Introduction:

The drugs and cometics act 1940 and rules 1945 have been passed to regulate the import, manufacture, distribution and sale of drugs and cosmetics. All the operations related to drugs should be done by qualified persons. To have a check, on search operation the central and state government are established the state and central drug control authorities. Drug and cosmetics rule have been divided into 18 parts, each belong with a particular subject. There are two schedules to the act and 25 schedules to the rules.

Schedule G

It contains the list of the drugs should be used under the medical supervision only.

List of drugs under schedule G:

Aminopterin
L-**A**sparaginase **B**leomycin
Busulphan; its salts
Carbutamide
Chlorambucil;its salts
Chlorothiazide and other derivatives of 1, 2, 4 benzothiadiazine
Chlorpropamide; its salts
Chlorthalidone and other derivatives of Chlorobenzene compound.
2[(**C**is-Platin)]
Cyclophosphamide; its salts
2[(**C**ytarabine)]
Daunorubicin
Di-Isopropyl Eluorophosphate **D**isodium 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-**P**henylhydantoin; its alkyl and aryl derivatives; its salts
Primadone
[(**P**rocarpazine Hydrochloride])
Quinthazone
Sarcolysine
[(**S**odium-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-N-Subs. derivatives of Ethylene Diamine or Prophylenediamine

Schedule H :

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
Linezplid

Lithium carbonate
Lofepramine decanoate
Loperamide
Lorazepam
Losartan potassium
Loteprednol
Lovastatin
Loxapine
Mebendazole
Mebeverine hydrochloride
Medroxyprogesterone acetate
Mefenamic acid
Mefloquine hydrochloride
Megestrol acetate
Meglumine iocarmate
Melagenina
Elitracenhydrochloride
Meloxicam
Mephenesin, its esters
Mephentermine
2[Meropenam]
Mesterolone
Metaxalone
Methicillin sodium
Methocarbamol
Methotraxate
Metoclopramide
Metoprolol tartrate
Metrizamide
Metronidazole
Mexiletine hydrochloride
Mianserin hydrochloride
Miconazole
2[Midazolam]
Mifepristone
Milrinone lactate
Miltefosine
Minocycline
Minoxidil
Mirtazapine
Misoprostol
Mitoxantrone hydrochloride
Mizolastine
Moclobemide
Mometasone furoate
Montelukast sodium
Morphazinamide
hydrochloride
Mosapride
2[Moxifloxacin]
Mycophenolate mofetil
Nadifloxacin
Nadolol
Nafarelin acetate
Nalidixic acid
Naproxen
Narcotics drugs listed in
Narcotic Drugs &
Psychotropic Substances Act,
1985
Natamycin
Nateglinide
N-butyl-2-cyanoacrylate
Nebivolol
Nebumetone
Nelfinavir mesilate
Netilmicin sulphate
Nevirapine
Nicergoline
Nicorandil
Nifedipine
Nimesulide
Nimustine hydrochloride
2[Nitrazepam]
Nitroglycerin
Norethisterone enanthate
Norfloxacin
Octylonium bromide
Ofloxacin
Olanzapine
Omeprazole
Ornidazole
Orphenadrine
Orthoclone sterile
Oxazepam
Oxazolidine
Oxcarbazepine
Oxethazaine hydrochloride
Oxiconazole
Oxolinic acid
Oxprenolol hydrochloride
Oxybutynin chloride
Oxyfedrine
Oxymetazoline
Oxyphenbutazone
Oxytocin
Ozothine
Paclitaxel
Pancuronium bromide
Pantoprazole
Para-amino benzene
sulphonamide, its salts &
derivatives
Parp-amino salicylic acid, its
salts, its derivatives
Parecoxib
Paroxetine hydrochloride
D-penicilamine
2[Pentazocine]
Pentoxifylline
Pepleomycin
Phenelzineh sulphate
Phenobarbital
Phenothiazine, derivatives of
and salts of its derivatives
Phenylbutazine
Pimozide
Pindolol
Pioglitazone hydrochloride
Piracetam
Piroxicam
Pituitory gland, active
principles of, not otherwise
specified in this schedule and
their salts
Polidocanol
Polyestradiol phosphate
Poractant alfa
Praziquantel
Prednimustine iothalamates
Prednisolone stearoylglycolate
Prenoxdiazinhydro-chloride
Promazine hydrochloride
Promegestone
Propafenon hydrochloride
Propanolol hydrochloride 416.
Propofol
Protristyline hydrochloride
2[Pyrazinamide]
Pyrvinium
Quetiapine fumerate
Quinapril
Quinidine sulphate
Rabeprazole
Racecadotril
Raloxifene hydrochloride
Ramipril hydrochloride
Ranitidine
Rauwolfia, alkaloids of, their
salts, derivatives of the
alkaloids or rauwolfia
Reboxetine
Repaglinide
Reproterol hydrochloride
Rilmenidine
Riluzone
Risperidone
Ritonavir
Ritodrine hydrochloride
Rituximab
Rivastigmine
Rocuronium bromide
Ropinirole
Rosoxacin
Rosiglitazone meleate

Salbutamol sulphate
Salicyl-azo-sulphapyridine
Salmon calcitonin
Saquinavir
Satranidazole
Secnidazole
Septopal beads & chains
Serratiopeptidase
Sertraline hydrochloride
Sibutramine hydrochloride
Sildenafil citrate
Simvastatin
Sirolimus
Sisomicin sulphate
S-neominophagen
Sodiumpico sulphate
Sodium cromoglycate
Sodium hyaluronate
Sodium valproate
Sodium and maglumine iothalamates
Somatostatin
Somatotropin
Sotalol
2[Sparfloxacin]
Spectinomycin hydrochloride
Spironolactone
Stavudine
Sucralfate
Sulphadoxine
Sulphamethoxine
Sulphamethoxypyridazine
Sulphaphenazole
Sulpiride
Sulprostone hydrochloride
Sumatriptan
Tacrine hydrochloride
Tamsulosin hydrochloride
Trapidil
Tegaserod maleate
Teicoplanin
Telmisartan
Temozolamide
Terazosin
Terbutaline sulphate
Terfenadine
Terizidone
Terlipressin
Testosteroneun decoanoate
Teratolol hydrochloride
Thalidomide
2[Thiacetazone]
Thiocolchicoside
Thiopropazate, its salts
Thymogene
Thymosin-alpha1
Tiaprofenic acid
Tibolone
Timolol maleate
Tinidazole
Tizanidine
Tabramycin
Tolfenamic acid
Topiramate
Topotecan hydrochloride
2[Tramadolhydrochloride]
Tranexamic acid
Tranylcypromine, its salts
Trazodone
Tretinoin
Trifluperazine
Trifluperidol hydrochloride
Triflusal
Trimetazidine dihydrochloride
Trimipramine
Tripotassium dicitrate bismuthate
Tromantadine hydrochloride
Urokinase
Valsartan
Vasopressin
Vecuronium bromide
Venlafaxine hydrochloride
Verapamil hydrochloride
Verteporfin
Vincristine sulphate
Vinblastine sulphate
Vindesine sulphate
Vinorelbine tatrate
Xipamide
Zidovudine hydrochloride
Ziprasidone hydrochloride
Zoledronic acid
2[Zolpidem]
Zopiclone
Zuclopenthixol

Scheulde M

The requirements of good manufacturing practices (GMP) and factory premises and the requirements of plant and equipements.

GOOD MANUFACTURING PRACTICES FOR PREMISES AND MATERIALS

1 GENERAL REQUIREMENTS:

1.1. ***Location and surroundings***.- The factory building(s) for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any factory which produce disagreeable or obnoxious odour or fumes, excessive soot, dust, smoke, chemical or biological emissions.

1.2. ***Buildings and premises***.- The building(s) used for the factory shall be designed, constructed, adapted and maintained to suit the manufacturing operations so as to permit production of drugs under hygienic conditions. They shall conform to the conditions laid down in the Factories Act, 1948 (63 of 1948).

The premises used for manufacturing, processing, warehousing, packaging, labelling and testing purposes shall be –

(i) compatible with other drug manufacturing operations that may be carried out in the same or adjacent area / section;
(ii) adequately provided with working space to allow orderly and logical placement of equipment, materials and movement of personnel so as to:

(a) avoid the risk of mix-up between different categories of drugs or with raw materials, intermediates and in-process material;

(b) avoid the possibilities of contamination and cross- contamination by providing suitable mechanism;

(iii) designed / constructed / maintained to prevent entry of insects, pests, birds, vermins and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks, and permit easy cleaning, painting and disinfection
(iv) air-conditioned, where prescribed for the operations and dosage forms under production. The production and dispensing areas shall be well lighted, effectively ventilated, with air control facilities and may have proper Air Handling Units (wherever applicable) to maintain conditions including temperature and, wherever necessary, humidity, as defined for the relevant product. These conditions shall be appropriate to the category of drugs and nature of the operation. These shall also be suitable to the comforts of the personnel working with protective clothing, products handled, operations undertaken within them in relation to the external environment. These areas shall be regularly monitored for compliance with required specifications;
(v) provided with drainage system, as specified for the various categories of products, which shall be of adequate size and so designed as to prevent back- flow and/or prevent insects and rodents entering the premises. Open channels shall be avoided in manufacturing areas and, where provided, these shall be shallow to facilitate cleaning and disinfection;
(vi) the walls and floors of the areas where manufacture of drugs is carried out shall be free from cracks and open joints to avoid accumulation of dust. These shall be smooth, washable, coved and shall permit easy and effective cleaning and disinfection. The interior surfaces shall not shed particles. A periodical record of cleaning and painting of the premises shall be maintained.
1.3 Water System. - There shall be validt. system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by the Bureau of Indian Standards or Local Municipality, as the case may be, so as to produce Purified Water conforming to Pharmacopoeial specification. Purified Water so produced shall only be used for all the operations except washing and cleaning operations where potable water may be used. Water shall be stored in tanks, which do not adversely affect quality of water and ensure freedom from microbiological growth. The tank shall be cleaned periodically and records maintained by the licensee in this behalf.
1.4. Disposal of waste. -
(i) The disposal of sewage and effluents (solid, liquid and gas) from the manufactory shall be in conformity with the requirements of Environment Pollution Control Board.
(ii) All bio-medical waste shall be destroyed as per the provisions of the Bio- Medical Waste (Management and Handling) Rules, 1996.
(iii) Additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of waste.
(iv) Provisions shall be made for the proper and safe storage of waste materials awaiting disposal. Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State Legislations.

2. Warehousing Area:
2.1 Adequate areas shall be designed to allow sufficient and orderly warehousing of various categories of materials and products like starting and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned or recalled, machine and equipment spare parts and change items.

2.2. Warehousing areas shall be designed and adapted to ensure good storage conditions. They shall be clean, dry and maintained with acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity), these shall be provided, monitored and recorded. Storage areas shall have appropriate house-keeping and rodent, pests and vermin control procedures and records maintained. Proper racks, bins and platforms shall be provided for the storage of materials.
2.3. Receiving and dispatch bays shall protect materials and products from adverse weather conditions.
2.4. Where quarantine status is ensured by warehousing in separate earmarked areas in the same warehouse or store, these areas shall be clearly demarcated. Any system replacing the physical quarantine, shall give equivalent assurance of segregation. Access to these areas shall be restricted to authorized persons.

3. Production area:
3.1. The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations.
3.2. In order to avoid the risk of corss-contamination, separate dedicated and self- contained facilities shall be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live micro-organisms. Separate dedicated facilities shall be provided for the manufacture of contamination causing and potent products such as Beta-Lactum, Sex Hormones and Cytotoxic substances.
3.3. Working and in-process space shall be adequate to permit orderly and logical positioning of equipment and materials and movement of personnel to avoid cross- contamination and to minimize risk of omission or wrong application of any manufacturing and control measures.
3.4. Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid 1[accumulation of dust]. Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

4. Ancillary Areas:
4.1 Rest and refreshment rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas.
4.2 Facilities for changing, storing clothes and for washing and toilet purposes shall be easily accessible and adequate for the number of users. Toilets, separate for males and females, shall not be directly connected with production or storage areas. There shall be written instructions for cleaning and disinfection of such areas.

5. Quality Control Area.
5.1. Quality Control Laboratories shall be independent of the production areas. Separate areas shall be provided each for physico-chemical, biological, microbiological or radio-isotope analysis. Separate instrument room with adequate area shall be provided for sensitive and sophisticated instruments employed for analysis.
5.2 Quality Control Laboratories shall be designed appropriately for the operations to be carried out in them. Adequate space shall be provided to avoid mix-ups and cross-contamination. Sufficient and suitable storage space shall be provided for test samples, retained samples, reference standards, reagents and records.
5.3. The design of the laboratory shall take into account the suitability of construction materials and ventilation. Separate air handling units and other requirements shall be provided for biological, microbiological and radioisotopes testing areas. The laboratory shall be provided with regular supply of water of appropriate quality for cleaning and testing purposes.
5.4. Quality Control Laboratory shall be divided into separate sections i.e. for chemical, microbiological and wherever required, biological testing. These shall have adequate area for basic installation and for

ancillary purposes. The microbiology section shall have arrangements such as airlocks and laminar air flow work station, wherever considered necessary.

6. Personnel:

6.1. The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience in the relevant dosage form and / or active pharmaceutical products.

6.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.

6.3. Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.

7. Health, clothing and sanitation of workers:

7.1 The personnel handling Beta-lactum antibiotics shall be tested for Penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects. These personnel should be moved out of these sections (except in dedicated facilities), by rotation, as a health safeguard.

7.2 Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof. The licensee shall provide the services of a qualified physician for assessing the health status of personnel involved in different activities.

7.3 All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.

7.4 Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.

8. Manufacturing Operations and Control:

8.1 All manufacturing operations shall be carried out under the supervision of technical staff approved by the Licensing Authority. Each critical step in the process relating to the selection, weighing and measuring of raw material addition during various stages shall be performed by trained personnel under the direct personal supervision of approved technical staff.

8.2. ***Precautions against mix-up and cross-contamination:***

8.2.1. The licensee shall prevent mix-up and cross-contamination of drug material and drug product (from environmental dust) by proper air-handling system, pressure differential, segregation, status labelling and cleaning. Proper records and Standard Operating Procedures thereof shall be maintained.

8.2.2 The licensee shall ensure processing of sensitive drugs like Beta-Lactum antibiotics, sex hormones and cytotoxic substances in segregated areas or isolated production areas within the building with independent air-handling unit and proper pressure differentials.

9. Sanitation in the Manufacturing Premises:

9.1 The manufacturing premises shall be cleaned and maintained in an orderly manner, so that it is free from accumulated waste, dust, debris and other similar material. A validt. cleaning procedure shall be maintained.

9.2 The manufacturing areas shall not be used for storage of materials, except for the material being processed. It shall not be used as a general thoroughfare.

9.3 A routine sanitation program shall be drawn up and observed, which shall be properly recorded and which shall indicate–

(a) specific areas to be cleaned and cleaning intervals;

(b) cleaning procedure to be followed, including equipment and materials to be used for cleaning; and

(c) personnel assigned to and responsible for the cleaning operation.
9.4 The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of mix- up between different pharmaceutical products or their components to avoid cross contamination, and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.
9.5 Production areas shall be well lit, particularly where visual on-line controls are carried out.

10. Raw Materials:
10.1 The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per Schedule U.
10.2 All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored under appropriate conditions and in an orderly fashion to permit batch segregation and stock rotation by a "first in/first expiry'first-out" principle. All incoming materials shall be checked to ensure that the consignment corresponds to the order placed.
10.3 All incoming materials shall be purchased from approved sources under valid purchase vouchers. Wherever possible, raw materials should be purchased directly from the producers.

11. Equipment:
11.1 Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products. Each equipment shall be provided with a logbook, wherever necessary.
11.2 Balances and other measuring equipment of an appropriate range, accuracy and precision shall be available in the raw material stores, production and in-process control operations and these shall be calibrated and checked on a scheduled basis in accordance with Standard Operating Procedures and records maintained.
11.3 The parts of the production equipment that come into contact with the product shall not be reactive, additive or adsorptive to an extent that would affect the quality of the product.

12. **Documentation and Records**:– Documentation is an essential part of the Quality assurance system and, as such, shall be related to all aspects of Good Manufacturing Practices (GMP). Its aim is to define the specifications for all materials, method of manufacture and control, to ensure that all personnel concerned with manufacture know the information necessary to decide whether or not to release a batch of a drug for sale and to provide an audit trail that shall permit investigation of the history of any suspected defective batch.
12.1 Documents designed, prepared, reviewed and controlled, wherever applicable, shall comply with these rules.
12.2 Documents shall be approved, signed and dt. by appropriate and authorized persons.
12.3 Documents shall specify the title, nature and purpose. They shall be laid out in an orderly fashion and be easy to check. Reproduced documents shall be clear and legible. Documents shall be regularly reviewed and kept up to date. Any alteration made in the entry of a document shall be signed and dt.

13. Labels and other Printed Materials:– Labels are absolutely necessary for identification of the drugs and their use. The printing shall be done in bright colours and in a legible manner. The label shall carry all the prescribed details about the product.
14. Quality Assurance:–This is a wide-ranging concept concerning all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that products are of the quality required for their intended use.

15. Self Inspection and Quality audit:– It may be useful to constitute a self-inspection team supplemented with a quality audit procedure for assessment of all or part of a system with the specific purpose of improving it.
Written instructions for self-inspection shall be drawn up which shall include the following: -

(a) Personnel.
(b) Premises including personnel facilities.
(c) Maintenance of buildings and equipment
(d) Storage of starting materials and finished products.
(e) Equipment.
(f) Production and in-process controls.
(g) Quality control.
(h) Documentation.
(i) Sanitation and hygiene.
(j) Validation and revalidation programmes.
(k) Calibration of instruments or measurement systems.
(l) Recall procedures.
(m) Complaints management.
(n) Labels control.
(o) Results of previous self-inspections and any corrective steps take

17. Specification

17.1 For raw materials and packaging materials. - They shall include-

(a) the designated name and internal code reference;
(b) reference, if any, to a pharmacopoeial monograph;
(c) qualitative and quantitative requirements with acceptance limits;
(d) name and address of manufacturer or supplier and original manufacturer of the material;
(e) specimen of printed material;
(f) directions for sampling and testing or reference to procedures;
(g) storage conditions; and
(h) maximum period of storage before re-testing.

17.2 For product containers and closures:–

17.2.1 All containers and closures intended for use shall comply with the pharmacopoeial requirements. Suitable validt. test methods, sample sizes, specifications, cleaning procedure and sterilization procedure, wherever indicated, shall be strictly followed to ensure that these are not reactive, additive, absorptive, or leach to an extent that significantly affects the quality or purity of the drug. No second hand or used containers and closures shall be used.

18. Master Formula Records:

There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff i.e. head of production and quality control.
The Master Formula shall include: -
(a) the name of the product together with product reference code relating to its specifications;
(b) the patent or proprietary name of the product along with the generic name, a description of the dosage form, strength, composition of the product and batch size;
(c) name, quantity, and reference number of all the starting materials to be used. Mention shall be made of any substance that may 'disappear‘ in the course of processing.
(d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.
(e) a statement of the processing location and the principal equipment to be used.
(f) the methods, or reference to the methods, to be used for preparing the critical equipments including cleaning, assembling, calibrating, sterilizing;
(g) detailed stepwise processing instructions and the time taken for each step; (h) the instructions for in-process control with their limits;
(i) the requirements for storage conditions of the products, including the container, labelling and special storage conditions where applicable;
(j) any special precautions to be observed; (k) packing details and specimen labels.

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

Sl. No.	Name of the drug	Period between date of manufacture and date of expiry(months)	Condition of storage
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 light, in a cool place.
8	Riboflavin	60	
9	Riboflavin-5-Phosphate	24	
10	Insulin Injection	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
11	Dried Plasma	60	At a temperature not exceeding 25°C
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.

A. SUBSTANCES, OTHER THAN PARENTERAL PREPARATIONS IN GENERAL.

1. Serial number
2. Name of the product
3. Reference of Master Formula Records.
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 test
    (h) Leak test in case of strip packing.
    (i) Filled volume of liquids.
    (j) Quantity of tablets/capsules in the final container.
    (k) Content of ointment in the filled containers.

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 Test‖ 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

A brief description of the drug and the therapeutic class to which it belongs.

2. Chemical and pharmaceutical information2.1. Information on active ingredients

Drug information (Generic Name, Chemical Name or INN)

2.2. Physicochemical Data

(a) Chemical name and Structure

- Empirical formula
- Molecular weight

(b) Physical properties

- Description
- Solubility
- Rotation
- Partition coefficient
- Dissociation constant

2.3. Analytical Data

- Elemental analysis
- Mass spectrum
- NMR spectra
- IR spectra
- UV spectra
- Polymorphic identification

2.4. Complete monograph specification including

- Identification
- Identity/quantification of impurities
- Enantiomeric purity
- Assay

2.5. Validations

- Assay method
- Impurity estimation method
- Residual solvent/other volatile impurities (OVI) estimation method

2.6. Stability Studies (for details refer Appendix IX)

- Final release specification
- Reference standard characterization
- Material safety data sheet

2.7. Data on Formulation

- Dosage form
- Composition
- Master manufacturing formula
- Details of the formulation (including inactive ingredients)
- In process quality control check
- Finished product specification

- Excipient compatibility study
- Validation of the analytical method
- Comparative evaluation with international brand(s) or approved Indian brands, if applicable
- Pack presentation
- Dissolution
- Assay
- Impurities
- Content uniformity
- pH
- Force degradation study
- Stability evaluation in market intended pack at proposed storage conditions
- Packing specifications
- Process validation

When the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container-closure system for the duration of the clinical trial (information covered in item nos. 2.1, 2.3, 2.6, 2.7) are required.

3. Animal Pharmacology (for details refer Appendix IV)
    3.1. Summary
    3.2. Specific pharmacological actions
    3.3. General pharmacological actions
    3.4. Follow-up and Supplemental Safety Pharmacology Studies
    3.5. Pharmacokinetics: absorption, distribution; metabolism; excretion
4. Animal Toxicology (for details refer Appendix III)
    4.1. General Aspects
    4.2. Systemic Toxicity Studies
    4.3. Male Fertility Study
    4.4. Female Reproduction and Developmental Toxicity Studies
    4.5. Local toxicity
    4.6. Allergenicity/Hypersensitivity
    4.7. Genotoxicity
    4.8. Carcinogenicity

[Note.- Where the data on animal toxicity as per the specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.]

5. Human / Clinical pharmacology (Phase I)
    5.1. Summary
    5.2. Specific Pharmacological effects
    5.3. General Pharmacological effects
    5.4. Pharmacokinetics, absorption, distribution, metabolism, excretion
    5.5. Pharmacodynamics / early measurement of drug activity
6. Therapeutic exploratory trials (Phase II)
    6.1. Summary
    6.2. Study report(s) as given in Appendix II
7. Therapeutic confirmatory trials (Phase III)
    7.1. Summary
    7.2. Individual study reports with listing of sites and Investigators.
8. Special studies

8.1. Summary
8.2. Bio-availability / Bio-equivalence.
8.3. Other studies e.g. geriatrics, paediatrics, pregnant or nursing women

9. Regulatory status in other countries
9.1. Countries where the drug is
a) Marketed
b) Approved
c) Approved as IND
d) Withdrawn, if any, with reasons
9.2. Restrictions on use, if any, in countries where marketed /approved
9.3. Free sale certificate or certificate of analysis, as appropriate.
10. Prescribing information
10.1. Proposed full prescribing information
11. Samples and Testing Protocol/s
11.1. Samples of pure drug substance and finished product (an equivalent of 50 clinical doses, or more number of clinical doses if prescribed by the Licensing Authority), with testing protocol/s, full impurity profile and release specifications.
12. New Chemical Entity and Global Clinical Trial:
12.1 Assessment of risk versus benefit to the patients
12.2 Innovation vis-à-vis existing therapeutic option
12.3 Unmet medical need in the country.]

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 (air-conditioned);
(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

Sale is defined as the seller transfers or agrees to transfer the property in goods to the buyer for a price. Wholesale means a dealer or an agent or a stockist appointed by the manufacturer for the sale of drugs to a retailer and a dealer 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 of licence 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 a inspector.
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 undr lock and key separately undr 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 scheduleC 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 bonafied 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	First conviction	Subsequent 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 harmfull 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/-.
anufacture, sale, distribution cking of drug without a ense	e court may however for any equate at special reason to be corded in judgement impose a m of less than a year and ser fine	e court may however for any equate at special reason to be corded in judgement impose a term less than 2 years and fine less than . 10,000/-
ilure to keep records or close required information	prisonment upto 1 year and a e upto 1000/-	me as first conviction-
ing the report of a government alyst for advertising any drug.	e upto 500/-	prisonment upto 10 years or with e 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 aveage 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".

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 Counscil 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.

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.

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 Pharmacopeal 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

Function

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.

Government 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.

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 othjer materials related to manufacturing , sale or stock of drugs and cosmetics.

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.]

References-
1. Drugs and Cosmetics Act ,1940 and Rules, 1945 As amended up to the 31st December, 2016
2. A text book of forensic pharmacy by B.M.Mithal
3. A text book of forensic pharmacy by Dr. B. Kuchhekar.
4. A text book of forensic pharmacy by N.K.Jain
5. A text book of forensic by B.Suresh.