: *Delete whichever is not applicable.

Date (Signature of the Analyst Person – in –Charge of testing)

Place Name & Designation and Seal……

Name & Address of the Laboratory……)

FORM 15

(To be seen in context of section 33EEC)

Order under section 22(1)(c) of the drugs and cosmetics act, 1940 requiring a person not to dispose of stock in his possession

Whereas, I have reason to believe that the stocks of drugs/cosmetics in your possession, detailed below contravene the provisions of Section 18 of the Drugs and Cosmetics Act, 1940;

Now therefore, I hereby require you under clause (c) of sub-section (1) of section 22 of the said Act, not to dispose of the said stock for a period of …….. days from the date of this order.

Date…… Inspector

Details of stock of drugs/cosmetics.

Date…… Inspector

FORM 16

Receipt for stock of drugs or cosmetics for record, register, document or material object seized under section 22(1) (c) or 22(1)(cc) of the drugs and cosmetics act,1940

The stock of drugs or cosmetics or records, registers, documents or material objects detailed below has/ have this day has seized by me under the provisions of clause (c) or clause(cc) of sub- section (1) of Section 22 of the Drugs and Cosmetics act,1940(23 of 1940) from the premises of…….. Situated at……..

Date…… Inspector……..

Details of drugs, cosmetics, records, registers, documents or material objects seized.

Date…… Inspector……

FORM 17

Intimation to person from whom sample is taken

To,

…….

I have this day taken from the premise s of ……situated at ……. samples of the drugs/ cosmetics specified below for the purpose of test or analysis.

Date…… Inspector……..

Details of sample taken

Date…… Inspector…….

FORM 17-A

Receipt for samples of drugs or cosmetics taken where fair price tendered thereof under sub-section (1) of section 23 of the drugs and cosmetics act, 1940 is refused

To,

Whereas I, this …… day of …….. [20]……..have taken, from the premises of …… situated at……. samples of drugs/ cosmetics as specified below,-

Details of samples ……..

And whereas I had offered to pay you rupees …….. as the fair price of the samples of drugs /cosmetics taken:

And whereas, you have refused to accept the fair price tendered thereof;

Now, therefore, I give you this receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date…… Inspector……..

FORM 18-A

Memorandum to government analyst

Serial No……. From……...

To,

The Government Analyst

The portion of sample/ container described below is sent herewith for test or analysis under the provisions of Section 33-H of the Drugs and Cosmetics Act, 1940.

The portion of sample/ container has been marked by me with the following mark.

Details of portion of sample or container with name of ingredients from which it is claimed to be made.

Date…… Inspector……..

FORM 24-D

Application for the grant / renewal of a license to manufacture for sale of ayurvedic / siddha or unani drugs

1. I/We ……of ……hereby apply for the grant /Renewal of a license to manufacture Ayurvedic (including Siddha) or Unani drugs on the premises situated at …….

2. Name of the drugs to be manufactured (with details).

3. Names, qualification and experience of technical staff employed for manufacture and testing of Ayurvedic (including Siddha) or Unani drugs …….

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

Date…….

Signature …….

(Applicant)

Note: The application should be accompanied by a plan of the premises

FORM 24-E

Application for grant or renewal of a loan license to manufacture for sale /ayurvedic (including siddha) or unani drugs

1. I/We* ……of !.....hereby apply for the grant /Renewal of a loan license to manufacture Ayurvedic (including Siddha) or Unani drugs on the premises situated at ……. C/#…….

2. Name of drugs to be manufactured (with details).

3. Names, qualification and experience of technical staff actually connected with the manufacture and testing of Ayurvedic (including Siddha) or Unani drugs in the manufacturing premises.

4. I/We enclose

a) A true copy of a letter from me / us to the manufacturing concern whose manufacturing capacity is intended to be utilised 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 product separately in this behalf.

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

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

Date…….. Signature (Applicant)……

* Enter here the name of the proprietary, partners of Managing Director as the case may be.

! Enter here the name of the applicant firm and the address of 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 license number under which the latter operator.

FORM 25-D

License to manufacture for sale of ayurvedic(including siddha) or unani drugs

No. of license……..

1. ……..is /are hereby licensed to manufacture the following Ayurvedic (Including Siddha) or Unani Drugs on the premises situated at…… under the direction and supervision of the following technical staff-

   a) Technical Staff(name)

   b) Name of the drugs (each item to be separately specify).

2. The license shall be in force from …….. to ……

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

Date of issue……. Signature…….

Designation

Condition of License

1. The license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector , appointed under the Drugs and Cosmetic Act,1940

2. Any change in the technical staff named in the license shall be reported forthwith to the license authority.

3. this license shall be deemed to extend to such additional items as the licensee may intimate to the license authority from time to time, and as may be endorsed by the licensing authority.

4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under license. Where nay change in the constitution of the firm takes place, the current license 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 license has been taken from the licensing authority in the name of the firm with change constitution.

FORM 25-E

Loan license to manufacture for sale of ayurvedic (including siddha) or unani drugs

1. Number of license……..

2. ……of……..is hereby granted a loan license to manufacture for sale Ayurvedic (Including Siddha) or Unani Drugs on the premises situated at…… C/o…….. under the direction and supervision of the following expert technical staff-

   a) Technical Staff (Name)…….

   b) Name of the drugs (each item to be separately specify).

3. The license shall be in force from …….. to ……

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

Date of issue……. Signature…….

Designation

Condition of License

1. The license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector , appointed under the Drugs and Cosmetic Act,1940

2. Any change in the technical staff names in the license shall be reported forthwith to the license authority.

3. This license shall be deemed to extend to such additional items as the licensee may intimate to the license authority from time to time, and as may be endorsed by the licensing authority.

4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under license. Where any change in the constitution of the firm takes place, the current license 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 license has been taken from the licensing authority in the name of the firm with change constitution.

FORM 26-D

Certificate of renewal of license to manufacture for sale of ayurveda/ siddha or unani drugs

1. Certified that license No……. granted on the …….. to Shri/Messer…… for the manufacture of Ayurvedic /Siddha or Unani Drugs at the premises situated at…….has been renewed from……..to……..

2. Name of technical staff…….

3. Name of the drugs each item to be separately specified……..

Date…….. Signature……

Designation……

FORM 26-E

Certificate of renewal of loan license to manufacture for sale of ayurveda/ siddha or unani drugs

1. Certified that license No. ……. granted on the …….. to……..for the manufacture of Ayurvedic /Siddha /Unani Drugs at the premises situated at…….C/o has been renewed from……..to……..

2. Name of technical staff…….

Date…….. Signature……

Designation……

FORM **26E-I**

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 requirements of Good Manufacturing Practices (GMP) of Ayurveda-Siddha-Unani drugs as laid down in scheduled T of the Drugs and Cosmetic Rules, 1945.

This certificate is valid for a period of five years and the Good Manufacturing Practices(GMP) is valid for various dosage forms or Rasaushadhis, as follows:-

Date……..

Place…….

Signature…… Designation……

*Licensing Authority/ Central License Approving Authority

Date of issue…….

* Delete whichever is not applicable.

FORM 35

Form in which the inspection book shall be maintained

(A) The cover of the Inspection Book shall contain the following particulars, namely:-

1 The name and address of the licensee……

2. License number and the date up to which the license is valid…….

(B) (i) The pages of the Inspection Book shall be serially numbered and duly stamped by the Licensing Authority. The pages, other than the first and the last pages, shall have the following particulars:-

Name and designation of the Inspector who inspects the premises of the licensee…….

Date of Inspection……

Observations of the Inspector……

Signature of the Inspector

(ii) The first and last pages of the Inspection Book shall be endorsed by the Licensing Authority with the following words, namely:-

'Inspection Book maintained by M/s ……. situated at …… for license number ……. in Form …… under Drugs and Cosmetics Rules, 1945.

Seal and Signature of the Licensing Authority

Notes:

(1) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment.

(2) The Inspection Book shall be maintained at the premises of the licensee.

(3) The observations made by the Drugs Inspector shall be in triplicate. The original copy shall be retained in the Inspection Book to be maintained in the premises of the licensee. The duplicate copy shall be sent to the Licensing Authority. The triplicate copy shall be taken as record by the Inspector.

FORM 47

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:

3)

Ayurveda and Siddha	Unani
1. Asava and Arista	1 Nabeez Khal (Sirka)
2. Arka-Tinir	2 Majoon and its sub-categories :- Itrifal, Jawarish, Khammera, Laooq halwa
Avaleha and paka-llakam	3. Sufoof, Zuroor, Sunoon
Kvatha Curna-Kutinir Curanam	4. Namak, khar
Guggulu	5. Raughan
Ghrita-Ney	6 Zimad
Churna-Curanam	7 Habb (Pill)
Taila-Tailam	8 Shiyaf
Dravaka-Tiravakam	9 Qutoor (drops)
Lavana-Uppu	10 Kohal (Surama), Kajal
Kshara-Saram	11 Satt, Usara
Lepa-Pacai	12 Kushta
Vati, Gutika-Kulika	13 Joshanda (single drugs)
Vartti	14 Sharbat, sikanjabeen
Netrabindu (Aschyotan)	15 Sayyal, Arq (Distillates)
Ajana-Kanmai	16 Qurs (Tablet)
Sattva-Sattu	17 Marham, Qairoota
Kupipakva Rasayan-Kuppi Centuram	18 Humool, Furzaja
Parpati	19 Bakhoor
Pishti	20 Nabati advia
Bhasma-Parpam	21 Maadni advia
Mandura-Atai-Kutinir	22 Ajsad Advia

Rasayoga-Centuram	23 Haiwani Advia
Lauha	24 Jauhar
Ghana Sattva	25 Natool
Kvath Pravahi-kutinir	26 Nashooq, Naswar
Panak (Syrup)- Manappaku	27 Shamoom
Tablet- Mattirai	28 Saoot(Nasai drops)
Capsule	29 Mazoogh
Ointment-Kalimapu	30 Tila
Phalavarti	31 Lashooq
Dhoomravarti/ Doopan	32 Gulqand
Kshar sutra/ Kshar Varti	33 Fateela
Single drugs: Plant based, Mineral based, Metal based Animal based, Synthetic Any other Ayurvedic , Siddha and Unani formulation	34 Ghaza, Ubtan, Sabhgh
Pushp (Phool)	35 Capsule
Nasya	36 Huqna
Swarsasa (Fresh Juice)	37 Naurah
Karna Bindu (Ear Drop)	38 Latookh
Any other dosage form of Patent and Proprietary and Ayurvedic, Siddha and Unani Drug.	39 Vajoor (Throat pain)
	40 Mazmazah (Mouth washer)

4. Names, qualifications and experience of experts employed for testing and the person –in – charge of testing.

5. List of testing equipment provided.

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

7. An inspection fee of rupees…….. has been credited to Government under the head of Account…….

Date…… Inspector……..

* Delete whichever is not applicable Full address of the applicant

FORM 48

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

Number of approval and date of issue

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

   Categories of Ayurvedic, Siddha and Unani drugs.

2. Name of the 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 condition s stated below and such other conditions as may be specified in the rules for the times being in force under the Act.

Signature …….

Designation…….

Date…….

Seal of State Licensing Authority

Place…….

CONDITIONS OF APPROVAL

1. This approval and any certificated 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 the any category of Ayurvedic, Siddha and Unani drugs it should apply to approving authority for necessary endorsement as provided in Rule160-B. This approval will be deemed to extend to this 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 b 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 take 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 constitutions.

FORM 49

Certificate of renewal 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.

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 and Unani drugs and the raw materials used in manufacture thereof at the premises situated at……..has been renewed from …… to…….(Date).

   Categories of Ayurvedic, Siddha and Unani drugs.

   ……..

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

Date…….

Place……. Signature…….

Designation…….

Seal of State Licensing Authority

Chapter III

Stepwise points for conducting GMP inspection
CHECKLIST OF GMP FOR DRUG INSPECTORS

CHECKLIST OF GMP INSPECTIONFOR DRUG INSPECTORS

S. No	GMP Clause	Areas/Activities to be Audited	Observations	
			Document Review	Remark
1.		**GENERAL**		
		Name and address of Unit MFG.Lic No. Telephone Fax: Email: Names and designation of the inspection team:		
2.		**PERSONAL**		
		Name of In charge a) production b) quality control		
		Number of Production Supervisors/Asstt. Mfg./Chemist		
		Number of Analysts		
		Have all personal received GMP Training?		
		Is Training Documented?		
		What is the periodicity of the training?		
3.		**FACTORY PREMISES**		
		Does manufacturing unit have adequate space for Receiving and storing raw material. Manufacturing process areas. Quality control section. Finished goods store. Office Rejected goods/drugs store.		

4.	**1.1 (A)**	**LOCATION AND SURROUNDINGS**		
		Is the establishment located away from environmentally polluted areas?		
		Is the establishment located away from areas adjacent to open sewerage, drain/public lavatory or any factory which produces excessive, disagreeable odour.		
		Are sewage, trash and other effluent disposal provided?		
5.	**1.1 (B)**	**BUILDINGS**		
		Do the internal design and layout of establishment permit good hygiene practices including protection from cross-contamination?		
		Are surfaces of walls, partitions and floors made of impervious materials and capable of being kept clean?		
		Do walls and partitions have smooth surface?		
		Are floors constructed to allow adequate cleaning and drainage?		
		Are doors, windows, ceiling and overhead fixtures constructed and finished to minimize buildup of dirt, condensation and shedding of particles and easy to clean?		
		Are working surfaces that come into direct contact with drugs of sound condition, durable and easy to clean, maintain and disinfect? Any open drain blocked sewer or public lavatory nearby? Are any products other than drugs manufactured in the same building?		
		Is there adequate space for equipment, material and movement of personal and materials?		
		Is there any programme/system to check of birds, rodents and insects?		
		Are lightening and ventilation adequate?		
		Are facilities for changing street clothes, footwear, washing and toilets adequately and satisfactorily maintained?		
		Is the space for drying of raw materials satisfactory?		

6.	**1.1 (C)**	**WATER SUPPLY**		
		Is there adequate supply of potable water?		
		Does the potable water meet the specifications published API specifications?		
		Is only potable water Used in ASU medicines?		
7.	**1.1 (D)**	**DISPOSAL OF WASTE**		
		Are drainage and water disposal systems designed, constructed and maintained in such a way as to avoid contamination of ASU products?		
		Are the waste water and residues disposed of after suitable treatment as per guidelines of pollution control authorities?		
		Are the arrangements for the following adequate? Disposal of solid/semi solid waste Disposal of sewage Disposal of Liquid laboratory waste? Disposal of Management of gaseous pollutants?		
		Is efficient treatment plant in existence / if yes, give comment on it?		
		Are fume hoods of adequate design in existence and used wherever necessary?		
8.	**1.1(E)**	**CLEANING OF CONTAINERS**		
		Is there proper arrangement for washing, cleaning and drying of containers? Is this area separated from manufacturing area?		
9.	**1.1(F)**	**STORES**		
		Is there independent adequate space for storage of different types of materials such as raw material, packaging material and finished products?		
		Are ASU medicine storage facilities designed and constructed to Permit adequate maintenance and cleaning? Avoid pest ace and harbourage? Enable drugs to be effectively protected from contamination? Provided the necessary environment to prevent spoilage?		

		Are storage facilities deigned, constructed and maintained to ensure that malicious or accidental contamination of ASU medicines with harmful materials is prevented?		
10.	**1.1(F)(A)**	**RAW MATERIALS STORES**		
		Are raw materials or ingredients checked for parasites, undesirable microorganisms, pesticide or decomposed or extraneous substances		
		Are raw materials or ingredients inspected and tested before processing?		
		Are raw materials or ingredients subjected to effective stock rotation?		
		Is the area adequate?		
		Are the ventilation and lighting of stores adequate?		
		Is the Raw Material store segregated for different types of Raw Material? Raw materials of metallic origin Raw materials of mineral origin Raw materials of animal source Fresh herbs Dry herbs or plant parts Excipients etc. Volatile oils/perfumes and flavours Plant extracts and exudates/resins Others		
		Is special area with special condition provided for special Raw Materials?		
		Are there labels for material of different status i.e. quarantine, tested and releases for use and rejected?		
		Are these labels of different colours?		
		Are labels on containers of RM to be used in manufacture checked with regard to identity, quantity and QA approval? If not give details/		

		Is there the following information on the labels? Name of material Batch number Analysis number Date of release/rejection? Date of testing? Date of expiry?		
		Is the sampling performed by quality control personal?		
		Are there sampling procedures?		
		Are the containers provided for storage of raw material suitable to preserve the quality?		
		Is exterior storage available for : Solvent storage area? Inflammable material storage area? Whether safety measures provided have been assessed by regulatory agency if any? Is SOP's available for handling of these materials? Are SOP's for cleaning of containers and closures available before packing of products?		
		Is the weighing area segregated?		
		Are lighting and ventilation adequate?		
		Is the area clean?		
		Do the personal wear appropriate clothing?		
		Is there danger of cross contamination during weighing?		
		Are the scales and balance calibrated regularly and records maintained?		
		Are the containers of the raw materials to be weighed, cleaned before opening?		
		After weighing, are these containers sealed?		
		Are the raw materials for each batch, after weighing properly identified and checked? Are adequately clean and dried equipment used for dispensing materials from the containers?		
		Is FIFO principle adopted?		

11	**1.1 (F)(B)**	**PACKING MATERIALS**		
		Is the area adequate with reference to packing material?		
		Are the containers and closures adequately cleared and checked?		
12.	**1.1 (F)(C)**	**FINISHED GOODS STORES**		
		Is the area adequate with reference to materials stored?		
		Are lighting and ventilation adequate?		
		Are there inventory records to show:		
		Quantities		
		Batch number		
		Date of receipt		
		Have the distribution records been maintained?		
		Do distribution records provide sufficient information for drug recall purpose?		
		Is there segregation area for retrieved good?		
		Are records available for the retrieved goods?		
		Is there any marked quarantine area?		
		Is there space for special storage conditions (environmental condition), if required?		
13.	**1.1 (G)**	**WORKING SPACE**		
		Is space adequate as per manufacturing operations?		
		Is machinery alongwith working manual orderly placed with adequate space?		
		Are there adequate precautions to check cross contamination?		
14.	**1.1 (H)**	**HEALTH ,CLOTHING, SANITATION AND HYGIENE OF WORKERS**		
		Are workers free from contagious disease?		
		Are workers properly uniformed?		
		Are there separate lavatories for men and women?		

		Is there provision for changing their cloth and to keep personal belongings?		
		Are adequate facilities like wash-basin with running water hand drier & clean towels, etc., available for personal hygiene before entering into production area?		
		Are personnel instructed to observe personal hygiene?		
		Are hygiene instructions displayed in change rooms and strategic locations?		
		Is the sanitation system monitored for effectiveness?		
		Is the sanitation system periodically verified by inspections? Is microbiological sampling of environment and ASU drugs contact surfaces carried out?		
		Is the sanitation system regularly reviewed and adapted to reflect changed circumstances?		
15	**1.1(I)**	**MEDICAL SERVICES**		
		Is medical file of each worker maintained separately?		
		Is recruitment of an employee preceded by medical examinations?		
		What is the periodicity of subsequent medical examinations?		
		Is an employee whose state of health is doubtful immediately removed from work site until he is fully recovered?		
16.	**1.1 (J)**	**MACHINERY AND EQUIPMENT**		
		Is manually operated or semioperated or automatic machines are used for Crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labelling and packing ?		
		Are equipment and containers coming into contact with ASU drugs designed such that they can be adequately cleaned, disinfected and maintained?		
		Are equipment made of nontoxic materials?		
		Are equipment used to cook, heat, treat, cool, store designed to achieve the required temperature as rapidly as necessary?		
		Are equipments used to cook, heat, treat, cool, store designed to monitor and control the required temperature?		

		Are containers for waste suitably identified?		
		Are containers for waste closable to prevent malicious or accidental contamination of ASU Medicines?		
		Is the equipment adequate for intended use?		
		Is it constructed in such a way that lubricants, coolant, etc. cannot contaminate the drug product?		
		Does the equipment permit cleaning and maintenance?		
		Does the equipment show its status i.e. clean, dirty, batch contents?		
		Do all apparatus/equipment bear appropriate labels to identify the product for which the equipment is used, its batch no., date of manufacturing etc.		
		Are SOPS available for cleaning maintenance and sanitation of major equipment?		
		Are log books maintained for cleaning maintenance and sanitation of major equipment?		
		Are SOP's readily available to operators		
		If automatic electronic or mechanical equipment is used ,are there: Written programs for calibration/inspection Checks to ensure that may changes are made only by authorized persons/ Are suitable closures or lids available to protect the changes in properties of material exposed to outside atmosphere?		
17.	**1.1(K)**	**BATCH MANUFACTURING RECORDS**		
		Are appropriate records of processing, production and distribution kept?		

		Are SOP's available for the following Receipt of raw material and other components? Quarantine and storage? Quality control system and approval/rejection Release of production In process testing and control Finished product? Storage of finished product? Distribution Returned goods Recalls and complaints Cleaning and maintenance? Quality control of water For reworking of non-conforming batches in existence? If yes, check)		
		Are there additional documents like log books, notebooks or other similar records available to show execution of various functions?		
		Are there records of receipts of materials and do these have following information? (goods receipt Note-GRN) Receiving GRN documents number? Date of receipt? Supplier? Manufacturer? Manufacture's batch number? Type and size of containers? Number of containers and conditions?		
		Are specifications available for all materials?		
		Are they dated authorized?		
		Are test methods validated?		
		Are periodic reviews of specification carried out to ensure compliance with new /revised National/international pharmacopoeia?		

		Are these records of stock and issue of raw materials and do these have following information: Opening balance? Date of receipt? Quantity received? Name and batch number assigned by the manufacturer? Invoice number,date name and address of supplier? Analysis receipt no. and date? Date of expiry ,if any? Name and batch number of product for manufacture for which issued? Balance? Signature of issuing person?	`	
		Are there master formulation records for each drug product being produced?		
		Is there a separate master production documents for each dosage form/batch size?		
		Are these master production records signed and dated by competent person?		
		Is a batch production record prepared for every batch produced?		
		Is it reproduction of the appropriate master production documents or it has all critical information about the batch?		
		Are batch records retained for at least one year after expiry date?		
		Has it been checked for accuracy, signed and dated by a responsible person?		

		Are the records maintained by QC for all the tests carried out? Do these records include: The name of the product Number of the batch being manufactured? Issue slip with lab ref. No Job cards? Graphs, chart, spectra, etc? List of major equipment used? In-process testing reports? Calculations of yield? Notes on deviations with signed authorization? Signature of individuals of who performed the tests? Material returns to store slip? Lab report of final product? Review of results for any raw material issued under "positive Recall"? Signature of the designated person responsible for the review of records for accuracy and compliance with established standards?		
		Are other associated records available?		
		Is documentation available readily for examination?		
		Are batch production records capable of giving complete history of the batch right from the raw material stage to the distribution of finished products?		
18	**1.1(L)**	**DISTRIBUTION RECORD**		
		Are records of sale and distribution of each batch of ASU drugs maintained? Are records maintained at least up to 5 years of the exhausting of stock?		
19	**1.1 (M)**	**RECORD OF MARKET COMPLAINTS**		
		Are the firm maintain a record of complaint received from market?		
		Does the firm have investigated the complaint and has taken any corrective action?		

		Does the firm has intimated such complaint six monthly to the Licensing Authority?		
		Does the firm maintain register of any ADR report received?		
		Are written procedure available for receipt and control of return products?		
		Are returned or salvaged drug products destroyed unless QC determines their reprocessing?		
		Are records of the returned products maintained including their disposition?		
		Is a safety manual available?		
20.	**1.1 (N)**	**QUALITY CONTROL**		
		Is the QC area more than 150 sq ft?		
		Has Quality Control section minimum of: a) One person with Degree qualification in Ayurveda/ Siddha/Unani; b) One chemist with bachelor in Science or Pharmacy or Pharmacy (Ayurveda) and; c) One Botanist (Pharmacognosist) with bachelor in Science (medical) or Pharmacy or Pharmacy (Ayurveda)?		
		Are master control procedures signed and stated by authorised persons?		
		Do these control procedure include specifications, test procedure or other control procedure for:		
		Raw materials		
		In process materials		
		Packaging and labelling materials?		
		Finished products?		
		Are the procedure in written form and readily available to QC personnel for acceptance of reprocessed material?		
		Are the procedure in written form and readily available for acceptance of reprocessed material?		
		Do these control procedure include specifications test procured or other control procedure for :		

		Raw material		
		In process material		
		Packaging and labelling materials		
		Finished products?		
		Are samples collected by QC personal		
		Is there special room for microbiological and sterility testing?		
		Is the environment of room controlled?		
		Are only materials, containers and appliance necessary for the job in hand stored in the vicinity of the manufacturing areas and are these properly labelled with name of the product, batch no. date etc.?		
		Are all raw materials, containers, closures, label and printed packaging material approved and released by QC for use in manufacture of drugs products		
		Are in-process controls carried out by QC personnel?		
		Are semi-finished products tested for appropriate tests when necessary?		
		Is bulk finished product tested for established specifications before packing?		
		Is every finished product tested for established specifications before release for sale?		
		Does the QC maintain records of all the tests carried out?		
		Does the QC review all production and control records to ensure compliance with established written procedure before a batch of the product is released for sale?		
		Reference standards: Are reference standards (R.S) available? Are these RS or working standards (WS)? Are WS standardised against RS or CRS? Are RS stored properly (at appropriate temperature under dehumidified conditions)? Are records of R.S and their standard maintained?		

		Are samples in sufficient quantity for testing twice retained of starting materials and finished products for future examination, in case of need?		
		Are quality control procedures validated?		
		Is written programs available for stability including the following:		
		Sample storage condition		
		Room temperature?		
		Sample size and test intervals?		
		Reliable and specific test methods?		
		Testing in the same containers closure system in which it is marketed?		
		Date and expiration date if any?		
		Established of in-house specification?		-
		Does the firm provided the equipment as recommended in Part II C ?		
21	**1.2**	**REQUIREMENT FOR STERILE PRODUCT**		
		Manufacturing areas		
		Is there separate manufacturing area		
		Are their air locks for entry?		
		Is there dust free and ventilated for air supply		
		Precautions against contaminations and mix.		
		Are manufacturing operations being carried out in a separate block of adequately isolated building		
		Is there appropriate pressure differential in the process area.		
		Is suitable exhaust system provided?		
		For asceptic manufacturing proper air supply (filtered through HEPA) provided?		

Chapter IV

Modalities for issuance of WHO GMP Site Certificate and CoPP for Herbal Products.

Many importing countries ask for Certificate of Pharmaceuticals Product (CoPP) during import of Herbal products.

1) Those who want to take WHO-GMP certificate for herbal medicine have to submit application to Drugs Controller General (India), giving following information for each product:

   i) Name and address of manufacturing facility.

   ii) Name of the contact person of product license holder.

   iii) Name and dosage form of product.

   iv) Name and amount of active ingredient(s) per unit dose (International Non-proprietary Name(s) where such exist(s).

   v) Formula (complete composition including all excipients; also particularly when no product license exists or when the formulation differs from that of the licensed product)

   vi) Product information for health professionals and for the public (patient information leaflets) as approved in the exporting country.

2) A "Site Master File" has to be submitted as recommended in the WHO technical report series.

3) The Drugs Controller General (India), in consultation with Department of AYUSH will fix the date of inspection.

4) Drugs Controller General (India) will constitute inspection team/ Committee comprising:

   a) Expert from Department of AYUSH

   b) Nominee of DCG(I)

   c) State Drugs Controller/Licensing Authority

5) Inspection team/ Committee will make inspection as per the Check list and submit report to DCG(I).

6) The recommendation of the Inspection team/committee, will be examined by DCG(I) and if found suitable, DCG(I) will issue Certificate of herbal Pharmaceutical Products.