JES's college of Pharmacy,Nandurbar

DRUG AND COSMETICS ACT,1940 AND ITS RULES 1945

Ms: Manisha K. Gavit
Assistant Professor
(Department of Pharmaceutical Chemistry)

OBJECTIVES

- Act was passed on **10th April 1940.**
- To regulate the import, manufacture, distribution and sale of drugs & cosmetics through licensing.
- Provision to Manufacture, distribution and sale of drugs and cosmetics by qualified persons only.
- To prevent the manufacturing of spurious(Bogus/Duplicate) and substandard drugs, presumably for maintaining high standards of medical treatment.
- To regulate the import of drugs into India.
- To regulate the manufacture and sale of Ayurvedic, Siddha and Unani drugs.
- To establish Drugs Technical Advisory Board(DTAB) and Drugs Consultative Committees(DCC) for Allopathic and allied drugs and cosmetics.

- Short title, extent and commencement-This Act may be called the Drugs and Cosmetics Act, 1940.
- It extends to the whole of India
- Application of other laws not barred – The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930, and any other law for the time being in force.

DRUGS:

1. All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
2. Such substances other than food intended to affect the structure or any function of the human body or intended to be used for destruction of vermin or insects which can cause disease in human beings or animals.
3. All substances intended for use as components of a drug including empty gelatin capsule.
4. Such device intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

Ayurvedic , Siddha or Unani

- Drug It includes all medicines for intended for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, and manufactured in accordance with the formulae described in the authoritative books of ayurvedic, siddha or unani system of medicine, specified in First schedule.

Cosmetic :

- Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

MISBRANDED DRUGS :

1. if it is so colored, coated, powdered or polished that, damage is concealed (hidden) or if it is made to appear of better or greater therapeutic value than it really is, or
2. if it is not labeled in the prescribed manner, or
3. if its label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular way.

Misbranded cosmetic : -

1. It contains a color which is not prescribed, or
2. It is not labeled in prescribed manner, or
3. The label or container or anything accompanying the cosmetic make any false or misleading claims.

ADULTERATED DRUG :

1. If it consists, in whole or in part, of any filthy (dirty), putrid (decay/decomposed) or decomposed substance; or
2. If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth(dust) or whereby it may have been rendered injurious to health; or
3. If its container is composed in whole or in part, of any poisonous or deleterious (harmful) substance which may render the contents injurious to health, or
4. If it bears or contains, a color other than one which is prescribed which may be used for the purpose of coloring only, or
5. If it contains any harmful or toxic substance which may render it injurious to health; or
6. If any substance mixed with it so as to reduce its quality or strength.

SPURIOUS DRUGS :

1. If it is imported under a name which belongs to another drug, or
2. If it is an imitation of or a substitute for another drug or resembles to another drug in a manner likely to deceive or bear upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
3. If the label or the container bears the name of an individual or company purporting (claiming) to be the manufacturer of the drug, which individual or company is fictitious or does not exist.
4. If it has been substituted wholly or in part by another drug or substance; or
5. If it purports (claim) to be the product of a manufacturer of whom it is not truly a product.

SPURIOUS COSMETIC:

1. If it is imported under a name which belongs to another cosmetic
2. If it is an imitation of, or a substitute for, another cosmetic: or resembles another cosmetic: in a manner likely to deceive or bears upon it or upon Its label or container the name of another cosmetic: unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic ;
3. If the label or the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic:, which individual or company is fictitious (false) or does not exist; or
4. If it purports (claims) to be the product of a manufacturer of whom it is not truly a product.

MANUFACTURE :

- In relation to any drug or cosmetic, it includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

Patent or Proprietary medicine :

- A drug which is remedy or prescription presented in a form ready for internal or external administration of human beings or animals prepared according to the formulae and which is not included in the edition of the Indian Pharmacopoeia or any other Pharmacopoeia or official book.

Inspector: -

1. In relation to ayurvedic, siddha or unani drug, an inspector appointed by central or state government under section 33-
2. In relation to any other drug or cosmetic, an inspector appointed by central or state government under section 21.

Government analyst: -

1. In relation to Ayurvedic, Siddha or Unani drug, a person appointed under section 33-F.
2. In relation to any other drug or cosmetic, a person appointed under section 20 of drug and cosmetic act.

New drug:-

A new substance of chemical, biological or biotechnological origin in bulk

- **Repacking of drugs:-** it is the process of breaking up any drug from a bulk container into small packages and the labeling of each package with a view to it's sale and distribution. But, it does not include the compounding dispensing or the packing of any drug in the ordinary course of retail business.
- **Loan License:-**It means a license issued by a licensing authority to a person, who does not have his own arrangement for manufacture but who intends to avail himself of the manufacturing facilities owned by another manufacturer.
- **Drug store:-** licensed premises for the sale of drugs, which do not require the service of registered pharmacist.
- **Pharmacy:-** licensed premises for the sale of drugs which require the services of a registered pharmacist and where the drugs are compounded (or sold) against prescription.
- **Registered homeopathic medical practitioner:-** A person who is registered in the central or state register of homeopathy.

- **Qualified person:-** A person who Holds a diploma or degree in pharmacy or pharmaceutical chemistry; OR
- Is a registered pharmacist, (under Pharmacy act, 1948)
- Has minimum 4 years experience of dispensing and has been approved by licensing authority as a qualified person on or before 31st December 1969.

- **Import:-** means to bring into India.

- **Retail sale:-** it means a sale whether to a hospital or a dispensary or a medical educational or research institute or to any other person other than a sale by the way of wholesale dealing.

- **Sale by the way of wholesale dealing:-** it means sale to a person for the purpose of selling again and also includes sale to hospitals, dispensaries, or medical, educational or research institutions

SCHEDULES TO THE ACT

- First schedule – List of Ayurvedic, Siddha and Unani Books.

- Second schedule – Standard to be complied with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed.

SCHEDULES TO THE RULES

- "A" List of forms used for making applications for Issuing licenses, Granting licenses, Sending memorandums. Proforma for forms no. 1 to 50 (Application, issue, renewal, etc.)
- "B" Fees for test or analysis by the CDL or Govt. analysts
- "C" Biological and special products (Injectable) Ex. Sera, Vaccines, Penicillin…..etc.
- "C1" Other special products (non-parenteral) applicable to special provisions. Ex. Digitalis, Hormones, Ergot
- "D" List of drugs that are exempted from certain provisions of import
- E -list of poisonous substances omitted
- "E1" List of Ayurvedic, Siddha and Unani poisonous substances.
- "F" Provisions applicable to Blood Bank requirements and licensing to process Blood Components.

- “F1” Provision applicable to Vaccines, Antisera and Diagnostic agents
- “F2” Standards for Surgical Dressings
- “F3” Standards for Umbilical Tapes
- “FF” Standards for Ophthalmic Preparations
- “G” List of substances required to be taken only under supervision of registered medical practitioner. Ex. Metformin, Anti Histaminic, …etc
- “H” List of substances (prescription) that should be sold by retail only on prescriptions of R.M.P. Ex. Atenolol, Lorazepam, Dapson …etc
- “J” List of diseases and ailments that drug may not claim to cure Ex. Cancer, AIDS, Diabetes…etc
- “K” List of drugs that are exempted from certain provisions regarding manufacture.

- “M” Requirements of manufacturing premises, GMP requirements of factory premises, plants and equipments
- “M1” Requirements of factory premises for manufacture of Homeopathic medicines
- “M2” Requirements of factory premises for manufacture of cosmetics
- “M3” Requirements of factory premises for manufacture of medical devices
- “N” List of minimum equipment to run a Pharmacy
- “O” Standards for disinfectant fluids Ex… Phenol, H2O2, alcohol….
- “P” Life period(expiry) of drugs Ex. Insulin Inj. – 24 months
- P1- pack sizes of drugs.
- “Q” List of Coal tar colors permitted to be used in cosmetics and list of colors permitted to be used in soaps. Ex. Caramel, TiO2.

- “R” Standards for condoms made up of rubber latex intended for single use.
- “R1” Standards for medical devices
- “S” Standards for cosmetics
- “T” Requirements (GMP) of factory premises for Ayurvedic, Siddha, Unani drugs
- “U” Particulars to be shown in Manufacturing and analytical records of drugs
- “U1” Particulars to be shown in Manufacturing and analytical records of cosmetics
- “V” Standards for patent or proprietary medicines and for patent and proprietary medicines containing vitamins.
- “W” List of drugs marketed under generic names.
- “X” List of habit forming, psychotropic and other such drugs EX. Opium, Morphine, Barbital……
- “Y” Requirement and guidelines on clinical trials for import and manufacture of new drugs

Administrative Bodies

A)Advisory :

1) Drugs Technical Advisory Board-DTAB

2) Drugs Consultative Committee-D.C.C.

B) Analytical :

1) Central Drugs Laboratory - CDL

2) Drug Control Laboratory in states

3) Government Analysts

C) Executives :

1) Licensing authorities

2) Custom collectors.

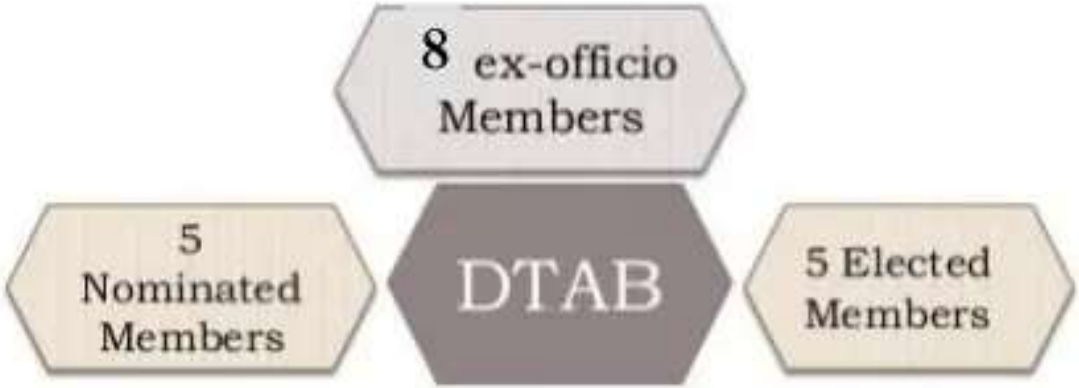
3) Drug Inspectors

DTAB

DRUG TECHNICAL ADVISORY BOARD

- The Central Government constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of D&C, Act 1940
- The Board shall consist of the following members,

- 18 **Members**



Ex-Officio:

1. Director General of Health Services (Chairman)
2. Drugs Controller, India
3. Director of the Central Drugs Laboratory, Calcutta
4. Director of Indian Veterinary Research Institute, Izatnagar
5. Director of Central Drug Research Institute, Lucknow
6. Director of the Central Research Institute, Kasauli
7. President of Medical Council of India
8. President of the Pharmacy Council of India

Nominated by Central Government:

1) Two persons from among persons who are in charge of drugs control in the States
2) One person from the pharmaceutical industry
3) Two Government Analyst

ELECTED

1) A teacher in Pharmacy or Pharmaceutical chemistry or Pharmacognosy on the staff of an Indian university or a college affiliated there to elected by the executive committee of Pharmacy council of India.
2) One person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto.
3) One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research.
4) One person to be elected by the Central Council of the Indian Medical Association.
5) One person to be elected by the Council of the Indian Pharmaceutical Association.

- Nominated and Elected members hold office for 3 years and are eligible for re-nomination and re-election
- Central Govt. Appoints the secretary of the board and also provides clerical and other staff.
- Board may constitute sub-committees and may appoint persons to such committees who are not members of the board.

Drugs Consultative Committee (DCC)

- Advises central, state government and DTAB.

Constitution:

- ✓ Two representatives of the Central Government (2)
- ✓ One representative of each State Government

Functions:

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
- The Drugs Consultative Committee shall meet when required
- Has power to regulate its own procedure

CENTRAL DRUG LABORATORY(CDL)

- Established in **Calcutta,** under the **control of a director** appointed by the Central Government.

Functions:

- Analysis or test of samples of drugs/cosmetics sent by the custom collectors [subsection 2 of sec ii] or courts subsection 4 of section 25].
- Any other duties entrusted by Central Government.
- In case of following drugs or classes of drugs, functions of CDL are carried out at central research institute Kasauli :- sera, vaccines, toxins, antitoxins etc. the functions are exercised by director of said institute. 21-08-201936

- Oral polio vaccine:- deputy director and head of polio vaccine testing laboratory of central research institute Kasauli.
- Antisera, vaccines toxoids or diagnostic agents for veterinary use:- Indian veterinary research institute Izatnagar or Mukteshwar.
- Contraceptives: - central Indian Pharmacopoeia Laboratory, Gaziabad.
- VDRL antigen:- Chemical examiner, laboratory of serologist and chemical examiner , Calcutta.
- IUD:- HOD, Dept of Biochemical Engineering, IIT New Delhi.

Drug control laboratories in the state

- Every state has laboratory for analysis and testing.
- Samples are sent by Drug Inspector.
- Even purchaser can send samples for test or analysis of drug on payment of specified fees prescribed in schedule B.

GOVERNMENT ANALYST

- Subsection 1 of Section 20.
- A person appointed as government analyst should not have any financial interest in the import, manufacture or sale of drugs or cosmetics.
- Government analyst for Ayurveda, siddha, unani:- sec 33 –F of the act.

Qualifications Government analyst

- Graduate in medicine or science or pharmacy or pharmaceutical chemistry of recognized university with not less than 5 years post graduate experience in testing of drugs OR
- Post-Graduate in medicine or science or pharmacy or pharmaceutical chemistry of recognized university with not less than 3 years experience OR
- Associate ship diploma of the institution of chemist (India) with "Analysis of drugs and pharmaceuticals" as one of the subjects and with not less than 3 years experience in testing of drugs in a laboratory under the control of

a) government analyst.

b) head of institution or testing laboratory approved for the purpose by the appointing authority.

PROVIDED THAT:-

1. For testing of Schedule C drugs: - the person appointed under clause 1 or 2 should have minimum 6 months experience and training in testing of said items in an approved institution or laboratory.
2. For a period of 4 years from the day chapter IV of the act (mfg, sale and distribution of drugs and cosmetics) takes into effect in state, persons whose training and experience are considered adequate and competence may be appointed as government analyst and such persons may be continued in service after 4 years also.
3. Should not be Engaged directly in trade or business connected with manufacture of drugs.
4. Analysis of Veterinary biological products:- graduate in veterinary science or general science or medicine or pharmacy with not less than 5 years experience in standardization of biological products or a person having post graduate degree in above faculties with not less than 3 years said experience.
5. The person already appointed as government analyst may continue to remain in service if the appointing authority so desires even though he does not fulfill the mentioned qualifications.

Duties of government analyst

- To analyze or test the samples of drugs and cosmetics sent to him by drug inspector or by other persons and to furnish the reports of the result of such analysis or test.
- To forward to the government the reports of analytical and research work with a view to their publication at the discretion of the government.

PROCEDURE ON RECEIPT OF SAMPLE

- On receipt of packet from drug inspector, the government analyst compares the seals on the package with the specimen impression of the seal received separately and notes the condition of the seals on the package.
- On completion of test or analysis, he supplies to the inspector a report of analysis in triplicate in form 13, together with full protocols of test applied.
- If the purchaser wants to analyse or test drug or cosmetic, he has to make an application for test or analysis in form 14-A accompanied with prescribed fees and the report of test or analysis of such drug or cosmetic is to be supplied in form 14-B, by government analyst.

Drug inspector Sec 21

- The central govt or state govt by notification in the Official Gazette appoints inspectors having prescribed qualifications under section 21 of the act, for the specified area.
- Should not have any financial interest in the import, mfg or sale of the drug or cosmetics.
- Is a public servant under sec. 21 of the Indian penal code.

Drug inspector

Qualification-

1. A graduate in pharmacy or pharmaceutical sciences or medicine with specialization in clinical pharmacology or microbiology from recognized university.
2. Provided that for the purpose of inspection of manufacture of substances specified in schedule C, a person appointed as drug inspector should have

- Not less than 18 months experience in the manufacture of at least one of the substances specified in schedule C; OR
- Not less than 18 months experience in testing of at least one of the substance specified in a schedule C in an approved laboratory.

3. Not less than 3 years experience in the inspection of firms manufacturing any of the substances specified in schedule C during the course of their service as the drug inspector.

- Provided further that for the first 4 years from the date of which chapter IV of the act takes effect in the states, persons whose qualifications, training and experience are considered adequate may be appointed as inspector and their appointments continued even after 4 years, if the state government is satisfied.

POWERS OF DRUG INSPECTOR

- Inspect.
- Take samples of any drug and cosmetic.
- Search any person.
- Enter and search.
- Stop and search.
- Give order in writing to a person in possession of drug or cosmetic in relation to which offence has been committed or is being committed, not to dispose stock of such drug or cosmetic for a specific period not exceeding 20 days.
- Examine records, documents, registers etc.
- Exercise other powers related to the act.

DUTIES OF DRUG INSPECTOR

1. Duties in relation to sale of drugs and cosmetics.

- To inspect twice a year all establishments licensed for sale of drug in the area assigned to him and to check that whether the conditions of license are being observed or not.
- Obtain samples of imported drugs and cosmetics for test and analysis, which are being sold, or stocked in contravention of the provisions of the act.
- To investigate any complaint in writing made to him.
- To institute prosecution in case of breach of act and rules.
- To maintain the records relating to all inspections and actions taken by him and to submit copies of such records to the controlling authority.
- To make inquiries and inspections regarding the sale of drugs in contravention of the act.
- To detain the imported packages.

2. Duties in relation to manufacture of the drugs and cosmetics:-

- To inspect at least twice a year, all premises licensed for manufacture of drugs within the area allotted to him and to satisfy whether the conditions of the license and the provisions of the act and rules there under being observed or not.
- To inspect premises licensed for manufacture of drugs specified in schedule C, C1 and observe process of manufacture , means employed, for standardization and testing of drugs, storage conditions, qualifications of technical staff employed, and all other details of location, construction , administration of establishment which may affect the potency or purity of product.
- After inspection send a detailed report of inspection to the controlling authority with which conditions of license and provisions of act and rules are being observed and which are not being observed.
- To take samples of drug manufactured on the premises and send them for analysis.
- To check all the records and registers required to be maintained under the rules.
- To institute prosecution in respect of the breach of the act and rules.

PROCEDURE OF INSPECTION

A) For taking samples of drug for analysis and their dispatch to the government analyst: when the inspector takes any sample of drug or cosmetic shall-

1. Intimate the purpose to a person from whom, he takes the sample, in writing in a prescribed form (Form -17).
2. Tender fair price of the sample and obtain acknowledgement thereof. If price is refused, by such person, he has to tender receipt thereof in prescribed form (form 16).
3. Divide the sample in the presence of such person in four parts unless he willfully absents himself and effectively seals and marks the portions so sealed.
4. If the sample is taken from manufacturing premises, it should be divided in only 3 parts.

- Further if the drug is packed in small volume containers or gets damaged or deteriorate on exposure, three or four containers to be taken as the case may be and sealed and marked.

a. Restore one portion or container with a person from whom the sample is taken.

b. Send one portion/ container to the government analyst for test or analysis.

c. Reserve one portion/ container for production before court if proceeding are instituted in case of such sample.

d. Send remaining portion to a warrantor if any, (whose name, address and other particulars have been disclosed.)

B) For seizure of stocks:-

Whenever inspector suspects that any drug or cosmetic contravenes any of the provisions of the act, he may seize any stock of such drug or records, registers, documents, etc. which are believed to be evidence of the commission of an offence and he should inform to a judicial magistrate as soon as possible and take his order for the custody of the same.

Penalty for obstructing Inspector:-

Imprisonment up to 3 years or fine or with both.

Reports of government analyst

- On receipt of sample from inspector, and on completion of analysis or tests, government analyst sends a signed report in triplicate in prescribed form.
- The inspector on receipt of reports from government analyst delivers one copy of the report to the person from whom the sample was taken and another copy to the warrantor if any, and reserves the third copy for use in any prosecution in respect of the sample.
- The reports signed by the government analyst taken to be the evidence of the facts stated therein and is considered conclusive unless, challenged within 28 days of receipt of report by a person from whom the sample is taken or by a person whose name is disclosed (warrantor).
- If such report is challenged, then sample of such drug or cosmetic sent to CDL and the report signed by director CDL is considered final.

LICENSING AUTHORITY

- Central government appoints an authority called licensing authority to issue license for import of drugs.
- Each state government appoints licensing authority to issue license for manufacture, distribution and sale of drugs and cosmetics, for a specified area.
- Powers:-

✓ issue

✓ refuse license

✓ cancel or

✓ suspend license.

QUALIFICATIONS OF LICENSING AUTHORITY

(i) Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a University established in India by laws; and

(ii) Experience in the manufacture or testing of drugs a minimum period of five years, Provided that the requirements as to the academic qualification shall not apply to those inspectors and govt analyst who has been appointed before 12 April 1989.

CONTROLLING AUTHORITY

Appointed by Central or State govt. All inspectors of central and state are under his control.

Qualification:

- 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
- Experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years:

Provided that the requirements as to the academic qualification shall not apply to those inspectors and govt analyst who has been appointed before **12 April 1989.**

CUSTOMS COLLECTOR

- The customs collector or any officer authorized in this behalf, may detain any imported package which he suspects to contain, any drug or cosmetic, import of which is prohibited. and send reports of such detention to drug controller, India, and if required forward samples of such drugs or cosmetics to CDL.

IMPORT OF DRUGS AND COSMETICS

Standards of quality-

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

- ✓ Misbranded drugs
- ✓ Adulterated drugs
- ✓ Spurious drugs
- ✓ Misbranded Cosmetics
- ✓ Spurious cosmetics

Classes of Drugs and Cosmetics Prohibited from Import

(a) any drug or cosmetic which is not of standard quality;

(b) any misbranded drug or misbranded or spurious cosmetics;

(bb) any adulterated or spurious drug;

(c) any drug or cosmetic which required import licence and which has been imported without licence.

(d) any patent or proprietary medicine, unless the true formula or list of active ingredients contained in it together with the quantities thereof not displayed in the prescribed manner on the label or container thereof.

(e) any drug which by means of any statement, design or device accompanying it or by any other means, claims to cure any diseases or ailment which has been prescribed in schedule J.

(ee) any cosmetic containing any ingredient, which is unsafe or harmful if use under the directions indicated or recommended.

(f) any drug or cosmetic the import of which is prohibited by rule made under this Chapter

Exemption-small quantities of any drug for the purpose of examination, test or analysis or for personal use

Import of Drugs and Cosmetics Permitted under License only

1. Drugs specified in Schedule C and C1
2. Drugs Specified in Schedule X
3. Drugs for Examination, Test and Analysis
4. Drugs for Personal Use
5. Any New Drug

Thank you