GUIDELINES FOR

INSPECTION OF GMP COMPLIANCE

BY HOMOEOPATHIC DRUG INDUSTRY

Government of India
Ministry of AYUSH
(Drug Control Cell)

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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 Homoeopathic drug manufacturing units aimed at providing orientation and training about various aspects related to Inspection of Homoeopathic 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, Ministry of AYUSH, 'B' Block, GPO Complex, INA, New Delhi-110023 by mail or by email at dcc-ayush@nic.in

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Introduction

Drugs and Cosmetics Act 1940 and Rules, 1945 thereunder provide for appointment of Inspectors of Homoeopathic system of medicine 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 Homoeopathic system is inspection of Homoeopathic Drug manufacturing Units before issuing license to manufacture Homoeopathic drugs under the provisions of the Drugs & Cosmetics Act and Rules thereunder.

Training level and experience of Inspectors for the purpose of regulatory implementation varies because of the qualifications prescribed as graduate in Pharmacy/ Pharmaceutical Chemistry/ Medicine (with specialization in Clinical pharmacology or Microbiology). This is all more important as there is no induction training when the person with requisite qualification is assigned the job of an inspector.

This inspection manual covering various aspects about the qualifications, duties and responsibilities of inspectors will be a much needed helpful guide for orientation of Homoeopathic inspectors for proper discharge of their duties under D & C Act and Rules thereunder. The Guidelines for Inspection of GMP compliance by Homoeopathic 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 Homoeopathic Drugs as described in Sub-Rule (2) of Rule 85E of Drugs & Cosmetics Rules, 1945 with conditions as specified in Schedule 'MI' 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.

(2) Importance of GMP

Unlike conventional pharmaceutical products, which are usually produced from synthetic materials by means of reproducible manufacturing techniques and procedures, Homoeopathic medicines are mainly prepared from materials of herbal and animal 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 Homoeopathic 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

Homoeopathic medicines. For this reason, application of GMPs in the manufacture of Homoeopathic 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.

(4) Legal provisions for GMP

The legal provisions related to GMP are specified in Schedule ‘M1’ under Sub-Rule (2) of Rule 85(E) of Drugs and Cosmetics Rules 1945.

(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 Homoeopathic drug, an inspector appointed by the Central Government or a State Government under section 21 of Drugs & Cosmetics Act 1940 is called as Inspector.

A person with any of the following qualifications mentioned in lines of Schedule M-I and Rule 49 of the Drugs & Cosmetics Act 1940 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 Homoeopathic drug, as the case may be; or
(b) Degree in Homoeopathy System or a degree in Homoeopathy Pharmacy, as the case may be, conferred by a University or State Government or a Statutory Faculty, Council or Board of Homoeopathy recognized by the Central Government or the State Government for this purpose; or
(c) Diploma in Homoeopathic System, 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.

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.

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.

Duties regarding regulation of manufacture for sale of Homoeopathic 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 Homoeopathic drug is being manufactured and the means employed for standardizing and testing the Homoeopathic drugs;
  ii. any premises wherein any Homoeopathic drug is being sold, or stocked or exhibited or offered for sale, or distributed .

- Take samples of any Homoeopathic 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 Homoeopathic 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 Homoeopathic drug in respect of which an offence under 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 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 Homoeopathic drug in respect of which an offence under D&C Act has been, or is being, committed, and order in writing the person in possession of the Homoeopathic drugs in respect of which the offence has been, or is being, committed, not to dispose of any stock of such Homoeopathic 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 Homoeopathic drugs, seize the stock of such Homoeopathic 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 Homoeopathic 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 Homoeopathic drugs in respect of which he has reason to believe that an offence under D&C Act has been, or is being, committed.

- Exercise such other powers as may be necessary for carrying out the purposes 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 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 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 Homoeopathic drugs—

i. to inspect not less than twice a year, all premises licensed for manufacture of Homoeopathic 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 the Drugs and Cosmetics Rules, 1945;
iv. to institute prosecutions in respect of violation of the Act and the Rules made thereunder.

Standard procedure for drug sample collection by a Drug Inspector

- Where an Inspector takes any sample of a Homoeopathic drugs under 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 Homoeopathic drugs, he shall tender a receipt therefore in the Form 17A of Drugs & Cosmetics Rules 1945.
- Where an Inspector takes a sample of a Homoeopathic 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 HOMOEOPATHIC drug is being manufactured, it shall be necessary to divide the sample into three portions only:

  Provided further that where the HOMOEOPATHIC drugs is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the HOMOEOPATHIC 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 HOMOEOPATHIC 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 HOMOEOPATHIC drug 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 HOMOEOPATHIC drugs contravenes any of the provisions of the section 18 and, if it is ascertained that the HOMOEOPATHIC 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 HOMOEOPATHIC 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 HOMOEOPATHIC 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 150B-K

- Before an approval in Form 36 is granted, the approving authority shall cause the laboratory at which the testing of Homoeopathic 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 150-F 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

[PART VIIA-Rules as in Drugs and Cosmetic Rules, 1945 regarding Manufacture for sale[or for distribution] of Homoeopathic medicines

85A . *Manufacture on more than one set of premises*..

If Homoeopathic medicines are manufactured in 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.

85B. *Application for licence to manufacture Homoeopathic medicines*.—

(1) *to manufacture Homoeopathic medicines*.¯(1) Application for grant or renewal of [licence to manufacture for sale or for distribution] of Homoeopathic medicines shall be made to the Licensing Authority appointed by the State Government for the purpose of this Part (hereinafter in this Part referred to as the Licensing Authority) and shall be made in Form 24-C.

[(2) The application in Form 24-C shall be accompanied–

(*a*) by a fee of [rupees two hundred] for the manufacture of Homoeopathic mother tinctures and potentised preparations and an inspection fee of [rupees one hundred] for the first inspection or [rupees fifty] in case of inspection for renewal of licence;

(*b*) by a fee of [rupees two hundred] for the manufacture of Homoeopathic potentised preparations only, and an inspection fee of [rupees one hundred] for the first inspection or [rupees fifty] in case of inspection for renewal of licence;

(*c*) by a fee of [rupees two hundred] for the manufacture of potentised preparations from back potencies by pharmacies which are already licensed to sell Homoeopathic medicines by retail and an inspection fee of [rupees one hundred] for the first inspection or [rupees fifty] in case of inspection for renewal of licence.

(3) If a person applied for renewal of a license after its expiry but within six months of such expiry, the fee payable for the renewal of such a license shall be-

(a) [rupees two hundred] plus an additional fee at the rate of the [rupees one hundred] per month or part thereof an inspection fee of [rupees fifty] for the manufacture of Homoeopathic mother tinctures and potentised preparations;

(b) [rupees two hundred] plus an additional fee at the rate of [rupees one hundred] per month or part thereof an inspection fee of [rupees fifty] for the manufacture of Homoeopathic potentised preparations only];

(c) [rupees two hundred] plus an additional fee at the rate of [rupees one hundred] per month or part thereof and an inspection fee of [rupees fifty] for the manufacture of potentised preparations from back potencies by pharmacies who are already licensed to sell homoeopathic medicines by retail.]

(4) A fee of [rupees fifty] shall be paid for a duplicate copy of the licence for the manufacture of Homoeopathic mother tinctures and potentised preparations issued under sub-rule (1) if the original is defaced, damaged or lost, while the fee to be paid for such a duplicate copy of the licence for the manufacture of Homoeopathic potentised preparations only shall be [rupees fifty].

[(5) Applications by licensee to manufacture additional items of Homoeopathic medicines shall be made to the Licensing Authority and such applications shall be accompanied by a fee of [rupees fifty] for each additional item.]

85C. *Application to manufacture 'New Homoeopathic medicines.'*—Subject to the other provisions of these Rules—

(1) no 'New Homoeopathic medicine' shall be manufactured unless it is previously approved by the Licensing Authority mentioned in Rule 21;

(2) the manufacturer of 'New Homoeopathic medicine', when applying to the Licensing Authority mentioned in sub-rule (1) shall produce such documentary and other evidence as may be required by the Licensing Authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.

(3) While applying for a licence to manufacture a 'New Homoeopathic medicine' an applicant shall produce along with his application evidence that the 'New Homoeopathic medicine' for the manufacture of which application is made has already been approved.

Explanation.—The term 'New Homoeopathic medicine' in this rule shall have the same meaning as in rule 30AA.

[**85D**. *Form of licence to manufacture Homoeopathic medicines*.—Licence for manufacture of Homoeopathic medicines is a licence to manufacture potentised preparations from back potencies by Pharmacies who are already licensed to sell Homoeopathic medicines by retail and shall be granted in Form 25C.]

85E. *Conditions for the grant or renewal of a licence in Form 25C*—Before a licence in Form 25C is granted or renewed the following conditions shall be complied with by the applicant:—

(1) The manufacture of Homoeopathic medicines shall be conducted under the direction and supervision of competent technical staff consisting at least of one person who is a whole time employee [and who is—

(a) a graduate in Science with Chemistry as one of the subjects with three years' experience in manufacture of Homoeopathic Medicines; or

(b) a graduate in Pharmacy with 18 months of experience in the manufacture of Homoeopathic medicines; or

(c) holds qualification as defined under sub-clause (g) of clause (1) of section 2 of Homoeopathy Central Council Act, 1973 (59 of 1973) with 18 months of experience in the manufacture of Homoeopathic medicines:

Provided that the persons who are already in employment with five years' experience in the manufacture of Homoeopathic medicines and whose name was accordingly entered in any licence granted in Form 25C for manufacture of different classes of Homoeopathic medicines included in them shall be deemed to be qualified for the purpose of this rule.]

[(2) The factory premises shall comply with the requirements and conditions specified in Schedule M-I:

Provided that where the Licensing Authority considers it necessary or expedient so to do, it may having regard to the nature and extent of manufacturing operations, relax or suitably alter the said requirements or conditions in any particular case for reasons to be recorded in writing.]

(3) The applicant for manufacture of Homoeopathic mother tinctures shall either (i) provide and maintain adequate staff, premises and laboratory equipment for identifying the raw materials and for testing the mother tinctures wherever possible, or (ii) make arrangements with some institution approved by the Licensing Authority under Part XV(A) of these Rules for such tests, wherever possible, to be regularly carried out on his behalf by that institution.

(4) The premises where Homoeopathic medicines are manufactured shall be distinct and separate from the premises used for residential purposes.

(5) Homoeopathic medicines shall not be manufactured simultaneously with drugs pertaining to other systems of medicine.

(6) The applicant shall make arrangements for proper storage of Homoeopathic medicines manufactured by him:

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

[**85-EA.** *Inspection before grant or renewal of licence.*-- Before a licence under this Part is granted or renewed in Form 25C or Form 26C, the Licensing Authority shall cause the establishment, in which the manufacture is proposed, to be conducted or being conducted, to be inspected by one or more Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the substances to be manufactured and inquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the requirements of plant and equipment as laid down in Part I of Schedule M read with the requirements of maintenance of records as laid down in Schedule U.

85EB. *Report by Inspector*.–The Inspector or Inspectors shall forward a detailed descriptive report giving his or their findings on each aspect of inspection along with his or their recommendations after completion of his or their inspection to the Licensing Authority.

85EC. *Grant or refusal of licence.*– (1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary is satisfied that the requirements of the rules under the Act have been complied with and that conditions of the licence and the rules under the Act shall be observed, he shall grant or renew a licence in Form 25-C or Form 26-C.

(2) If the Licensing Authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted or renewed and shall supply the applicant with a copy of inspection report.

85ED. *Further application after rejection.* .–If within a period of six months from the rejection of an application for a licence, the applicant informs the Licensing Authority that the conditions laid down have been fulfilled and deposits an inspection fee of [rupees two hundred and fifty], the Licensing Authority may, if, after causing further inspection to be made, he is satisfied that the conditions for the grant of licence have been complied with, issue a licence in Form 25-C or Form 26-C.

85EE. *Appeal to the State Government.*–Any person who is aggrieved by the order passed by the Licensing Authority refusing to grant or renew a licence under this Part may within ninety days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as is considered necessary and after giving the said person an opportunity for representing the case, pass such order as it thinks fit.]

85F. *Duration of licence*.–An original licence or a renewed licence unless it is sooner suspended or cancelled shall be [valid for a period of five years on and from the date on which] it is granted or renewed:

[Provided that if the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry, after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed to have expired if application for its renewal is not made within six months of its expiry.]

85G. *Certificate of renewal*.–The certificate of renewal of a licence in Form 25-C shall be issued in Form 26-C.

85H. *Conditions of licence*.–A licence in Form 25-C shall be subject to the conditions stated therein and to the following further conditions, namely :—

(a) the licensee shall provide and maintain staff and premises as specified in Rule 85-E;

(b) the licensee shall allow an Inspector appointed under the Act to enter, with or without prior notice, any premises where the manufacture of a Homoeopathic medicine in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured Homoeopathic medicines;

(c) the licensee shall allow an Inspector 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 made thereunder have been observed;

[(d) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and defects noticed;]

(e) the licensee shall comply with the following conditions in respect of mother tinctures manufactured by him–

(i) the crude drug used in the manufacture of the mother tincture shall be identified and records of such identification shall be kept [for a period of five years];

(ii) the total solids in the mother tincture shall be determined and records of such tests shall be kept [for a period of five years];

(iii) the alcohol content in the mother tincture shall be determined and records of the same shall be maintained [for a period of five years];

(iv) the containers of mother tinctures shall preferably be of glass and shall be clean and free from any sort of impurities or adhering matter. The glass shall be neutral as far as possible;

(v) in the process of manufacture of mother tinctures hygienic conditions shall be scrupulously observed by the licensee. Storage and handling conditions shall also be properly observed by the licensee according to Homoeopathic principles;

[(ea) no colour shall be added to any Homoeopathic medicines :

Provided that caramel may be added to combination of Homoeopathic preparations with syrup base;]

(f) records shall be maintained of Homoeopathic medicines containing alcohol and the quantities sold together with names and addresses of parties to whom sold.[2] [Such records shall be maintained for a period of five years.]

[**85HH.** *Additional information to be furnished by an applicant for the licence or a licensee to the Licensing Authority*.–The applicant for the grant of licence or any other person granted a licence under this Part shall, on demand, furnish to the Licensing Authority, before the grant of the licence or during the period the licence is in force, as the case may be, documentary evidence in respect of the ownership or occupation in rental or other basis of the premises, specified in the application for licence or in the licence granted, constitution of the firm or any other relevant matters which may be required for the purpose of verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the licence, as the case may be.]

85-I. *Cancellation and suspension of licences*.– (1) The Licensing Autority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, 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 substances 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 or Rules made thereunder.

[(2) A licensee whose licence has been suspended or cancelled may, within three months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.]

SCHEDULE M-1

[See Rule 85-E(2)]

GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR HOMOEOPATHIC MEDICINES

1. GENERAL REQUIREMENT

1.1 Location and surroundings:- The premises shall be situated at a clean place which shall not be adjacent to open drains, public lavatory or any factory producing pollution of any kind, garbage dump, slaughter house or any other source likely to cause contamination from the external environment. The premises shall be located away from railway lines so that the performance of sensitive electronic equipment is not affected by vibrations. There shall be no open drains inside or outside the manufacturing premises. It shall be so designed that the entry of rodents is checked. The drains shall facilitate easy flow of the effluent and shall be cleared periodically.

1.2 Building. – The premises shall not be used for any purpose other than manufacture of homoeopathic drugs and no part of the manufacturing premises shall be used for any other purpose. Other facilities, if needed, could be provided in separate building (s) in the same campus. Crude raw materials, packing materials, etc. shall be stored and handled in places ear marked for them and shall not be taken inside areas where critical operations of manufacture are done excepting processed raw material. Heating, washing, drying, packing and labelling, etc. wherever needed, shall be done in dedicated ancillary areas adjacent to the manufacturing sections concerned. The walls and floorings of manufacturing areas shall be smooth and free from chinks, cracks and crevices and shall be washable. The design of the windows, windowpanes and all fittings shall be such that they will not facilitate accumulation/lodging of dust and other contaminants.

(a). Rooms. – The rooms shall be airy, ventilated, and maintained at temperatures which are moderate and comfortable. Sections which are required to be sterile, air – conditioned and provided with air handling systems shall be designed accordingly. All sections shall be free from insects, birds, rodents, worms etc. and suitable measures shall be taken to prevent the same from finding ways to the sections and equipment.

(b) Water. – The water used for manufacture of drugs shall be of the quality as prescribed in the rules or in the Homoeopathic Pharmacopoeia concerned, as the case may be, and shall be prepared from pure drinking quality water, free from pathogenic organisms.

(c) Disposal of waste. – Effluents, organic and inorganic wastes shall be disposed of in such a manner as may be prescribed in the laws pertaining to pollution control and if no such law exists in the place of manufacture, they

shall be rendered harmless and shall be disposed of in such a manner that they are not hazardous to health of the public or cattle or plants.

(d)Factories Act. – The provisions of the Factories Act, 1948 (Act 63 of 948), as applicable shall be adhered to.

(e)Medical services. – All persons concerned with any activity pertaining to manufacture of drugs including handling of raw material, packing material, packing and labelling of drugs, etc. shall be medically examined for fitness at the time of employment and subsequently at periodic intervals and records thereof shall be maintained.

(f)Safety measures. – First-aid facilities shall be provided in such a manner that they are easily accessible and the staff shall be imparted knowledge and training in first-aid measures as may be needed. Fire control equipment in suitable numbers shall be provided at easily accessible places near all sections including stores and warehouses.

(g)Workbenches.- workbenches suitable to the nature and quantum of the work involved shall be provided in all sections. Such work benches in general, shall have smooth, washable and impervious tops and the parts shall not be rough or rusty or damaged otherwise.

(h)Container management. – Proper arrangements shall be made for receiving containers, closures and packing materials in secluded areas and for dusting the same, removal of wastes, washing, cleaning and drying. Suitable equipment shall be provided as may be needed, considering the nature of work involved. Where soaps and detergents are used to wash containers and closures used for primary packing, suitable procedure shall be prescribed and adopted for total removal of such materials from the containers and closures. Plastic containers which are likely to absorb active principles or which are likely to contaminate the contents may not be used.

Glass containers used shall be made of neutral glass. The closures and washers used shall be of inert materials which shall not absorb the active principles or contaminate the contents or which may otherwise be likely to cause deterioration of quality. The containers, closures and packing materials shall protect the properties of the medicines. Tablets, if blister-packed, shall have secondary protective packaging to protect the medicines from moisture, odour etc. Neutral glass phials and epoxy-coated closures shall be used for eye-drops. Transparent plastic containers may be used for eye drops containing only aqueous preparations. Sterile plastic nozzles may be provided to eye drops, separately along with the medicine, whatever needed.

2. PLANT AND EQUIPMENT –

2.1General . – The design of the plant shall be suitable for the nature and

Quantum of the activates involved. Equipment shall be installed in such a manner as to facilitate easy flow of materials and to check criss-cross movement of the personnel. The entry to all manufacturing sections shall not have access to them. There shall be

arrangements for personal cleanliness of workers and toilets. These shall be separate for men and women, to change from their outside dress and footwear into the factory dress and footwear. Uniforms of suitable colours and fabric which facilitate proper washing and which do not shed fibres other contaminants shall be provided. Suitable head-covers and gloves shall be provided to the workers. The manufacturing premises shall not be used for dining. There shall be separate area for the personnel to take food or rest. Toilets shall not be located in or adjacent to any of the areas concerned with any manufacturing activity. Spitting, smoking, chewing, littering, etc. in the manufacturing or ancillary areas shall not be permitted. Standard operating Practices (SOPs) for cleaning and sanitation, personal hygiene of the workers, general and specific upkeep of the plant, equipment and premises and every activity associated with manufacture of drugs including procurement, quarantine, testing and warehousing of materials shall be written and adopted. No person with any contagious disease shall be involved in any of the manufacturing activates. There shall be proper arrangements for maintenance of the equipment and systems. The performance of every equipment and system shall be properly validated and their use shall be monitored. Dos and don'ts in the matter of the use of the plant and equipment as may be applicable shall be written and displayed in all places.

The shall be separate dedicated areas for each ancillary activity such as receipt, cleaning, warehousing and issue of raw materials, packaging materials, container and closures, finished goods etc. Adequate measures shall be taken to prevent entry/ presence etc of insects, rodents, birds, lizards and other animals into the raw material handling areas. Every material shall have proper identification and control numbers and inventory tags and labels displaying status of the quality being used, etc. There shall be proper arrangements and SOPs for preventing mix-up of materials at every stage of handling. There shall be separate arrangements for handling and warehousing of materials of different origins. Materials with odour shall be kept in tightly closed containers and shall be well protected from other materials. Fresh materials and odorous materials shall, preferably be stored in separate dedicated areas. Where bonded manufacturing and or warehousing facilities are required as per Excise laws, the facilities required shall be provided without compromise on the requirements specified above.

A well-equipped laboratory for quality control/quality assurance of raw materials and finished products and for carrying out in- process controls shall be provided.

2.2 Personnel – Manufacture of drugs shall be under the control of approved technical staff that shall possess the qualifications prescribed in Rule 85E.

3. REQUIREMENT OF EQUIPMENT AND FACILITES:

3.1 Mother tinctures and mother solutions-

The following equipment and facilities shall be provided.

(i) Disintegrator;
(ii) Sieved separator;
(iii) Balances, weights and fluid measures, all in metric system;
(iv) Chopping table/board and knives;
(v) Macerators with lids (all made of stainless steel of grade 304 or neutral glass);
(vi) Percolators (all made of stainless steel of grade 304);
(vii) Moisture determination apparatus;
(viii) Filter press/Sparkler filter (all metal parts shall be of stainless steel);
(ix) Mixing and Storage vessels.(Stainless steel of grade 304);
(x) Portable stirrers (Rod, blades and screws shall be of stainless steel);
(xi) Water still/water purifier;
(xii) Macerators and percolators for preparing mother solutions of materials of chemical origin. These shall be of material, which will not react with the chemicals, used and which do not bleach; and
(xiii) Filling and sealing machine.

The area and facilities for manufacture of mother tinctures and mother solutions shall be separate and shall be 55 square meters for each for basic installations.

3.2 Potentisation section. – The section shall have the following facilities:

(i) Work benches with washable impervious tops;
(ii) Facilities for orderly storage of different potencies and back-potencies of various drugs;
(iii) Suitable devices for measuring and dispensing of potencies/back-potencies into the potentisation phials;
(iv) Potentiser with counter.

An area of 20 square meters shall be provided for basic installations.

Note –

(a) The requirement of potentiser is not mandatory. The process may be done manually also with proper SOPs. Potentiser, if used, shall be properly validated and shall be calibrated every time before commencement of work for proper performance.
(b) The manufacturer shall use back-potencies procured from Licensed manufacturer and the firm shall maintain proper records of purchase or shall prepare own back-potencies. Every container of potencies and back –potencies shall be kept properly labelled and there shall not be mix-up of different medicines and different potencies.

3.3 Containers and Closures Section. –

Separate area for preparation of containers and closures shall be provided adjacent to the potentisation section. This area shall have the following facilities:

(i) Washing tanks with suitable mechanical or hand operated brushes;
(ii) Rinsing tanks. Purified water shall be used for rinsing;

(iii) Closures washing/macerating tanks;
(iv) Driers;

Note:

(a) Different droppers shall be used only for each different medicine and different potency.
(b) All measures shall be in metric system. Measures used shall be of neutral glass. Metal droppers and plastic droppers shall not be used.
(c) Glass droppers shall be reused only after proper cleaning and sterilization.
(d) Potentisation shall be done by the method (s) prescribed in the Homoeopathic Pharmacopoeia of India.

3.4 Trituration, Tableting, Pills and Globules making sections.-

The following basic equipment and facilities shall be provided:-

(i) Triturating Machine;
(ii) Disintegrator;
(iii) Mass Mixer;
(iv) Granulator;
(v) Electrical oven;
(vi) Tablets punching Machine;
(vii) Kettle (steam or electrically heated) for preparing solutions;
(viii) Driers for drying granules and tablets;
(ix) Sieved separator (stainless steel);
(x) Tablet counter;
(xi) Balances;
(xii) Coating Pan with spray-gun;
(xiii) Multi-sifter;
(xiv) Mill with perforations.

An area of 55 square meters shall be provided for basic installations. The area shall be suitably divided into cubicles to minimize cross contamination, mix-up etc.

Note:

The section shall be free from insects, worms, rodents dust and other floating particles and moisture.

3.5 Syrups and other oral liquids section.-

The following basic equipment and facilities shall be provided:-

i. Mixing and storage tanks. (stainless steel of grade 304);
ii. Portable stirrer (rod. Blades and screws shall be of stainless steel);
iii. Filter press/Sparkler filter (all metal parts shall be of stainless steel);
iv. Filling and sealing machine;

pH meter.

An area of 20 square meters shall be provided for basic installations. The section shall be free from dust and other floating particles, cobwebs, flies, ants and other insects, birds, lizards and rodents.

(1) Adequate number of workbenches shall be provided.
(2) Visual inspection table shall be provided. This shall comprise of a colour contrast background with lamp for providing diffused light, mounted on a suitable table.

3.6 Ointments and lotions section:-

The following basic equipment and facilities shall be provided:-

(i) Mixing tanks(Stainless steel)
(ii) Kettle (steam or electrically heated) for preparing solutions
(iii) Suitable powder/planetary Mixer
(iv) Ointment mill/colloidal Mill/Emulsifier
(v) Filling and sealing machine/crimping machine
(vi) Filtering equipment.
(vii) Balance and weights.

A minimum area of 20 square meters shall be provided for basic installations. An ancillary area for washing vessels and equipment shall be provided. An ancillary area for heating purposes shall also be provided.

3.7 Ophthalmic preparations section. –

The following basic equipment and facilities shall be provided:

(i) Hot air oven, electrically heated, with thermostatic control;
(ii) Laminar Air Flow bench;
(iii) Air Handling Unit with HEPA filters to provide filtered air and positive pressure to the section and air – locks;
(iv) Ointment mill/colloidal Mill;
(v) Mixing and storage tanks.(stainless steel of grade 304);
(vi) Pressure vessels, as may be needed;
(vii) Sintered glass funnels, Seitz Filter/Filter candle;
(viii) Vacuum pump;
(ix) Filling machines for liquids ointments etc.;
(x) Autoclaves with pressure and temperature gauges; and
(xi) Necessary workbenches, visual inspection bench, etc.;

Area: Minimum area of 20 square meters shall be provided for basic installations.

Note:

1. The section shall have a clean room facility of class 100 specification.
2. The section shall be air-conditioned and humidity controlled.

3. Entry to the sections shall be regulated through air-locks with differential air pressures with the air-lock adjacent to the section having higher pressure and the first one through which entry is made with the least pressure.
4. Materials shall be passed to the sections through suitable hatches.
5. The personnel shall wear sterile clothing including headgear, which shall not shed fibre.
6. Washing of phials shall be done in separate areas with proper equipment. Proper facilities shall be provided in the area for washing vessels.
7. Separate area shall be provided for packing and labelling.

4. QUALITY CONTROL DIVISION

4.1 Functions.- A separate quality control division shall be provided in the premises. The section shall be under the control of an approved technical officer, independent of the manufacturing division and directly responsible to the management. The section shall be responsible for ensuring the quality of all raw materials, packing materials and finished goods. The section shall also carry out in-process quality checks of the products. The section shall be responsible for the stability of the products and for prescribing their shelf life wherever applicable.

The functions of the division shall include:-

(1) To test the identity, quality and purity of the raw materials and to recommend rejection of the material of poor quality and approve materials of the prescribed quality only.

(2) To test the identity, quality and purity of the finished products and to recommend rejection of the material of poor quality and approve materials of the prescribed quality only.

(3) To prepare and validate the methods of analysis, validate the equipment, monitor their use, take steps for proper maintenance etc.

(4) To approve or reject containers, closures and packaging materials in accordance with the prescribed norms.

(5) To exercise/carry out in-process control of products.

(6) To prescribe SOPs on all matters concerning quality of materials and products.

(7) To monitor the storage and handling of raw materials, finished products, containers, closures and packaging materials.

(8) To investigate complains on quality of products and take/recommend appropriate measures and to examine returned goods and recommend their proper disposal.

4.2 **Personnel**. – The quality control staff shall be full – time personnel. Analysis and tests of drugs, raw materials, etc. shall be done by qualified and approved technical staff. The technical staff shall have the minimum qualification of degree in Homoeopathy Pharmacy or Science with Chemistry or Botany as the principal subject and experience of not less than two years in the test and analysis of medicine including handling of instruments.

4.3 **Equipment** – The following equipment shall be provided:-

(i) Microscope of suitable magnification and photographic device;
(ii) Dissecting microscope;
(iii) TLC apparatus;
(iv) UV lamp viewer;
(v) Monopan Digital Electronic Balance;
(vi) Hot air oven;
(vii) Distillation apparatus;
(viii) Water Bath;
(ix) Polarimeter;
(x) Refractometer;
(xi) Melting point apparatus;
(xii) PH meter;
(xiii) Magnetic stirrer;
(xiv) Table Centrifuge;
(xv) Muffle furnace/electric Bunsen;
(xvi) Moisture determination apparatus;
(xvii) U.V. Spectrophotometer;
(xviii) Rotary microtome/Section cutting facilities;
(xix) Tablet Disintegration Machine.

5. RAW MATERIALS:-

5.1 Raw materials of Plant Origin-

(a) The raw materials of plant origin used for manufacture of drugs shall be of the following specification-

(i) The materials shall be those recently collected and dried and shall be free from moisture so as to eliminate the risk of deterioration and infestation with pests moulds, etc. The materials shall be collected when the atmospheric temperature is suitable where its active constituents are not changed/damaged/destroyed;

(ii) When fresh materials are to be used, the time lapse from the time of collection to use shall be minimized to the extent possible;

(iii) The material should be taken from healthy plants and shall be free from parasites, moulds, etc.;

(iv) The materials shall be free of inorganic or organic foreign matter;

(v) When dry materials are procured, they shall be from healthy plants and shall be in un-processed form, free from all extraneous matters such as fungus, insects, moulds, pathogenic organisms, etc. and should not be more than six months old. Plant materials of Agaricaceae, which are perishable shall be used within one week of collection.

(b) To facilitate proper identification and purity of the material and to exercise proper quality control of the material, the following conditions must be satisfied:-

(i) a small twig of the plant with leaves shall be available if the part used is bark of the plant;

(ii) an entire plant or part or aerial twig with leaves and some uncut roots/rhizomes/bulbs shall be available if the part used is a root/rhizome/bulb;

(iii) if plants with flowers are to be used, a few dry flowers shall also be available with the aerial twig

(iv) if the material used is a mould or of the plant families Agaricaceae, Polyporaceae/ amanitacaea/ Boletaceae/ Russulaceae, a whole specimen plant mould shall be available in properly dried form;

(v) the materials shall be free from insecticides, fungicides, etc.;

(vi) the materials shall be in open mesh bags or in suitable material which permits the passage of air inside;

(vii) each consignment of the material shall be accompanied by a statement of the supplier's name; name of the plant with description of the part supplied; the pharmacopoeial reference, place of collection/harvest, date and time of collection and packaging and weight.

5.2 **Raw material of Chemical origin**. – They shall be respective pharmacopoeial standards of their specification shall accompany the materials.

5.3 **Raw materials of animal origin**. – The materials shall be those collected from healthy animals and shall be of pharmacopoeial specifications. The materials shall be those collected, packed and transported under proper hygienic conditions and well protected from all contamination. The materials shall be accompanied by statements as in para 'a' above. In case of drugs derived from a whole insect, bulk of such drugs along with some uncut whole insect should be provided/maintained for records.

5.4 **Sarcodes.** – The materials shall be those collected from healthy animals and shall be of pharmacopoeial specification. The materials shall be those collected, packed and transported under proper hygienic conditions and well protected from all contamination. The materials shall be accompanied by statements as in the para 'a' above. The materials shall be tested to see that they are free from pathogenic organisms such as E. Coli, Salmonella, etc.

5.5 **Nosodes.** – These shall be of pharmacopoeial specifications. As these are derived from diseased animals or human beings, they shall be autoclaved immediately after collection and preserved and transported under proper hygienic conditions and well protected from all contamination. Before use, these shall be sterilized by autoclaving and shall comply with the test for sterility as specified in the Homoeopathic Pharmacopoeia.

6. PROCEDURES:

6.1 Manufacture of Mother Tinctures. –

a) Every material shall be identified and checked for its purity. They shall be cleaned and process by cutting, chopping, etc. for use in macerators/percolators. A specimen of the material shall be preserved till approval of the product for release for sale.
b) The design and procedures adopted shall ensure reproduction of the product of the same quality every time.
c) Mother tinctures shall be preserved in tight closed neutral containers at temperatures preferably below 25° C, protected from light.

6.2 Manufacture of Attenuations.-

a) Attenuations shall be prepared in a clean room environment with filtered air and positive pressure inside suitable for the operations.
b) The methods used shall be reproducible and shall be validated.
c) The containers, tubings, etc. of the machines used for manufacture of attenuations shall be thoroughly washed, cleaned and dried after attenuation of a drug. Regular checks shall be carried out on the materials.
d) The parts of the equipments that come into contact with the attenuation materials shall be of neutral quality and shall not cause any contamination to the material.
e) Attenuations shall be preserved in properly labelled glass containers.
f) Alcohol and other vehicles used shall be of Homoeopathic Pharmacopoeia specification and shall be free from impurities.

6.3 Trituration.- Trituration technique is used to manufacture drugs from insoluble strains. The procedure/method specified in the Homoeopathic Pharmacopoeia shall be adopted.

6.4 Formulations. – Compound formulations shall preferably be in liquid and solid forms and the potency of the ingredients shall be in detectable quantity preferably be in 3X except in case of highly poisonous material and toxins which should not be below 6X. The ingredients shall be compatible to each other. Complete pharmacopoeial name of each ingredient shall be printed on the label along with composition.

6.5 Medicated Insert pellets.-

a) Pellets shall be manufactured in clean rooms free from particulate contaminants. The equipment used shall enable prevention of contamination and cross-contamination.
b) The procedures shall be validated.

7. Laboratory Controls. –

Tests as per the pharmacopoeia and requirements shall be carried out on products and materials. The stability of the products shall be established by proper methods. Sterility test, wherever applicable, shall be carried out. Control samples shall be preserved for not less than three years after the last sales.

8. Packing and Labeling.-

A minimum area of 50 square meters shall be provided for packing and labelling section.

9. Expiry Date.-

Not exceeding sixty (60) months from the date of manufacture.

10. Standard Operating Practices. –

Standard Operating Practices (SOPs) shall be developed for various activities such as receipt, identification, cleaning, drying, warehousing, issue, handling, sampling etc of all materials. Labels and packing materials shall be examined for correctness and compliance with rules. Rules shall be maintained for their printing, use, destruction etc.

11. Records and Registers. –

Records shall be maintained for all the activities. These shall include records of production, records of raw materials, records of testing, records of sales and other supplies, records of rejection, complaints and actions taken, SOPs and records in respect of compliance thereof, log books of equipment, master formula records, records of medical examination and fitness of personnel etc. All records shall be maintained for a period of one year after the expiry of a batch or for three years whichever is later.

FORM 1

(*See* rule 4)

Memorandum to the Central Drugs Laboratory

Serial Number.....

To the Director, Central Drugs Laboratory.....

From.....

I send herewith, under the provisions of section 25 (4) 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.

(2) The distinguishing number on the packet is.....

(3) Particulars of offence alleged.....

(4) Matter on which opinion is required.....

(5) A fee of Rs.....has been deposited in Court.

..... Magistrate

Date.....

FORM 2

(*See* rule 6)

Certificate of test or analysis by the Central Drugs Laboratory

Certified that the sample 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 condition of the seals on the packet on receipt was as follows: —

*3. In the opinion of the undersigned the sample <u>is of standard quality as defined</u>
is not of standard quality as defined

<u>in the Drugs and Cosmetics Act, 1940 and Rules thereunder</u> for the reasons given below:–
in the Drugs and Cosmetics Act, 1940, and Rules thereunder

Date…….. Director

Central Drugs Laboratory or other authorised officer

Details of results of test or analysis with protocols of test applied

Date..... Director

Central Drugs Laboratory or other authorised officer

* *<u>If opinion is required on any other matter, the paragraph should be suitably amended.</u>*

[FORM 15

(*See* rules 54 and 145C)

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 reasons 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

(*See* rules 55 and 145-B)

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

The stock of drugs or cosmetics for records, registers, documents or material objects detailed below has / have this day been 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

(*See* rules 56 and 145A)

Intimation to person from whom sample is taken

To.

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

Date..... Inspector.....

Details of samples taken

Date..... Inspector.....]

[FORM 17A

(*See* rules 56A and 145AA)

Receipt for samples of drugs or cosmetics taken where fair price tendered thereof under sub-section (I) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused

To.....

Whereas I, this..... day of.....19.....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 the receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date: ..... *Inspector* ….. …..]

FORM 18

(*See* Rule 57)

Memorandum to Government Analyst

Serial No. of Memorandum.....

From:

To
The Government Analyst
……
……
The portion of sample / container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of Section 23 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 [1][name of drug/cosmetic] which it purports to contain—

Date..... Inspector.....

[FORM 18A

[*See* rule 163 (1)]

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 33H 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 24C

(*See* rule 85B)

Application for the grant or renewal of a [licence to manufacture for sale or for distribution of] Homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensees holding licence in Form 20-C

[1. I / We* ..... of ..... holder of licence

no.....in Form 20-C hereby apply for the grant/renewal of licence to manufacture the undermentioned Homoeopathic mother tinctures/potentised preparations on the premises situated at…… …….

Name of the Homoeopathic preparations.....……. ….
(*Each item to be separately specified*)].

2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.

3. A fee of rupees.....has been credited to Government under head

of account.....

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

Note 1. Delete whichever portion is not applicable.
2. The application should be accompanied by a plan of the premises.

FORM 25C

(*See* rule 85-D)

[*Licence to manufacture for sale or for distribution of*] *Homoeopathic medicines*

Number of Licence and date of issue.....

1 [*1. ……. of.....who holds a licence in Form 20-C is hereby licensed to manufacture undermentioned Homoeopathic Mother Tinctures/ potentised and other preparations on the premises situated at....under the direction and supervision of the following technical staff:
Names of the Homoeopathic preparations.
(*Each item to be separately specified*).
Names of the Technical Staff.....]

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

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

Date..... Signature……

Designation….

Conditions of Licence

1. This licence 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 Cosmetics Act, 1940.

2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.

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

**Delete* the words "who holds a licence in Form 20C" in case this is not applicable.

FORM 26C

(*See* rule 85G)

Certificate of renewal of licence to manufacture for sale of Homoeopathic medicines

1. Certified that licence No.....granted on the……. to…… for the manufacture for sale of the Homoeopathic mother tinctures/potentised preparation at the premises situated at.....has been renewed for a period from the.....to.....……

2. Name of the technical staff.....……

[3. Names of the drugs (*each item to be separately specified*).....]

Date……..

Signature.....……..
Designation..……..

[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. Licence number and the date upto which the licence 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 licence number……. . in Form……under the Drugs and Cosmetics Rules, 1945.

Seal and Signature of the Licensing Authority.

Notes:

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

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

(iii) The observations made by the Drug 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 36

(*See* rule 150B)

Application for grant or renewal of approval for carrying out tests on drugs/ cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs /cosmetics

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

(2) *Categories of drugs, items of cosmetics:

(a) Drugs other than those specified in Schedules C and C (1) and also excluding Homoeopathic Drugs:-

1. Crude vegetable drugs.
2. Mechanical contraceptives.
3. Surgical dressings.
4. Drugs requiring the use of ultravoilet / Infra Red. or Chromatography.
5. Disinfectants.
6. Other drugs.

(b) Drugs specified in Schedules C and C (1):—

1. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.
2. Antibiotics.
3. Vitamins
4. Parenteral preparations.
5. Sterilized surgical ligature / suture.
6. Drugs requiring the use of animals for their test.
7. Drugs requiring microbiological tests.
8. Drugs requiring the use of Ultravoilet/ Infra Red/ Spectrophotometer or Chromatography.
9. Other drugs.

(c) **Homoeopathic drugs.**

(d) Cosmetics.

(3) Name, qualifications and experience of expert staff employed for testing and the person-in-charge of testing.

(4) List of testing equipments provided.

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

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

Date..... Signature……

** Delete whichever is not applicable*

FORM 37

(*See* rule 150C)

Approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs /cosmetics

Number of approval and date of issue:

(1) Approval is hereby granted to.....…….for carrying out tests for identity, purity, quality and strength on the following categories of drugs/items of cosmetics and the raw materials used in the manufacture thereof on the premises situated.....

Categories of drugs / items of cosmetics

_____

_____

_____

(2) Names of [1][competent technical staff] employed for testing and the person-in- charge of testing.

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

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

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

Designation.....

Conditions of Approval

(1) This approval and any certificate of renewal in Form 38 shall be kept in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.

(2) If the approved institution wishes to undertake during the currency of the approval the testing of any other category of drugs or items of cosmetics it should apply to the approving authority for necessary endorsement as provided in rule 150-B.This approval will be deemed to extend to the item so endorsed.

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

[2][(4) The approved institution shall inform the approving authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the approving authority in the name of the institution with the changed constitution.]

FORM 38

(*See* rule 150J)

Certificate of renewal of approval for carrying out tests on drugs / cosmetics and raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs / cosmetics

(1) Certified that approval number.....granted on the

.....for carrying out tests of identity, purity, quality and strength on the following categories of drugs/ items of cosmetics and the raw materials used in the manufacture thereof at the premises situated at……has been renewed from……to.....

Categories of drugs/items of cosmetics

_____

_____

. _____

(2) Names of [1][competent technical staff] and person-in-charge of testing.

Date..... Signature.....……..

Designation……..

FORM 39

[*See* rule150E(f)]

Report of test or analysis by approved institution

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

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

(3) Date of receipt of the sample.

(4) Name of drug / cosmetics / raw material purporting to be contained in the sample.

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

(a) Original manufacturer's name in the case of raw materials and drugs repacked.

(b) Batch number.

[1][(c) Batch size as represented by sample.]

(d) Date of manufacture, if any.

(e) Date of expiry, if any.

(6) Results of test or analysis with protocols of test or analysis applied.

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

Date..... .....

Signature of Person-in-charge of testing

Note:- Final product includes repacked material.

**Delete whichever is not applicable*

Chapter III

Stepwise points for conducting GMP inspection

CHECKLIST OF GMP INSPECTION FOR 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.	**1.1**	**FACTORY PREMISES**		
		Does manufacturing unit have adequate space for a) Receiving and storing raw material. b) Manufacturing process areas. c) Quality control section. d) Finished goods store. e) Office f) Rejected goods/drugs store.		
4.	**1.1**	**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.	**1.2**	**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 build up 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? a) Any open drain blocked sewer or public lavatory nearby? b) 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.	**1.2 (b)**	**WATER SUPPLY**		
		Is there adequate supply of potable water?		
		Does the potable water meet the specifications published HPI specifications?		
		Is only potable water Used in HOMOEOPATHIC medicines?		
7.	**1.2 (c)**	**DISPOSAL OF WASTE**		
		Are drainage and water disposal systems designed, constructed and maintained in such a way as to avoid contamination of HOMOEOPATHIC 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? a) Disposal of solid/semi solid waste b) Disposal of sewage c) Disposal of Liquid laboratory waste? d) 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.	**3.3**	**CLEANING OF CONTAINERS**		
		Is there proper arrangement for washing, cleaning and drying of containers? Is this area separated from manufacturing area?		
9.	**5**	**STORES**		
		Is there independent adequate space for storage of different types of		

		materials such as raw material, packaging material and finished products?		
		Are HOMOEOPATHIC medicine storage facilities designed and constructed to - Permit adequate maintenance and cleaning? - Avoid pest menace 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 HOMOEOPATHIC medicines with harmful materials is prevented?		
10.	**5**	**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)**	**PACKING MATERIALS**		
		Is the area adequate with reference to packing material?		
		Are the containers and closures adequately cleared and checked?		
12.	**1.2**	**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.	**1.2 (g)**	**WORKING SPACE**		
		Is space adequate as per manufacturing operations?		
		Is machinery along with working manual orderly placed with adequate		

		space?		
		Are there adequate precautions to check cross contamination?		
14.	**1.2**	**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 HOMOEOPATHIC drugs contact surfaces carried out?		
		Is the sanitation system regularly reviewed and adapted to reflect changed circumstances?		
15	**1.2(e)**	**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.	**2**	**MACHINERY AND EQUIPMENT**		
		Is manually operated or semi-operated 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 HOMOEOPATHIC 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 HOMOEOPATHIC Medicines?		
		Is the equipment adequate for intended use?		
		Is it constructed in such a way that lubricants, coolant, etc. cannot contaminate the drug product?		
		Does the equipment permit cleaning and maintenance?		
		Does the equipment show its status i.e. clean, dirty, batch contents?		
		Do all apparatus/equipment bear appropriate labels to identify the product for which the equipment is used, its batch no., date of manufacturing etc.		
		Are SOPS available for cleaning maintenance and sanitation of major equipment?		
		Are log books maintained for cleaning maintenance and sanitation of major equipment?		

		Are SOP's readily available to operators		
		If automatic electronic or mechanical equipment is used ,are there: • Written programs for calibration/inspection • Checks to ensure that may changes are made only by authorized persons/ Are suitable closures or lids available to protect the changes in properties of material exposed to outside atmosphere?		
17.		**BATCH MANUFACTURING RECORDS**		
		Are appropriate records of processing, production and distribution kept?		
		Are SOP's available for the following - Receipt of raw material and other components? - Quarantine and storage? - Quality control system and approval/rejection - Release of production - In process testing and control - Finished product? - Storage of finished product? - Distribution - Returned goods - Recalls and complaints - Cleaning and maintenance? - Quality control of water - For reworking of non-conforming batches in existence? If yes, check)		
		Are there additional documents like log books, notebooks or other similar records available to show execution of various functions?		

		Are there records of receipts of materials and do these have following information? (goods Receipt Note-GRN) - Receiving GRN documents number? - Date of receipt? - Supplier? - Manufacturer? - Manufacture's batch number? - Type and size of containers? - Number of containers and conditions?		
		Are specifications available for all materials?		
		Are they dated authorized?		
		Are test methods validated?		
		Are periodic reviews of specification carried out to ensure compliance with new /revised National/international 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	**11**	**Records And Registers**		
		Are records of sale and distribution		

		of each batch of HOMOEOPATHIC drugs maintained? Are records maintained for a period of one year after the expiry of a batch or for three years whichever is later?		
19.	**4**	**QUALITY CONTROL**		
		What is the QC area?		
		Has Quality Control section minimum of: a) One person with Degree qualification in Homoeopathy; b)One chemist with Bachelor in Science or Pharmacy or Pharmacy (Homoeopathy) and; c)One Botanist (Pharmacognosist) with bachelor in Science (medical) or Pharmacy or Pharmacy (Homoeopathy)?		
		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: a) Are reference standards (R.S) available? b) Are these RS or working standards (WS)? c) Are WS standardised against RS or CRS? d) Are RS stored properly (at appropriate temperature under dehumidified conditions)? e) 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 ?		
20	**1.2**	**REQUIREMENT FOR STERILE PRODUCT**		
		A. Manufacturing areas		
		- Is there separate manufacturing area		
		- Are their air locks for entry?		
		- Is there dust free and ventilated for air supply		
		B. Precautions against contaminations and mix.		
		- Are manufacturing operations being carried out in a separate block of adequately isolated building		
		- Is there appropriate pressure differential in the process area.		
		- Is suitable exhaust system provided?		
		- For aseptic manufacturing proper air supply (filtered through HEPA) provided?		