Drugs & Cosmetic Act,1940 and its Rules

B.Pharm 5th sem.

Introduction

The drugs and cosmetic act act,1940 & its rules 1945 have been enacted with the objective of regulating the import, manufacture, distribution and sale of drugs and cosmetics. The act regulates the manufacture and sale of drugs and cosmetics through licensing so that these are manufactured, distributed and sold only by qualified persons.

The act and rules have been amended from time to time, the major amendment was made in 1982. Accordingly schedules E, I and L were deleted, schedules G and H were revised and expanded add a new schedule X was added.

Schedule G

[List of substances to be used only under medical supervision and to be labelled accordingly]

Most of these drugs are hormonal preparations. The drug label must display the text "Caution: It is dangerous to take this preparation except under medical supervision" prominently.

Aminopterin
L-Asparaginase Bleomycin
Busulphan; its salts
Carbutamide
Chlorambucil;its salts
Chlorothiazide and other derivatives of 1, 2, 4 benzothiadiazine
1. Chlorpropamide; its salts
Chlorthalidone and other derivatives of
Chlorobenzene compound.
2[(Cis-Platin)]
Cyclophosphamide; its salts
2[(Cytarabine)]
Daunorubicin
Di-Isopropyl
Eluorophosphate Disodium
Stilboestrol
Diphosphate
Doxorubicin Hydrochloride
Ethacrynic Acid, its salts
Ethosuximide
Glibenclamide
Hydantoin; its salts; its derivatives, their salts
Hydroxyurea
Insulin, all types
[(Lomustine
Hydrochloride)]
Mannomustine; its salts
Mercaptopurine; its salts
Metformin; its salts
Methsuximide
Mustine, its salts
Paramethadione
Phenacemide
Phenformin; its salts
5-Phenylhydantoin; its alkyl and aryl derivatives; its salts
Primadone
[(Procarpazine
Hydrochloride])
Quinthazone
Sarcolysine
[(Sodium-2-
Mercaptoethanesulfonate]
Tamoxiten Citrate
Testolactone
Thiotepa
Tolbutamide
Tretamine; its salts Troxidone
Antihistaminic substances the following, their salts, their derivatives,
salts of their derivatives
Antazoline
Bromodiphenhydramine
Buclizine
Chlorcyclizine
Chlorpheniramine
Clemizole Cyproheptadine
Diphenhydramine
Diphenylpyraline
Doxylamine Succinate
Isothipendyl
Mebhydrolin Napadisylate
Meclozine Phenindamine
Pheniramine Promethazine
Thenalidine Triprolidine
Substances being tetra-NSubs. derivatives of
Ethylene Diamine or
Prophylenediamine

Schedule H [Prescription Drugs]

This schedule contains the list of the drugs to be sold by retail only in the prescription of a registered medical practitioner (RMP)

List of drugs under schedule H:

Abacavir Abciximab Acamprosate calcium Acebutol hydrochloride Aclarubicin Albendazole Alclometasone dipropionate Actilyse Acyclovir Adenosine Adrenocorticotrophic hormone (acth) Alendronate sodium Alopurinol Alphachymotrypsin 2[Alprazolam Alprostadil Amantadine hydrochloride Amifostine Amikacin sulphate Amiloride hydrochloride 21. Amineptine Aminoglutethimide Amino salicylic acid Amiodarone hydrochloride Amitriptyline Amlodipine besylate Amoscanate Amoxopine Amrinonelactate Analgin Androgenic anabolic, oestrogenic & progestational substances Antibiotics Apraclonidine Aprotinin Organic compound of arsenic Arteether Artemether Artesunate Articaine hydrochloride Atenolol Atracurium besylate injection Atorvastatin Auranofin Azathioprine Aztreonam Bacampicillin Baclofen Balsalazide Bambuterol Barbituric acid Basiliximab Benazepril hydrochloride Benidipine hydrochloride Benserazide hydrochloride Betahistine dihydrochloride Bethanidine sulphate Bezafibrate Bicalutamide Biclotymol monohydrate lactate Bifonazole Bimatoprost Biperiden hydrochloride Biphenyl acetic acid Bitoscanate Bleomycin Primonidine tartrate Bromhexine hydrocloride Bromocriptine mesylate Budesonide Bulaquine Bupivacaine hydrochloride Bupropion Buspirone Butenafine hydrochloride Butorphanol tartrate Cabergoline Calcium dobesilate Candesartan Capecitabine Captopril Carbidopa Carbocisteine Carboplatin Carboquone Carisoprodol L-carnitine Carteolol hydrochloride Carvedilol Cefadroxyl Cefatoxime sodium Cefazolin sodium 92. 2[Cefdinir Cefepime hydrochloride Cefetamet pivoxil Cefpirome Cefpodoximepoxetil Ceftazidime pentahydrate Ceftizoxime sodium] Cefuroxime Celecoxib Centchroman Centbutindole Centpropazine Cetirizine hydrochloride 2[Chlordiazepoxide Chlormezanone Chlorpromazine Chlorzoxazone Ciclopiroxolamine Cimetidine Cinnarizine Ciprofloxacin hydrochloride Cisplatin Citalopram hydrobromide Clarithromycin Clavulanic acid Clidiniumbromide Clindamycin Clobazam Clobetasol propenate Clobetasone 17-butyrate 2[Clofazimine] Clofibrate Clonazepam Clonidine hydrochloride Clopamide Clopidogrel bisulphate Clostebolacetate Clotrimazole Clozapine 2[Codeine]

Colchicine Corticosteroids Cotrimoxazole Cyclandelate Cyclosporins Daclizumab Danazole Dapsone Desloratadine Desogestrol Dexrazoxane Dextranomer Dextropropoxyphene 2[Diazepam] Diazoxide Diclofenac sodium/potassium Dicyclomin hydrochloride Didanosine Digoxine Dilazep hydrochloride Diltiazem Dinoprostone 2[Diphenoxylate, its salts] Dipivefrin hydrochloride Di-sodiumpamidronate Disopyramide Docetaxel Domperidone Donepezil hydrochloride Dopamine hydrochloride Dothiepin hydrochloride Doxapram hydrochloride Doxazosin mesylate Doxepin hydrochloride Doxorubicin hydrochloride Drotrecogin-alpha Ebastine Econozole Efavirenz Enalapril meleate Enfenamic acid Epinephrine Epirubicine Eptifibatide Ergot, alkaloids of whether hydrogenated or not, their homologoues, salts Esomeprazole Estradiol succinate Estramustine phosphate 182. Etanercept Ethacridine lactate 2[Ethambutol hydrochloride] Ethamsylate Ethinyloestradiol 2[Ethionamide] Etidronate disodium Etodolac Etomidate Etoposide Exemestane Famciclovir Famotidine Fenbendazole Fenofibrate Fexofenadine Finasteride Flavoxate hydrochloride 5-fluorouracil Fludarabine Flufenamic acids Flunarizine hydrochloride Fluoxetine hydrochloride Flupenthixol Fluphenazine enanthate and decanoate Flurazepam Flurbiprofen Flutamide Fluticasone propionate Fluvoxamine maleate Formestane Fosfestril sodium Fosinopril sodium Fossphenytoin sodium Fotemustine Gabapentin Galanthamine hydrobromide Galamine, its salts, its quaternary compound Gancyclovir Ganirelix Gatifloxacin Gemcitabine Gemfibrozil Gemtuzumab Genodeoxycholic acid Gliclazide Glimepiride Glucagon Glycopyrrolate Glydiazinamide Goserelin acetate Granisetron Guanethidine Gugulipid Halogenated hydroxyquinolines Haloperidol Heparin Hepatitis b. Vaccine Hyaluronidase Hydrocorisone 17-butyrate Hydrotalcite Hydroxizine Ibuprofen Idebenone Indapamide Imipramine Indinavir sulphate Indomethacin Insulin human Interferon Intravenous fat emulsion Iobitridol Iohexol Iopamidol Iomeprol Iopromide Irbesartan Irinotecan hydrochloride Iron preparation for parenteral use Isepamicine Isocarboxside Isoflurane Isonicotnic acid hydrazine and other-hydragine derivatives of isonicotinic acid Isosorbide dinitrate/ mononitrate Isotretinoin Isoxsuprine Itopride Ketoconazole Ketoprofen Ketorolactromethamine Labetalol hydrochloride Lacidipine Lamivudine Lamotrigine Latanoprost Lefunomide Lercanidipine hydrochloride Letrozole Leuprolide acetate Levamesole Levarterenol Levobunolol Levocetirizine Levodopa 2[Levofloxacin] Levovist Lidoflazine

Schedule M [The requirements of good manufacturing practices [GMP] and factory premises and the requirements of plant and equipment's].

GOOD MANUFACTURING PRACTICES FOR PREMISES AND MATERIALS

A. General Requirements B. Warehouse C. Production Area (New concept)

D. Ancillary area (New concept) E. Quality Control Area (New concept)

F. Personnel (new concept) G. Health, clothing & sanitation of workers

H. Manufacturing Operations & Controls I. Sanitation in the manufacturing Premises

J. Raw Material K. Equipment L. Documentation & Records (New concept)

M. Labels & other Printed Materials N. Quality Assurance (New concept)

O. Self inspection & internal Quality Audit (New concept) P. Quality Control System

Q. Specifications (New concept) R. Master Formula Records S. Batch Processing Record

T. Packaging Record (New concept) U. Batch Packaging Record V. SOPs (New concept)

W. Reference Sample (New concept) X. Reprocessing & Recovery

Y. Distribution Record Z. Validation & Process Validation (New concept)

AA. Product Recall (New concept) AB. Market Complaints & Adverse Reaction AC. Site Master File (New concept)

PART-IA: Requirements For Manufacture Of Parenteral & Ophthalmic Preparations
PART-IB: Requirement For Manufacturing Of Oral Solid Dosage Forms (Tablets & Capsules)
PART-IC: Specific Requirements For Manufacture Of Oral Liquids PART-ID: Specific Requirements for Manufacture of External Preparations:

Schedule N

[List of minimum equipment for the efficient running of a pharmacy]

1. Entrance. - The front of a pharmacy shall bear an inscription —Pharmacy in front.

2. Premises. - The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and, of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a clearly visible and appropriate manner. The areas of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters.

The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.

A pharmacy shall be provided with ample supply of good quality water.

The dispensing department shall be separated by a barrier to prevent the admission of the public.

3. Furniture and apparatus. - The furniture and apparatus of a pharmacy shall be adopted to the uses for which they are intended and correspond to the size and requirements of the establishment.

Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of contents of containers kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size, easily readable with names of medicaments as given in the Pharmacopoeias.

A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastic, etc.

A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the work 'POISON' in red letters on a white background.

Containers of all concentrated solution shall bear special label or marked with the words —To be dilute.

A Pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions

SCHEDULE P [LIFE PERIOD OF DRUGS]

S No.	Name of the drug	Period between date of manufacture and date of expiry (months)	Condition of Drugs
1	Ampicillin	**36**	In a cool place
2	Ampicillin Capsules	**24**	
3	Bacitracin	**18**	In a cool place
4	Carbenicillin Sodium Injection	**24**	At temperature not Exceeding 5°C
5	Colistin Sulphate	**60**	Protected from light
6	Gentamycin Sulphate	**60**	In a cool place.
7	Thiamine Mononitrate	**48**	In a well closed container, protected from
8	Riboflavin	**60**	light, in a cool place.
9	Riboflavin-5-Phosphate	**24**	
10	Insulin Injection	**24**	At temperature between 2oC and 8oC, must not be allowed to freeze
11	Dried Plasma	**60**	At a temperature not exceeding 25oC
12	Frozen Plasma	**60**	In deep freeze

SCHEDULE T [GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES]

The Good Manufacturing Practices (GMP) are prescribed as follows to ensure that:

(i) Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.

(ii) The manufacturing process is as has been prescribed to maintain the standards.

(iii) Adequate quality control measures are adopted.

(iv) The manufactured drug which is released for sale is of acceptable quality.

(v) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. However, under IMCC Act 1970 registered Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of G.M.P.

SCHEDULE U [Particulars to be shown in various records of manufacturing of drug].

1. Serial number
2. Name of the product
3. Reference of Master Formula Records.
2. 4. Lot/Batch Size.
5. Lot/Batch Number.

6. Date of commencement of manufacture and date of completion of manufacture and assigned date of expiry.

7. Name of all ingredients, specifications quantities required for the lot/Batch size and quantities actually used. All weighings and measurements shall be carried out by a responsible person and initialled by him and shall be counter-checked and signed by the competent technical staff under whose personal supervision the ingredients are used for manufacture.

8. Control Numbers of raw materials used in the formulation.

9. Date, time and duration of mixing.

10. Details of environmental controls like room temperature, relative humidity.

11.Date of granulation, wherever applicable.

12. Theoretical weight and actual weight of granules/powder blend

13. Records of in-processes controls (Periodically whenever necessary):

(a) Uniformity of mixing. (b) Moisture content of granules/powder in case of Tablet/Capsules. (c) pH of solution in case of liquid. (d) Weight variation. (e) Disintegration time. (f) Hardness (g) Friability

B. PARENTERAL PREPARATIONS.

1. Serial number. 2. Name of the product. 3. Reference of the master formula record. 4. Batch /Lot size. 5. Batch No. and/or Lot No. 6. Date of commencement of manufacture and date of completion.

7. Names of all ingredients, specifications and quantity required for the Lot/Batch size and quantity actually used. All weighings and measurements shall be carried out by a responsible person and initialled by him and shall be countersigned by the technical staff under whose personal supervision the stock are issued and by another competent technical staff under whose supervision the ingredients are used for manufacture.

8. Control numbers of raw materials used in the formulation.

9. Date, time and duration of mixing.

10. Details of environmental controls like temperature, humidity, microbial count in the sterile working areas.

11. pH of the solution, wherever applicable. 12. Date and method of filtration.

13. Sterility test, reference on bulk batch wherever applicable. 14. Record of check on volume filled.

15. Date of filling. 16. Records of tests employed

(a) To ensure that sealed ampoules are leak proof (b) To check the presence of foreign particles. (c) Pyrogen test, wherever applicable (d) Toxicity test, wherever applicable.

17. Records of checking of instruments and apparatus of sterilization (indicators). 18. Records of cleaning and sterilization of containers and closures, if necessary. 19. Records of sterilization in case of parenteral preparations which are heat sterilized including particulars of time, temperature and pressure employed. Such records should be marked to relate to the batch sterilized.

SCHEDULE V [STANDARDS FOR PATENT OR PROPRIETARY MEDICINES]

Standards for patent or proprietary medicines, containing vitamins: Patent or proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified. General Standards for Different Categories of Patent or Proprietary Medicines. - In the case of pharmaceutical products containing several active ingredients, the selection shall be such that the ingredients do not interact with one another and do not affect the safety and therapeutic efficacy of the product.

Subject to the provisions of these rules, patent or proprietary medicines shall comply with the following standards, namely: -

1. Patent or proprietary medicines shall comply with the general requirements of the dosage form under which it falls as given in the Indian Pharmacopoeia. If the dosage form is not included in the Indian Pharmacopoeia, but is included in any other pharmacopoeia, prescribed for the purpose of the Second Schedule to the Act, it shall comply with the general requirements of the dosage of such pharmacopoeia. Without prejudice to the generality of the foregoing requirements, general requirements shall include compliance with colour consistency, clarity, stability, freedom from contamination with foreign matter or fungal growth, defects like chipping and capping of tablets, cracking of the coating, mottled appearance and other characteristic defects that can be perceived by visual inspection

2. Without prejudice to the generality of the following paras, dosage forms of patent or proprietary medicines shall comply with the following requirements, namely:-

a) Tablets: Medicines shall comply with requirements for tablets as laid down in the Indian Pharmacopoeia. The nature of coating shall be indicated on the label. Permitted colours may, however, be added and declared on the label. Nature of tablets, such as uncoated, sugar coated or film coated, shall be declared on the label.

(b) Capsules : Medicines shall comply with the requirements for capsules laid down in the Indian Pharmacopoeia. However, the capsules shall be free from distortion or shape, dis-colouration and other physical defects like leakage of powder from joints, pinholes or cracks in the capsules;

(c) Liquid oral dosage forms: Emulsions and suspensions shall disperse uniformly on shaking. Homogeneous solutions shall contain no sediments. The volume of the product (net content) in the container shall be not less than the labelled volume. The limit for ethanol content of pharmaceutical products shall be not less than 90 per cent and not more than 110 per cent of the labelled contents.

(d) Injections: Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

(e) Ointments: Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

3. The content of active ingredients, other than vitamins, enzymes and antibiotics, in patent or proprietary medicines shall be not less than 90 per cent and not more than 110 per cent of the labelled content; however, for enzymes and vitamins, only for lower limit of 90 per cent shall apply. In all dry formulations containing antibiotics, the limit shall be 90 to 130 per cent of the labelled contents and in case of liquid antibiotic formulations, the limit shall be 90 to 140 per cent of labelled contents. Fiducial limits for error for microbiological assay of antibiotics may be estimated depending upon the design of assay procedure. Methods, used for assaying active ingredients shall employ the same basic principles and shall use same organisms as given in the latest edition of the Indian Pharmacopoeia or shall follow any other methods as approved by the authority competent to grant licence to manufacture.

4. All patent or proprietary medicines containing aspirin shall be subjected to —Free Salicylic Acid Testو and the limit of such acid shall be 0.75 per cent. Except in case of soluble type aspirin in which case the limit of such acid shall be 3 per cent.

5. Patent or proprietary medicine to be tested under the provisions of rule 121-A for pyrogen shall be tested by injecting into rabbits not less than the human dose of the medicine based on body weight of a 60 kg. human being. Methodology and limits shall be based on the method recorded in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall be not greater than 5 times the human dose based on body weight of 60 kg for man.

6. In injectable patent or proprietary medicines, the test for freedom from toxicity, shall be performed as described in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall not be less than five times the human dose based on body weight of 60 kg. human being

SCHEDULE X [List of the drugs which are habit forming and are likely to be misused for addictive purposes]

Amphetamine

Meprobamate

Phencyclidine

Barbital

Methamphetamine

Phenometrazine

SCHEDULE Y [REQUIREMENTS AND GUIDELINES FOR PERMISSION TO IMPORT AND / OR MANUFACTURE OF NEW DRUGS FOR SALE OR TO UNDERTAKE CLINICAL TRIALS]

DATA TO BE SUBMITTED ALONG WITH THE APPLICATION TO CONDUCT CLINICAL TRIALS/IMPORT/MANUFACTURE OF NEW DRUGS FOR MARKETING IN THE COUNTRY

1. Introduction
2. Chemical and pharmaceutical
3. Animal Pharmacology
4. Animal
5. Human / Clinical pharmacology (Phase I)
6. Therapeutic exploratory trials (Phase II)
7. Therapeutic confirmatory trials (Phase III)
8. Special studies
9. Regulatory status in other countries
10. Prescribing information
11. Samples and Testing Protocol/s
12. New Chemical Entity and Global Clinical Trial:

Schedule F [PART XII B REQUIREMENTS FOR THE FUNCTIONING AND OPERATION OF A BLOOD BANK AND / OR FOR PREPARATION OF BLOOD COMPONENTS]

BLOOD BANKS / BLOOD COMPONENTS

A. GENERAL

1. Location and Surroundings : The blood bank shall be located at a place which shall be away from open sewage, drain, public lavatory or similar unhygienic surroundings.

2. Building : The building (s) used for operation of a blood bank and/or preparation of blood components shall be constructed in such a manner so as to permit the operation of the blood bank and preparation of blood components under hygienic conditions and shall avoid the entry of insects, rodents and flies. It shall be well lighted, ventilated and screened (mesh), wherever necessary. The walls and floors of the rooms, where collection of blood or preparation of blood components or blood products is carried out shall be smooth, washable and capable of being kept clean. Drains shall be of adequate size and where connected directly to a sewer, shall be equipped with traps to prevent back siphonage. Health, clothing and sanitation of staff: The employees shall be free from contagious or infectious diseases. They shall be provided with clean overalls, head-gears, foot-wears and gloves, wherever required. There shall be adequate, clean and convenient hand washing and toilet facilities.

B. ACCOMMODATION FOR A BLOOD BANK.

A blood bank shall have an area of 100 square meters for its operations and an additional area of 50 square meters for preparation of blood components. It shall be consisting of a room each for –

(1) registration and medical examination with adequate furniture and facilities for registration and selection of donors;

(2) blood collection (air-conditioned);

(3) blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degree centigrade to 25 degree centigrade);

(4) laboratory for blood group serology (air-conditioned);

(5) laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV-antibodies (airconditioned);

(6) sterilization-cum-washing;

(7) refreshment-cum-rest room (air-conditioned)

(8) store-cum-records.

C PERSONNEL staff:-

Every blood bank shall have following categories of whole time competent technical

(a) Medical Officer, possessing the qualifications specified in condition (i) of rule 122-G.

(b) Blood

Bank Technician(s) possessing –

(i) Degree in Medical Laboratory Technology (M.L.T) with six months‘ experience in the testing of blood and/or its components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year‘s experience in the testing of blood and / or its components, the degree or diploma being from a University / Institution recognized by

the Central Government or State Government.

(c) Registered Nurse(s)

(d) Technical supervisor (where blood components are manufactured), possessing-

(i) Degree in Medical Laboratory Technology (M.L.T) with six months‘ experience in the preparation of blood components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year‘s experience in the preparation of blood components, the degree or diploma being from a University / Institution recognized by the Central Government or State Government.

D. MAINTENANCE

The premises shall be maintained in a clean and proper manner to ensure adequate cleaning and maintenance of proper operations.

E. EQUIPMENT

Equipment used in the collection, processing, testing, storage and sale/distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance. The equipment shall be observed, standardized and calibrated on a regularly scheduled basis as described in the Standard Operating Procedures Manual and shall operate in the manner for which it was designed so as to ensure compliance with the official.

F. SUPPLIES AND REAGENTS:

All supplies and reagents used in the collection, processing, compatibility, testing, storage and distribution of blood and blood components shall be stored at proper temperature in a safe and hygienic place, in a proper manner and in particular.

Sale of drugs

Under the Sale of Goods Act ‘sale’ is defined ‘as a contract for goods is a contract whereby the seller transfers or agrees to transferthe property in goods to the buyer for a price’.

‘Wholesaler’ means a dealer or an agent or a stockist appointed by the manufacturer for the sale of drugs to a retailer and a retailer means a dealer carrying on the retail business of sale of drugs of customers.

For the sale of drugs a licence is required. For issuing the sale licence, the drugs are divided into following categories.

1. Drugs other than those specified in schedule C, C1 and X
2. Drugs specified in schedule C and C1 but excluding X
3. Drugs specified in schedule X.

Conditions for license for retail sale of drugs

1. An application is made together with the prescribed fee to the licensing authorities for the retail sale of drugs in form19 for drugs other than those specified in schedule X and in form 19C for those specified in schedule X.
2. The licensing authority issues the licence for retail sale of drugs in form-20 for the application made for the drugs other than those specified in schedule C, C1 and X, in form-21 for those specified in schedule C and C1, in form 20-F for those specified in schedule X.

These are the following conditions.

a) The licence premises are adequate and equate with the facilities of proper storage of drugs.

b) The pharmacy shall comply the requirements of schedule N.

c) The licence shall be displayed in a prominent place.

d) All the compounding and dispensing of drugs shall be made under the direct supervision of qualified person.

e) The supply of drugs other than schedule X drugs on a prescription shall be recorded in register or credit memo book.

f) The supply of schedule C drug shall be recorded in register or credit memo book.

g) The drugs shall be purchased from a duly licensed dealer, or a duly licensed manufacturer and purchase bill shall be numbered and maintained in a order.

h) All registers and records shall be produced for inspection by an inspector.

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i) All registers and record shall be preserved for a period of 2years from the date of last entry.

j) Schedule H and X drugs shall be sold with the prescription of a registered medical practitioner.

k) The supply of schedule H and X drugs to the registered medical practitioner, hospital and nursing home shall be made only the signed order in writing. Such orders shall be preserved for a period of 2 years.

l) The schedule H and X drugs shall not be supplied more than once.

m) Only the prescribed schedules H and X drugs shall be dispensed but not the substitutes.

n) Schedule X drugs shall be stored in a cupboard under lock and key separately under the control of a responsible person.

o) An inspection book in form-35 shall be maintained.

p) The drugs after the expiry shall not be sold or stocked.

q) The physician sample drugs, and the drugs meant for the government supply shall not be sold or stocked.

r) The supply of schedule X drugs shall be recorded in separate register and separate pages for each drug.

s) For the sale of additional categories of drugs listed in schedule C and C1 excluding X, the licensee must take prior permission of the licensing authorities

Wholesale of drugs

Application for the grant of wholesale of drug licence is made in form-19 for drugs other than specified in schedule X. And in form 19-C for drugs specified in schedule X.

On being satisfied with the condition fulfilled by the applicant the licensing authority issue the license in form 20-B for other than those schedule C, C1 and X and in Form 21-B for those specified in schedule C and C1 and in Form-20G for those specified in schedule X.

CONDITION OF WHOLESALE LICENSE.

1. The area of the proposed premises shall not be less than 10sq.mt.

2. It shall be in the charge of competent person who is a registered pharmacist or who has passed the matriculation examination or its equivalent with 4 years experience in dispensing of drugs.

3. The premises would have adequate facility for the storage of drugs.

4. The license shall be displayed in a prominent place.

5. The drugs shall be purchased from a duly licensed dealer or duly licensed manufacturer.

6. The supply of drug by wholesale shall be made against a case memo and it should be preserved for a period of 3 years from the date of last entry.

7. Records of purchase of drugs shall be maintained, purchase bills shall be serially numbered and maintained in an order

8. All registers and records shall be produced for inspection by a inspector.

9. All registers and record shall be preserved for a period of 2years from the date of last entry.

10. An inspection book in form-35 shall be maintained.

11. The drugs after the expiry shall not be sold or stocked.

12. The physician sample drugs and the drugs meant for the government supply shall not be sold or stocked.

13. The supply of schedule X drugs shall be recorded in separate register and separate pages for each drug.

14. The copies of invoice of sale of schedule X drugs to the retailer shall be forwarded to the licensing authorities.

15. Any changes in the firm should be reported to the licensing authorities.

Restricted license

Restricted license are issued for the retail sale of drugs to

1. Dealers or persons in respect of drugs whose sale doesn't require the supervision of a qualified person.
2. Itinerant vendors in exceptional cases for bonafide travelling agents of firms dealing a drugs.
3. A vendor who purchases drugs from a licensed dealer for distribution in populated areas where other channels of distribution of drugs are not available.

Restricted license may also be issued to a travelling agent of a firm for the special purpose of distribution to the medical practitioner or dealers for supply of biological and other special products specified in schedule C.

Offence and penalties

Offences	*Penalties* **First conviction**	**Second conviction**
Manufacture, sale, distribution stocking of any adulterated or spurious drug or drug not of standard quality.	Imprisonment for a minimum of 5years extending upto life imprisonment and fine of not less than RS 10,000/-	Imprisonment upto 10 years and fine upto RS 20,000/- or both.
Manufacture, sale, distribution stocking of any adulterated drug but not containing any toxic or harmful substances which may render injurious to health	Imprisonment from 1-3 years and fine not less than Rs 5000/-.	Imprisonment from 2-4 years and fine not less than Rs 10,000/-.
Manufacture, sale, distribution stocking of drug without a license	The court may however for any adequate at special reason to be recorded in judgement impose a term of imprisonment of less than a year and lesser fine	The court may however for any adequate at special reason to be recorded in judgement award imprisonment for less than 2 years and fine of less than Rs. 10,000/-
Using the report of a government analyst for advertising any drug or cosmetic.	Fine upto Rs. 5000	Imprisonment upto 10 years or fine or both

Labelling and packaging of drug

The containers of all the drugs and medicines are to be labelled in accordance with the Drugs and Cosmetic Rule 1945. Following particulars should be appeared on the label of the innermost container.

General labelling requirements and specimen level for drugs and cosmetics.

1. Labelling of drugs manufacture for sale

a) Proper name of the drug or for official product the name or synonyms specified in the pharmacopeia. Ex;- analgin tablets IP

b) For a new drug containing a single active ingredient or a preparation containing single active ingredients specified in schedule W. ex:- Ferrous Sulphate Tablets.

2. The net content a. Weight in grams (solids, semisolids) b. Volume in ml (Liquids). c. Units in number (unit dosage form like tablets and capsules)

3. The content of active ingredients in a single dose or in 5ml or in 1ml or in 1 unit.

4. The name and the address of the manufacturer.

5. Batch number or lot number.

6. Manufacturing license number; Mfg.Lic.No. or M.L.

7. Date of manufacturing. Mfg.Date

8. Date of expiry for the preparation containing schedule P or schedule-C1 drugs.

9. Import License number for the imported preparation containing schedule-C1 drugs

10. ‘Physician’s samples’ not to be sold’ for the free sample to distribute to the medical professionals.

11. The quantity of alcohol as average percentage by the volume of absolute alcohol, if the preparation contains more than 3% alcohol.

12. The words “For single use only” for mechanical contraceptives.

13. Retail price not to exceed Rs. _____+ Local tax Extra.

14. The drug for internal use, containing schedule-G substance labelled with the words. “CAUTION: It is dangerous to intake this preparation except under medical supervision.

15. The drug for internal use, containing schedule-H substance labelled the symbol Rx on the left top corner of the label and with the following words. “SCHEDULE-H DRUGS”

WARNING: To be sold by retail on the prescription of a Registered medical Practitioner only.

16. The drugs for internal use containing schedule X substances labelled the symbol Rx on the left top corner of the label and with the following words. “SCHEDULE-X DRUGS”

WARNING: To be sold by retail on the prescription of a Registered medical Practitioner only.

17. The preparation used as liniment, lotion, liquid antiseptic and other liquid medicine for external use shall be labelled with the words “FOR EXTERNAL USE ONLY”

18. The drugs for animal treatment shall be labelled with words “not for human use, for animal treatment only” and with a symbol of the head of the animal.

19. The drug containing industrial methylated spirit for human treatment shall be labelled with the word “ for external use only”.

SPECIMEN LABELS FOR DRUGS & COSMETICS (SCHEDULE G DRUGS)

PHENIRAMINE TABLETS IP

Each uncoated tablet contains:
Pheniramine maleate IP.....25 mg
Dosage: 1 tablet 2-3 times daily or as directed by the Physician.
Store protected from light

Schedule G Drug

Caution: It is dangerous to take this preparation except under medical supervision.

Mfg Lic. No. 2/20 — M.R.P not to exceed Rs.....
Batch No. 2019 — Inclusive of all taxes
Mfg. Date — Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

SPECIMEN LABELS FOR DRUGS & COSMETICS (SCHEDULE X DRUGS)

XXx PENTOBARBITONE SODIUM INJECTION USP

Each ml contains:
Pentobarbitone Sodium USP .....50 mg
For Intramuscular Injection only
Dosage: As directed by the Physician

Schedule X Drug

Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

The Injection must be discarded if any precipitate is observed

Mfg Lic. No. 2/20 — M.R.P not to exceed Rs.....
Batch No. 2019 — Inclusive of all taxes
Mfg. Date — Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

SPECIMEN LABELS FOR DRUGS & COSMETICS (DRUGS FOR EXTERNAL USE ONLY)

POVIDONE IODINE OINTMENT USP

Composition:
Povidone-Iodine USP.....5% w/w
(0.5% w/w available Iodine)
Water-soluble ointment base q.s.
Store in a cool, dark and dry place

FOR EXTERNAL USE ONLY

Mfg Lic. No. 2/20 — M.R.P not to exceed Rs.....
Batch No. 2019 — Inclusive of all taxes
Mfg. Date — Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

PHENIRAMINE TABLETS IP

Each uncoated tablet contains:
Pheniramine maleate IP.....25 mg
Dosage: 1 tablet 2-3 times daily or as directed by the Physician.
Store protected from light

Caution: It is dangerous to take this preparation except under medical supervision.

Mfg Lic. No. 2/20 — M.R.P not to exceed ₹.....
Batch No. 2019 — inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

List of permitted colors

Following colors may be permitted to be used in medicines.

1. Natural colours: annatto, carotene, chlorophyll, cochineal, curcumine, redoxide, iron oxide, yellow oxide, titanium oxide, black oxide of iron.
2. Artificial colours: a. Caramel, b. Riboflavin

3. Coal tar colours. The common coal tar colours are green, yellow, red, blue, orange, brown and black.

4. Lakes: the aluminium or calcium salts lakes are used.

Administration of the Act and Rules

Administration of the drugs and cosmetic act and rules are divided into 3 parts.

1) Admistrative part or advisory part. a) DTAB(Drug Technical Advisory Board) b) DCC (Drug Consultative Committee)

2) Analytical part. a) Central Drug Laboratory b) Drug testing laboratory of the state. c) Government analyst.

3) Executive Part a) Controlling authority b) Licensing authority c) Drug inspector.

DTAB(Drug Technical Advisory Board)

The following are the members of drugs technical advisory board.

1. Ex-officio members:

i. Director General Health Services.(Chairman)

ii. Drugs Controller of India

iii. Director Central Drugs Laboratory, Kolkata

iv. Director Central Research Institute, kasauli.

v. Director Indian Veterinary Research Institute, Izatnagar.

vi. President Pharmacy Council of India

vii. President Medical Council of India.

viii. Director Central Drug research Institute, Lucknow.

2. Nominted members:

i. 2 persons nominated by central government who are incharge of drugs control in states.

ii. 1 person from the pharmaceutical industry nominated by central government.

iii. 2 government analysts nominated by central government.

3. Elected members.

i. A teacher in Pharmacy or Pharmaceutical chemistry or Pharmacognosy of an Indian university or an affiliated college elected by the executive committee of the Pharmacy Council of India.

ii. A teacher in medicine or therapeutics of an Indian University or an affiliated college elected by executive committee of Medical Council of India.

iii.1 Pharmacologist elected by the governing body of the Indian Council of Medical Research.

iv.1 person elected by the central Council of Medical Association.

v. 1 person to be elected by the council of Indian Pharmaceutical Association.

The nominated and elected members hold the office for 3 years. .They are eligible for re-nomination or re-election.

Function of DTAB

1. The board advises the central government and the state government on the technical matters arising out of the administration of the Act.

2. It advices the central government in framing and modifying the rules under the act related to import, manufacture, sale and distribution of drugs.

CDL [Central Drug Laboratory]

The central government established a central drug laboratory under the Act. The director of central drug laboratory is appointed by central government. The different types of samples are tested in different laboratories, which are working on behalf of CDL Kolkata.

Types of sample to be tested	Laboratory where tested
• Sera, Vaccines, toxins, antigens, antitoxins, sterilized surgical sutures and ligatures. Bacteriophages	Central research Institute, kasauli
• Antisera, vaccines, toxoids and diagnostic antigen. All for veterinary use	Veterinary Research Institute. Izatnagar
• Samples of condoms	Central Pharmacopeial laboratory , Gaziabad
• Samples for oral Polio vaccines	National Institute of Communicable diseases
• Samples of VDRL antigen	Laboratory of serology and chemical examiner to the government of India, Kolkata

1. To analyze or test the sample of drugs and cosmetics sent it by the customs collectors.
2. To carry out other duties given by the central government or state government or DTAB.
3. All the test reports of the samples shall be sent under the register post in a sealed packet with a memorandum form-1.f of CDL Kolkata.

DCC [Drug consultative committee]

It is constituted under section 7 of the Drug and Cosmetics Act.

Constitution.

1. 2 representative nominated by central government.

2. 1 representative nominated by each state government.

The committee meets when required by the central government. It has the power to regulate its own procedure.

Function:

The committee advises the central government, the state government and the DTAB on any matter to secure uniformity throughout India in the administration of the act.

Government drug analyst

A Government Analyst appointed by the Central Government or a State Government under section 33F in case of Ayurvedic, Siddha and Unani drugs and; and under section 20 in relation to other drugs and cosmetics.

Qualifications of Government Analyst.

Government Analyst under the Act shall be a person who

(a) is a graduate in medicine or science or pharmacy or Pharmaceutical Chemistry of a 3[University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] and has had not less than five years‘ post-graduate experience in the testing of drugs in a laboratory under control of

(i) a Government Analyst appointed under the Act, or

(ii) the head of an Institution or testing laboratory approved for the purpose by the appointing authority, 4[or has completed two years‘ training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory], or

(b) possesses a post-graduate degree in medicine or science or pharmacy or Pharmaceutical chemistry of a 3[University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] or possesses the Associateship Diploma of the Institution of Chemists (India) obtained by passing the said examination with "Analysis of Drugs and Pharmaceuticals" as one of the subjects and has had after obtaining the said post-graduate degree or diploma not less than three years‘ experience in the testing of drugs in a laboratory under the control of

(i) a Government Analyst appointed under the Act, or (ii) the head of an Institution or testing laboratory approved for the purpose by the appointing authority 4[or has completed training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory]:

Function of Government Analysts.—

(1) The Government Analyst to whom a sample of any drug has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken, and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst‘s report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

Licensing Authority.—

No person shall be qualified to be a Licensing Authority under the Act unless:-

(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a University established in India by law; and

(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years: 3[Provided that the requirements as to the academic qualification shall not apply to those inspectors and the Government Analysts who were holding those positions on the 12th day of April,1989.]]

Controlling authority.

(1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.

(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.

(3) For the purposes of these rules an officer appointed by the Central Government under sub-rule (1), or as the case may be, an officer appointed by the State Government under sub-rule (2), shall be a controlling authority.]

Qualification of a Controlling Authority.

To be a Controlling Authority under the Act

(1) No person shall be qualified unless

(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law; and

(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years: 2[Provided that the requirements as to the academic qualifications shall not apply to those Inspectors and the Government Analysts who were holding those positions on the 12th day of April, 1989.]

Drugs Inspector :

Inspectors.—(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks 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.

(2) 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.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

Qualifications of Inspectors. —A person who is appointed an Inspector under the Act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law:

Provided that only those Inspectors: —

i) Who have not less than 18 months‘ experience in the manufacture of at least one of the substances specified in Schedule C, or

(ii) Who have not less than 18 months‘ experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority, or

(iii) Who have gained experiences of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as

Drugs Inspectors; shall be authorised to inspect the manufacture of the substances mentioned in Schedule C:]

Duties of Inspectors of premises licensed for sale.

Subject to the instructions of the controlling authority, it shall be duty of an Inspector authorized to inspect premises licensed for the sale of drugs

(1) to inspect 3[not less than once a year] all establishments licensed for the sale of drugs within the area assigned to him;

(2) to satisfy himself that the conditions of the licences are being observed;

(3) to procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the Act or Rules thereunder;

(4) to investigate any complaint in writing which may be made to him;

(5) to institute prosecutions in respect of breaches of the Act and Rules thereunder;

(6) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority;

(7) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act;

(8) when so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

Duties of Inspectors specially authorized to inspect the manufacture of [drugs or cosmetics].

Subject to the instructions of the controlling authority it shall be the duty of an Inspector authorized to inspect the manufacture of drugs

(1) to inspect [not less than once a year], all premises licensed for manufacture of [drugs or cosmetics] within the area allotted to him to satisfy himself that the conditions of the licence and provisions of the Act and Rules thereunder are being observed;

(2) in the case of establishments licensed to manufacture products specified in Schedules C and C(1) to inspect the plant and the process of manufacture, the means employed for standardizing and testing the [drugs or cosmetics], the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product;

(3) to send forthwith to the controlling authority after each inspection a detailed report indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed;

(4) to take samples of the 1[drugs or cosmetics] manufactured on the premises and send them for test or analysis in accordance with these Rules;

(5) to institute prosecutions in respect of breaches of the Act and Rules thereunder.

Prohibition of sale.

No person in possession of a drug 2[or cosmetic] in respect of which an Inspector has made an order under clause (c) of sub-section (1) of section 22 of the Act shall in contravention of that order sell or otherwise dispose of any stock of such drug 2[or cosmetic].

Power of DI

Under the section 22 of DC Act. Drugs Inspectors have been assigned with following powers.

1. To inspect any premises where drug or cosmetic is being manufactured.

2. Inspection of premises where any drugs or cosmetics is being sold or stocked or offered for sale or distributed.

3. Taking samples of any drug or cosmetics which is being manufactured or sold or stocked or offered for sale or distributed.

4. Taking samples of drugs or cosmetics from any person sent that sample for the test and analyses.

5. at all reasonable times with necessary assistance can search any person, enter and search any place where an offence under the act.

6. Examine any record , register document or any other materials related to manufacturing , sale or stock of drugs and cosmetics.