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DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945

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BP505T-UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

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Introduction

Drug is an essential commodity and is required to be regulated in terms of its import, manufacture, sale and distribution. The Central Government and State Government are charged with the responsibility of providing the drugs of desired quality to the needy patients and in order to ensure this primary obligation of the Government, the network is required to be developed to root out adulterated, misbranded and spurious drugs from the society.

Objectives

1. For preventing substandard in drugs, probably for treatment and preserving high medical standards.
2. For controlling the import, manufacture, distribution, and sale of drugs and cosmetics by licensing.
3. For ensuring that manufacture, distribution, and sale of drugs and cosmetics is done by qualified persons only.
4. For controlling the manufacture, and sale of Ayurvedic, Siddha, and Unani drugs.
5. Establishment of Drugs Technical Advisory Board (DTAB) and Drugs Consultive Committees (DCC) for Allopathic and Allied drugs and Cosmetics [1].

Important Definitions

1. **Drug**

It Includes:

(i) All medicines for internal or external use of human beings or animals and substances used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including, preparations applied on human body for the purpose of repelling insects like mosquitoes.

(ii) The substances other than food which may affect the structure or any function of the human body or used for the destruction of insects or vermin which cause disease in human beings or animals as specified from time to time by the Central Government by notification in the Official Gazette.

(iii) The substances used as components of a drug including, empty gelatin capsules.

(iv) The devices used for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette after consultation with the Drugs Technical Advisory Board (DTAB).

2. Cosmetic

It means any article intended to be sprayed, poured, rubbed or sprinkled on, or introduced into, or applied to the human body or its any part for cleansing, beautifying, promoting attractiveness or altering the appearance. It also includes any articles intended for use as a component of cosmetic.

3. Ayurvedic, Siddha or Unani Drugs

These include all medicines used for internal or external purposes or used in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibby Systems of Medicines specified in the First Schedule to the Drugs and Cosmetics Act, 1940.

4. Gudakhu

It is a tobacco product used for rubbing against human teeth. It contains tobacco powder, lime and molasses along with red mineral matter. It is a cosmetic within the provisions of the Act.

5. Patent or Proprietary Medicine

It means:

(i) In relation to Ayurvedic, Siddha or Unani System of Medicine, all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of

Ayurvedic, Siddha or Unani System of Medicine specified in First Schedule to the Act but does not include the medicine .administered by parenteral route.

(ii) In relation to any other system of medicine including, allopathic, a drug presented in a form ready for internal or external administration of human beings or animals and which is not included for the time being in the editions of Indian Pharmacopoeia or any other Pharmacopoeia.

6. Misbranded Drug

A drug is considered as a misbranded drug:

(i) if it is not labeled in the prescribed manner,

or

(ii) if it is so coloured, coated, powdered or polished that damage is concealed or it is made to appear of better or greater therapeutic value than it really is,

or

(iii) if the label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or gives misleading information.

7. Adulterated Drug

A drug is considered to be adulterated:

(i) if it consists in whole or in part of any filthy, putrid, or decomposed substance,

or

(ii) if it has been prepared, packed or stored under poor sanitary conditions whereby, it may have been contaminated with filth and rendered injurious to health,

or

(iii) if container of the drug is composed in whole or in part of any poisonous substance which may render the contents injurious to health,

or

(iv) if it contains a colour other than one which is prescribed,

or

(v) if the drug contains any harmful or toxic substance which may render it injurious to health,

or

(vi) if the drug is admixed with any substance so as to reduce its quality or strength.

8. Manufacture in relation to Drug or Cosmetic

Any process fully or partly used for making, altering, ornamenting, finishing packing, labeling, breaking up or otherwise treating or adopting any drug/cosmetic with a view to its sale or distribution but, does not include the compounding or dispensing of any drug or the packing of any drug or cosmetic in the ordinary course of retail business.

9. Spurious Drug

A drug is deemed to be a spurious drug:

(i) if it is imported under a name which belongs to another drug,

or

(ii) if it is an imitation of or a substitute for another drug or if it resembles another drug in a manner likely to deceive or bears upon it or its label or container the name of another drug,

or

(iii) if it has been substituted wholely or in part by another drug substance,

or

(iv) if it claims to be the product of a manufacturer or company of whom it is not truly a product.

10. Misbranded Cosmetic

A cosmetic shall be deemed to be misbranded:

(i) if it contains a colour which is not prescribed,

or

(ii) if it is not labelled in prescribed manner, or

(iii) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading.

11. Spurious Cosmetic

A cosmetic shall be deemed to be spurious:

(i) if it is imported under a name which belongs to another cosmetic,

or

(ii) if it is an imitation of or a substitute for another cosmetic; resembles another cosmetic in a manner likely to deceive; or bears upon it or upon its label or container the name of another cosmetic,

or

(iii) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist,

or

(iv) if it purports to be the product of a manufacturer of whom it is not truly a product.

Schedules to the Act and Rules [2]

There are two Schedules to the Act and 35 Schedules to the Rules.

The Schedules to the Act

1. First Schedule: It comprises the list of books of references for Ayurvedic, Siddha and Unani medicines. There are 57 books of Ayurveda, 30 books of Siddha and 13 of Unani Tibb systems listed in the Schedule which are used for different formulations in accordance with the provisions of the Act.

2. Second Schedule: It comprises of the standards to be complied with for imported drugs, manufacture of drugs, their sale, stocking and storage etc.

The Schedules to the Rules

Schedule A: Different Forms for application to procure licence, renewal of licence, and for all other activities.

Schedule B: Rates of fees charged for analysis by COL or State Drugs Laboratories.

Schedule C: List of biological and other special products governed by special provisions

Schedule C (I): List of other special products governed by special provisions

Schedule D: Class of drugs: extent and conditions of exemption

Schedule D (I): Undertaking of the manufacturer or his authorized agent required to be submitted along with application form for obtaining a registration certificate.

Schedule D (II): Undertaking of the manufacturer or his authorized agent required to be submitted along with application form for registration of a bulk drug or its formulation or its import into India

Schedule E (I): List of poisonous substance under Ayurvedic , Siddha and Unani medicines

Schedule F: Requirement for operation of blood bank and / or preparation of blood components

Schedule F(I): Provisions for bacterial vaccines, viral vaccines, antisera, diagnostic antigens, etc.

Schedule F (II): Standards for surgical dressings

Schedule F (III): Standards for Umbilical tapes

Schedule FF: Standards for ophthalmic preparations

Schedule G: Drugs required to be taken under medical supervision.

Schedule H: List of prescription drugs

Schedule J: List of diseases or ailments which a drug may not purport to prevent or cure.

Schedule K: Drugs exempted from certain provisions related to manufacturer.

Schedule M: GMP (Good Manufacturing Practices) comprising requirements of factory premises, plant and equipment

Schedule M-l: Homoeopathic preparations requirements of factory premises, plants and equipments

Schedules M-(II): Cosmetics - requirements of factory premises for manufacture

Schedules M-(III): Requirements of factory premises for manufacture of medical devices

Schedule N: List of minimum equipment of running a pharmacy

Schedule O: Standards for disinfectant fluids

Schedule P: Life period of drugs

Schedule P-l: Pack sizes of drugs

Schedule Q: List of colours, dyes and pigments permitted in cosmetics and soaps, list of colours permitted in soaps

Schedule R: Standards for condoms of rubber latex and other mechanical contraceptives

Schedule R-I: Standards for medical devices

Schedules S: Standards for Cosmetics

Schedules T: GMP (Good Manufacturing Practices) for manufacture of Ayurvedic, Siddha and Unani medicines, G.M.P., machinery, equipment minimum manufacturing premises, etc.

Schedules U: Particulars required to be shown in manufacturing records; raw material and analytical records

Schedules U (1): Particulars required to be shown in manufacturing records.

Schedules V: Standards for patent or proprietary medicines

Schedules X: Psychotropic substances

Schedules Y: Requirements and guidelines on clinical trials for import and manufacture of new drug

Import of drugs and cosmetics [3]

The import of drugs and cosmetics is regulated by the provisions of this Act.

Classes of drugs and cosmetics prohibited from import

The following categories of drugs and cosmetics are prohibited from import:

1. Drugs or cosmetics which are not of standard qualities.
2. Drugs or cosmetics which are misbranded, spurious and adulterated.
3. Drugs or cosmetics for import of which licence is required.
4. Any patent or proprietary medicine *without* true formula or list of active ingredients and their quantities.
5. Any drug or formulation which claims to prevent or cure diseases mentioned schedule J.
6. Any drug or cosmetic for which manufacture, sale or distribution is prohibited in country of its origin.
7. Any drug which is not packed or not labeled in conformity with the Rules of the Act.
8. Any cosmetic containing an ingredient which may render it unsafe or harmful.
9. Any drug or cosmetic the import of which is prohibited by Act.

Exemptions

The drugs exempted from provisions regulating the import of drugs are shown in Table 1.

Table 1: Drugs exempted from provisions regulating the import

Class of drugs	**Extent and conditions of Exemption**
1.Substances not intended for medicinal use	They can be imported without any restriction, provided imported in bulk and the importer certifies that they are imported for non medicinal uses.
2. Substances included in Schedule C1 required for manufacturing purposes but not intended for medicinal use.	Exempted from all provisions regulating import except that the importer should be holding license for manufacture of Schedule C and C1 drugs.
3.Substances used both as drugs as well as articles e.g. powdered milk, Farex, oats, lactose etc.	Exempted from all provisions regulating import.
4. Ginger, pepper, cumin, cinnamon, and all other similar spices and condiments other than those of official quality.	Exempted from all provisions regulating import.

Import of drugs under license

1. License is required for the import of drugs.
2. License is obtained on application to the proper licensing authority.

3. License is valid up to 31st December.
4. Licensee should inform to licensing authority if any changes.

Import under license or permit.

The licensing authority grants a license for the import of following classes of drugs

A. Drugs specified in schedule C and C1 excluding those specified in schedule X
B. Drugs specified in schedule X
C. Small quantities of drugs imported for examination, test or analysis
D. Drugs for personal use prescribed by a Registered Medical Practitioner
E. Any new drug

A. Drugs specified in schedule C and C1 excluding those specified in schedule X

Conditions to be fulfilled

1. Licensee must have adequate facilities for storage.
2. Licensee must maintain a record of the sale, showing the particulars of the names of drugs and of the persons to whom they have been sold.
3. Licensee must allow an inspector to inspect premises and to check the records.
4. Licensee must furnish the sample to the authority.
5. Licensee must comply with undertaking given in the Form No:09.

B. Drugs specified in schedule X

Conditions to be fulfilled

1. A license is necessary.
2. Licensee must have adequate facilities for storage.
3. Applicant must be reputable in the occupation, trade or business.
4. The license granted ever before should not be suspended or cancelled.

C. Small quantities of drugs imported for examination, test or analysis

Conditions to be fulfilled

1. A license is necessary.
2. Imported under license in Form-11.
3. The licensee must use the imported drug only for the said purpose and use at the place specified in the license.
4. The licensee must keep the record to the quantities, name of the manufacturer and date of import.

D. Drugs for personal use prescribed by a Registered Medical Practitioner

Conditions to be fulfilled

1. The drug must be bonified personal use.
2. The quantity should be reasonable and covered by RMP prescription.
3. The drug must be declared to the Custom Collector if so directed.
4. More than 100 doses are imported with license. Applying in Form No. 12A and 12B.

E. Any new drug

Conditions to be fulfilled

1. License is required.
2. The licensee is required to provide the documents of standards of quality, purity and strength.

Application and Duration of Import Licence and Registration Certificate

An application for import licence is made to licensing authority in Form 8 for drugs excluding Schedule X and in Form 8-A for schedule X drugs. The licence is issued in Form-l0 orl0-A as the case may be. The application for Registration Certificate is made to Licensing Authority in Form 40 and Registration Certificate is issued in Form 41. The application for both import licence and Registration Certificate may be made by manufacturer himself or his authorized agent in India having a valid licence. Both the import licence and Registration Certificate are valid for a period of *three* years from date of issue. If the application is made three months in advance before expiry of licence or certificate, it is valid until orders are passed on application.

Permitted Places for Import of Drugs

The import of drug into India is *permitted* only from following places:

(i) By rail: Ferozepur Cantonment and Amritsar railway stations for drugs from Pakistan. Ranaghat, Bongaon and Mohiassan railway stations for drugs from Bangladesh

(ii) By road: Raxual for drugs from Nepal

(iii) By sea: Chennai, Kolkatta, Mumbai, Nhava Sheva, Kandla, and Cochin

(iv) By air: Mumbai, Chennai, Kokatta, Delhi, Ahmedabad and Hyderabad.

Conditions of Import Licence [4]

The importer has to fulfil the conditions that are stipulated in the Rules and also comply with following conditions.

1. The manufacturer shall observe undertaking given in Form 9

2. The Licensee should maintain a proper record of imported drug wherein the entries should be made serially for the stock of imported material, its distribution, persons to whom the imported drug is issued, price charged, remaining and quantity of imported drugs. The drug imported for the purpose of test or analysis or the new drugs imported are not for general use.
3. The importer should maintain all proper storage facilities for drugs imported as required in accordance with the provisions of the Act.
4. The importer should permit the inspector or officer on behalf of the State Government or Central Government without notice to inspect the premises, stocking facilities, records, analytical details, and sale of imported substance.
5. The licensee should withdraw the substance from market if asked to do so by Authority, if found that the substance is substandard.

An import licence is for one category of drug from single manufacturer abroad, or it could be for more drugs from same manufacturer from one location. Separate licence is required for import of drugs from different manufacturers or from the same manufacturer located at different places.

Other Features of Import

1. No new homoeopathic medicine can be imported without permission in writing from the Licensing Authority
2. Small quantities of a new drug may be permitted for import by a Government hospital or Autonomous medical institution for the treatment of patient suffering from life threatening disease, subject to fulfillment of conditions laid down for the purpose.
3. Small quantities of drugs for examination, test or analysis may be imported subject to the conditions that the licensee shall use the drug exclusively, for the purpose for which it is imported; the licensee shall allow any inspector authorized by the licensing authority to inspect premises without prior notice and investigate the manner in which substances are being withdrawn and used. The licence is issued in Form 11. The licensee should maintain all the records and comply with conditions stipulated for licence.

Suspension and Cancellation of Import Licence or Registration Certificate

If the manufacturer or licensee fails to comply with any conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause may suspend or cancel the Registration Certificate for such period as it thinks fit. However, the

aggrieved person may appeal to the Central Government within thirty days against such order and the decision of the Government in this regard shall be final.

Offences and Penalties

The offences and penalties related to import of drugs is given in Table 2.

Table 2: Offences relating to import of drugs

Offences	**penalties**	
	First Conviction	**Subsequent Conviction**
1. An offence of any adulterated (section *9-A)* or spurious drug (section 9-B) or cosmetic (section 9-0) being imported into the country in violation of provisions of the Act	Imprisonment upto three years and a fine upto five thousand rupees.	Imprisonment upto 5 years or a fine upto ten thousand rupees or both.
2. Import of drugs or cosmetics other than those referred above the import of which is forbidden.	Imprisonment upto 6 months or a fine upto 500 rupees or both.	Imprisonment upto 12 months or a fine upto 1000 rupees or both.
3. Any drug or cosmetic imported in contravention with provisions of any notification issued under Section 10-A	Imprisonment upto three years or a fine upto five thousand rupees or both.	Imprisonment upto 5 years or a fine upto ten thousand rupees or both.

Manufacture of Drugs [5]

Manufacture in relation to any drug includes any process or part of a process for making, altering, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution, but does not include compounding or dispensing of any drug or packing of any drug in ordinary course of retail business. Manufacture of drugs is a blend of art and science, to be achieved strictly in accordance with the provisions of Good Manufacturing Practices (GMP).

Prohibition of manufacture and sale of certain drugs

The following categories of drugs and cosmetics are prohibited to be manufactured or sold in our country.

1. Any drug or cosmetic which is substandard, misbranded, adulterated or spurious.
2. Any patent or proprietory medicine without clear indication of ingredients.
3. Any drug claiming for accurate cure or prevention of diseases listed in Schedule J.
4. Any manufacturing of formulation containing drug or cosmetic which has been imported into our country in contravention to the provisions of the Act and Rules.
5. Manufacturing for sale of any drug or cosmetic containing any harmful ingredient.
6. Manufacturing for sale of any drug or cosmetic in contravention to the provisions of the Act and Rules, provided that manufacture of small quantities of any drug for the purpose of examination, test or analysis is permitted, subject to prescribed conditions. Separate applications for separate licences for more than one premises of manufacture are required to be made.

Conditions for grant of license and conditions of license for manufacture of drugs

A person who is interested in starting manufacturing of drugs is required to fulfill several conditions laid down in DCA and Rules. The conditions to be fulfilled before licence is granted are collectively called as "Conditions Precedent" and conditions that are required to be fulfilled after the licence is obtained for manufacturing are called "Conditions Subsequent". The Licensing Authority is both in States and at Central Government. The Central Government is empowered to prohibit manufacturing and sale of any drug formulation in public interest.

The types of licenses are granted are

1. Manufacturing of drugs for examination, test or analysis
2. Manufacture of new drug
3. Manufacturing under Loan licences
4. Licence for Repacking
5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X
6. Licence to Manufacture of Biologicals and Special Products in Schedules C and C (1)
7. Manufacturing of drugs belonging to Schedule X

Manufacture of drugs

Licences are required for the manufacturing of following categories of drugs.

1. Manufacturing of drugs for examination, test or analysis

2. Manufacture of new drug
3. Manufacturing under Loan licences
4. Licence for Repacking
5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X
6. Licence to Manufacture of Biologicals and Special Products in Schedules C and C (1)
7. Manufacturing of drugs belonging to Schedule X

1. Manufacturing of drugs for examination, test or analysis

If the manufacturer does not hold separate licence for test, analysis or examination, the licence is obtained in Form 29. The provisions relating prohibition of manufacturing of certain drugs do not apply for such manufacturing meant for test or analysis. The validity of the licence is for I year.

Conditions

1. The manufactured drugs should be kept in containers bearing appropriate label indicating the purpose of test or analysis.
2. The drugs should be used for the purpose for which they are manufactured.
3. When the material is supplied to other manufacturer, the label stating the name and address of manufacturer, scientific name of the drug, licence number, date of manufacture etc., should be provided.
4. The manufacturer should allow the Inspector to inspect the premises, manufacturing, and analytical records and withdraw the samples if required for analysis. The manufacturer should comply with the provisions of the Act and Rules.
5. The manufacturer should maintain an Inspection Book and the same be shown to the Inspector.
6. The licensee should comply with other requirements for which a notice has been given to him one month before by the Licensing Authority.

2. Manufacture of new drug

In addition to provisions for manufacture of drugs, there should be documentary evidence for quality, purity, therapeutic trials of new drugs and evidence for approval under schedule 'Y' (Clinical trials).

3. Manufacturing under Loan licences

Loan license is given to a person who does not have his own arrangements for manufacturing but wishes to avail the manufacturing facilities owned by another licensee. For drugs other than Schedules C, C(I) and X, loan licences can be given. Drugs specified in Schedules C/C(I),

Procedure

A licence is obtained from licensing authority on application in prescribed form No. 24 A, 27 A with prescribed fees. Application for grant or renewal of loan licence is made in Form 24-A. The licence is issued by Licensing Authority in Form 25-A, which is valid for 1 year.

Conditions

1. The general conditions applicable to other than Schedules C, C(I) and X.

Additional conditions

1. Application must be supported by the parent firm.
2. Drug inspector inspects the premises of parent firm and checks and assesses the spare capacity.
3. Loan license is required to test each batch of raw materials and finished products.
4. Records of testing should be maintained for 5 years or 2 years in case of expiry drugs from such data.
5. Patent medicines must be safe for use in the context of vehicle and additives.
6. The production must be supervised by competent person of loan licensee.

4. Licence for Repacking

Process of breaking up any drug from its bulk container [8] into small packages and labeling with a view to their sale and distribution is done under repacking licence. It is issued for drugs other than Schedules C, C1 and X, subject to fulfillment of conditions.

Procedure:

The application is made for grant or renewal of licence in Form 24-B. The licence is issued by Licensing Authority after inspection in Form 25-B.

Conditions

1. Adequate space and equipment should be provided. Hygienic conditions of working should always be maintained.
2. Repacking should be supervised by competent person.
3. There should be adequate arrangement for testing of samples.
4. The licence should always be displaced at premises of repacking.

5. The factory primises for repacking should comply with provisions of Schedule M.
6. 6.Adequate staff should be appointed and any change in staff structure should be immediately informed to Controlling Authority.
7. The container or package of repacked drug should bear on its label the words - "Rpg.Lic.No".
8. The licence is valid till31^{Ist} December every year and required to be renewed. There should be separate application for separate licence.

5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X

A license is obtained from licensing authority on application in prescribed Form No, 24 with prescribed fees. If conditions are fulfilled then license is issued in prescribed Form No. 25.

Conditions

1. The factory premises shall comply with conditions laid down in the Schedule M.
2. The manufacture shall be conducted under active supervision of Competent Technical Staff.
3. Adequate facilities for testing should be provided and it should be separate from manufacturing unit.
4. Adequate facilities for storage of drugs.
5. Licensee must allow an Inspector to inspect the premises, check the record and to take the sample.
6. Licensee must display the licence on the premises and produce it when asked for.
7. Licensee must pay fees and get endorsement on the licence if the licensee wishes to manufacture any additional product.
8. Record of testing and manufacture (Schedule U) should be maintained at least for 2 years from the date of expiry of drugs and for 5 years in case of other drugs.
9. Licensee must provide samples to the Authority.
10. Licensee must furnish the data of stability of drug if demanded.
11. Licensee must provide any additional requirement as directed by Authority.
12. Inspection book must be maintained.
13. The licensee shall comply with the requirements of GMP.

6. Licence to Manufacture of Biological and Special Products in Schedules C and C (1)

A licence is obtained from licensing authority on application in prescribed Form No. 27 with prescribed fees.

Conditions

1. The general conditions applicable to other than Schedules C, C(I) and X.

Special conditions for Biologicals

1. All Schedule C drugs must be issued in previously sterilized, sealed glass of other suitable containers.
2. All containers should comply with Schedule F/F1.
3. The drug must comply with standards specified in Schedule F.
4. Serum should be tested for freedom from abnormal toxicity.
5. Multidose containers for liquids should contain preservatives to prevent growth of microorganism.
6. Sterility testing should be done.
7. Some classes of substances should be tested for the absence of aerobic and anaerobic microorganisms like bacterial vaccines, dry preparation of insulin, sera etc.
8. Solution for parenteral administration in dose of 10 ml or more should be tested for freedom from pyrogens.
9. There should be separate laboratories culture and manipulation of spore bearing pathogens.

7. Manufacturing of drugs belonging to Schedule X

A licence is obtained from licensing authority on the application in prescribed Form No. 27B with prescribed fees. If conditions are fulfilled then licence is issued in prescribed Form No. 28B.

Conditions

1. The general conditions applicable to other than Schedules C, C(I) and X.

Special conditions

1. Account of all transactions regarding manufacture should be maintained in a serially bound and paged register as follows. This should be prescribed for 5 years.
   - ✓ **Accounts of drug used in manufacture** (Date of issue, Name of the drug, Opening balance, Quantity received, Quantity used, Balance quantity, Sign.)

- ✓ **Account of production** (Date of manufacturer, Name of drug, Batch No., Quantity of raw material, Wastage, Quantity of manufactured drug)
- ✓ **Amount of manufactured drug** (Date of manufacturer, Name of drug, Batch No., Opening balance, Quantity manufactured, Quantity sold, Name of purchaser, Balance quantity)

2. Manufacturer is required to send the copies of invoice of sale of drugs to licensing authority every 3 months.
3. Preparations should be labeled as X_{RX} (red ink).
4. No Schedule X drugs should be supplied by the way of physician sample.
5. Drugs specified in Schedule X drugs shall be marketed in packaging not exceeding 100 Units dose- Tablets/Capsule, 300 ml –Oral liquid and 5 ml –Injection**.**

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