ONE shot

COMPLETE CONCEPT

PHARMACY INDIA

B.PHARMA | 5 SEMESTER

PHARMACEUTICAL JURISPRUDENCE

DRUGS AND COSMETIC ACT

UNIT-1

- OBJECTIVES
- MANUFACTURE OF DRUGS
- IMPOR OF DRUGS
- CONDITIONS FOR LICENSES

B. PHARMA 5TH SEM ONE SHOT NOTES

UNIT-1

DRUGS AND COSMETICS ACT 1940

TABLE OF CONTENTS

INTRODUCTION

- Drugs and Cosmetics Act was passed on 10th April 1940 & Rule in 1945 by the Indian Legislature.
- This Act was amended in 1955 by the Indian Parliament and Subsequently amended in 1960 1962, 1964, 1972, 1982, 1986, 1995, 2000, 2008, 2011 and 2018.

OBJECTIVES

- This is an act to regulate the import, manufacture, distribution and sales of drugs. The Act consists of five chapters:

Chapter I	Introductory
Chapter II	Administrative bodies
Chapter III	Import of drugs and cosmetics
Chapter IV	Manufacture, sale and distribution of drugs and cosmetics
Chapter IV-A	Provisions relating to Ayurvedic, Siddha and Unani drugs
Chapter V	Miscellaneous

CHAPTER I- INTRODUCTORY

- Drug and cosmetic rules have been divided into 18 parts, each dealing with particular subjects.
- There are 2 schedules to the act and 23 schedule to the rules.

SCHEDULE TO THE ACT

1. **First Schedule:** It prescribes the list of books specified in Ayurvedic, Siddha or Unani systems of medicine.

2. **Second Schedule:** It prescribes the standards to be complied with by imported drugs and by the drugs manufactured for sale, sold stocked or exhibited for sale or distributed.

SCHEDULES TO THE RULES (35 SCHEDULE)

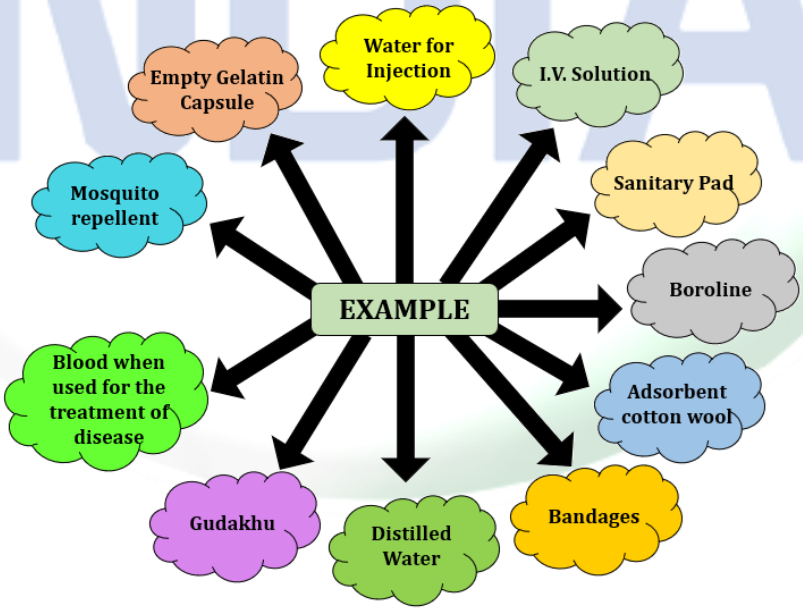
Schedules		Applied to
A		**Performa for application for the licenses, issues and renewal of licenses**, for sending memoranda under the act.
B		**Rates of fee for test or analysis** by the Central Drug Laboratory or the state drug laboratories.
B_1		**Fee for the test or analysis** by the pharmacopeial laboratory for Indian medicine or the govt analyst.
C		**List of biological and other special products** whose import, sale, distribution and manufacture are governed by special provision.
C_1		**List of other special products** whose import, sale, distribution and manufacture are governed by special provision.
D		List of **drugs exempted from the provisions to import of drugs.**
E		List of **poisonous substances under the Ayurvedic, siddha and unani** systems of medicine.
F		Requirement for the functioning and operation of **the blood bank and/ or for preparation of blood components.**
F_1	**Part I**	Provisions applicable to the production of all **bacterial and viral vaccines.**
	Part II	Provisions applicable to the production of all **sera from living animal.**
	Part III	Provisions applicable to the manufacture and standardization of **diagnostic agents (bacterial origin).**
F_2		Standards for **surgical dressings.**
F_3		Standards for **Sterilized umbilical tapes**
FF		Standards for **ophthalmic preparations.**
G		List of substances that are required to be used only **under Medical supervision** and which are to be labelled accordingly.
H		List of prescription drugs
J		List of diseases or ailments which a drug may not purport to prevent or cure.
K		Drugs exempted from certain provisions related to manufacturer of drugs.
L		**Good laboratory Practice (GLP)** and requirement of premices and equipment.
M		**GMP (Good Manufacturing Practices)** comprising requirements of **factory premises, plant and equipment.**
M_1		requirements of factory premises etc. for **manufacture of homeopathic preparations.**
M_2		requirements of factory premises etc. for **manufacture of cosmetics.**
M_3		requirements of factory premises etc. for **manufacture of medical devices.**
N		List of minimum equipment for efficient running of a pharmacy.
O		Standards for **disinfectant fluids.**
P		**Life period** of drugs
P_1		**Pack sizes** of drugs

Q	List of **colours, dyes and pigments permitted** to be used in **cosmetics**
R	Standards for **condoms made of rubber latex and other mechanical contraceptives**.
R_1	Standards for **medical devices.**
S	Standards for **Cosmetics**
T	GMP (Good Manufacturing Practices) for manufacture of **Ayurvedic, Siddha and Unani Medicines.**
U	Particulars required to be shown in **manufacturing records; raw material and analytical records of drugs.**
U_1	Particulars required to be shown in **manufacturing records; raw material and analytical records of cosmetics.**
V	Standards for **patent or proprietary medicines.**
W	List of drugs which are to be marketed **under generic names only.**
X	List of drugs whose import, manufacture, sale, labelling and packaging are **governed by special provision.**
Y	Requirements and guidelines on **clinical trails for import and manufacture of new drug.**

DEFINITION OF IMPORTANT TERMS

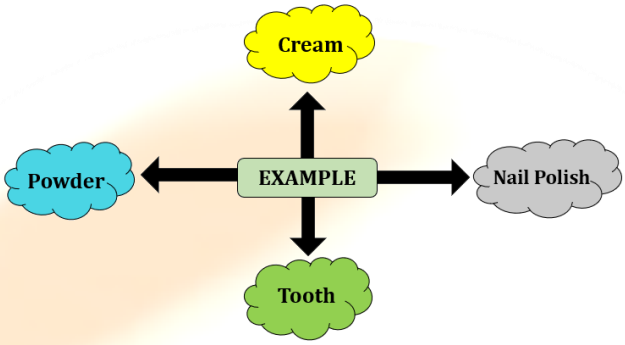
DRUG [SECTION 3 (B)]

All medicine for internal or external use of human beings or animals and all substance intended to be used for diagnosis, treatment, mitigation, or prevention of any disease or disorder in human being or animal including preparation applied on human body for the purpose of repelling insect like Mosquito.



COSMETIC: [SECTION 3 (A)]

It means any article intended to be rubbed, sprayed, poured, sprinkled on or introduced into or otherwise applied to the human body thereof, for cleansing, beautifying or promoting the attractiveness or altering the appearance and also includes any article intended to be used as a component of cosmetic but does not include soap.

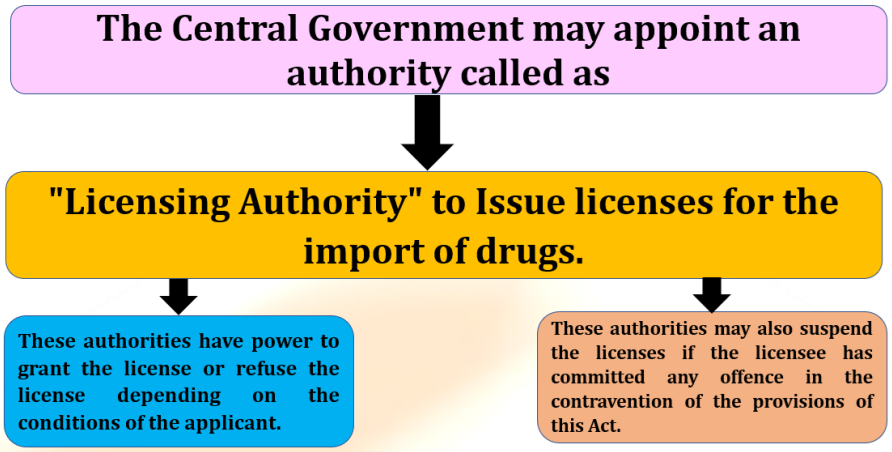


OVER-THE-COUNTER (OTC)

Over-the-counter (OTC) drugs are medicines sold directly to a consumer without a prescription from a healthcare professional, as opposed to prescription drugs, which may be sold only to consumers possessing a valid prescription.

Misbranded Drug	Adulterated Drug	Spurious Drug
• If it is not labeled in the prescribed manner	• If it is consist in whole or in. part, of any filthy, putrid, of decomposed substance.	• If it is imported (manufactured in relation to manufacture, sale and distribution of drugs) under a name which belong to another drugs.
• If it is so coloured, coated, powdered or polished that damage is concealed or if it is made appear of better or greater therapeutic value than it's really.	• If it has been prepared packed or stored under insanitary conditions whereby have been render injurious to health.	• If it has been substituted wholly or in part by another drugs or substance.
• If it is label or container or anything accompanying the drug bears any statement, design or device which make any false claim for the drug or which is false or misleading in any particular.	• If its container is composed, in whole or in part of any poisonous substance to health. • If it contain harmful or toxic substance injurious to health • Any substance mixed which reduce the quality.	• If it purports to be the product of a manufacture of whom it is not truly a product.

LICENSING AUTHORITY



OVERVIEW OF FORMS FOR APPLICATION AND LICENSE GRANTING

- ❑ Import
- ❑ Whole Sale Drugs
- ❑ Retail Sale
- ❑ Restricted Drugs
- ❑ Manufactured Drugs

Purpose	Drugs	Application made in form	License granted in form
Import	a. Drugs specified in schedule C and C1	8	10
	b. Drugs specified in schedule X	8A	10A
	c. Import of drugs or of testing	-----	11
	d. Small quantity of drugs for personal use	12	12B
Sales of Drugs			
Whole sale	a. Homoeopathic drugs	19B	20C, 20D
	b. Drugs other than those specified in schedule C, C1 and X	-----	20B
	c. Drugs other than those specified in schedule C, C1 and X from a motor vehicle	-----	20BB
	d. Drugs specified in schedule X	-----	20G
	e. Drugs specified in schedule C and C1 but not included in schedule X	19	21B
	f. Drugs specified in schedule C and C1 but not included in schedule X from a motor vehicle	-----	21BB
Retail Sale	a. Homoeopathic drugs	19B	20C
	b. Drugs other than those specified in	19	20

	schedule C, C1 and X		
	c. Drugs specified in schedule C and C1 but not included in schedule X	-----	21
	d. Drugs specified in schedule X	-----	20F
Restricted	a. Drugs other than those specified in schedule C, C1 and X	-----	20A
	b. Drugs specified in schedule C and C1 but not included in schedule X	-----	21A
Manufacture	Homoeopathic drugs	24C	25C
	Cosmetics	31	32
	Loan manufacture of cosmetics	31A	32A
	Ayurvedic and Unani drugs	24D	25D
	Loan manufacturing of Ayurvedic and Unani drugs	24E	25E
	Drugs specified in schedule C, C1 and X	27B	28B
	Drugs specified in schedule C and C1 but not included in schedule X	27	28
	Drugs other than those specified in schedule C, C1 and X	24	25
	Drugs specified in schedule X	24F	25F
	Manufacture for examination test or analysis	-----	29
Repacking License	Drugs other than those specified in schedule C and C1	24B	25B

LOAN LICENSE

A loan license is a permit that a licensing body may grant to a candidate who does not already have manufacturing arrangements in place but plans to use the manufacturing facilities used by another licensee.

A business that holds the marketing authorization for a medicine that is legally permitted to be manufactured and marketed enters into a loan license manufacturing agreement.

REPACKING LICENSE

The process which involves breaking up any drug from a bulk container and packing into small packages and labeling with a view to their sale and distribution is called repackaging license.

Repackaging of drugs is granted of drugs other than Schedule-C/C1 and X.

CHAPTER - III IMPORT

- It is a licenses granted to a person for the import of drugs specified in Schedule X, C and C (i).
- For the import of drugs specified in Schedule C, C (i) and X, the licenses shall be granted in Form 10 and 10 respectively.
- For the import of small quantities of drugs, a licenses is granted in Form 11.

IMPORT LICENSES

Classes of drugs which are prohibited for import in India. The following classes of drugs are prohibited for its import in India**.**

1. Adulterated, spurious, misbranded drugs or drugs which are not of standard quality.
2. Patent and proprietary medicine of which formula is not disclosed.
3. Drug imported in contravention of the provisions of the Act.
4. Drugs which may claim to cure any of the diseases as specified in the Schedule J.
5. Expired drugs.
6. Drugs which have not claimed therapeutic value.
7. Drugs which are likely to cause risk or injurious to human body or animal
8. Drugs not intended for import

DURATION OF IMPORT LICENSE

- Import licenses is valid for three years from date of its issue unless it is suspended or cancelled.
- Provided that if application for a fresh registration is made three months before the expiry of existing licenses the current licenses shall deemed to continue in a force until orders are passed.

Exemptions

(i) The import of small quantities of any drug, subject to prescribed conditions, is permitted for test, analysis or personal use.

(ii) The Central Government, in consultation with DTAB, may permit import of any drug or class of drugs not being of standard quality.

APPLICATION AND DURATION OF IMPORT LICENSE AND REGISTRATION CERTIFICATE

- **Form 8:** An application for import licenses is made to licensing authority in Form 8 for drugs excluding Schedule X.
- **Form 8-A**: For schedule X drugs.
- **Form 40**: The application for Registration Certificate is made to Licensing Authority in Form 40.

- **Form 41**: Registration Certificate is issued in Form 41.

PERMITTED PLACES FOR IMPORT OF DRUGS

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

(i) By rail (i) Ferozepur Cantonment and Amritsar railway stations for drugs from Pakistan (ii) Ranaghat, Bongaon and Mohiassan railway stations for drugs from Bangladesh
(ii) By road Raxual for drugs from Nepal
(iii) By sea Chennai, Kolkata, Mumbai, Nhava Sheva, Kandla, and Cochin
(iv) By air Mumbai, Chennai, Kolkata, Delhi, Ahmedabad and Hyderabad

OFFENCES AND PENALTIES

S. NO.	OFFENCE	PENALTIES
1.	An offence of any adulterated (section 9-A) or spurious drug (section 9-B) or cosmetic (section 9-0) being imported into the country in violation of provisions of the Act	Fine Rs. 500.00 / 6 month
2.	If any drug or cosmetic other than one referred to under:	Fine Rs. 5000/ 3 years
	(i) if illegally imported (ii) Any drug or cosmetic imported in contravention with provisions of any notification issued under Section 1 0-A	Fine Rs. 5000/ 3 years

CHAPTER IV- MANUFACURE

AREA REQUIREMENT FOR DOSAGE FORM

S.No.	Dosage Form	Basic Installation (sq. m)	Ancillary (sq. m)
1.	Oral liquid	30	10
2.	Powder		-----
3.	External dosage form		10
4.	Capsule	25	10
5.	Ophthalmic		10
6.	Pessaries and Suppositories		----
7.	Inhalers and vitrallae		-----
8.	Tablet	60	20
9.	Large volume parenteral	250	150
10.	Surgical area	30	100(packaging)
11.	Repackaging of drugs and pharmaceutica.	35	30(if medicated)
12.	. Recommended area for retail	10	

	sale	
13.	Recommended are for Wholesale	10
14.	Recommended are for Retail and Wholesale	10

DURATION OF LICENSE

- The licences are valid up to 31st December of the year, following the year it should be renewed.
- The licences should be renewed within 6 months after its expiry. Even after 6 months the licences can be renewed under specified conditions.

RENEWAL OF LICENCES

- The licences in Form 20, Form 21, Form 20B, Form 21B, Form 20F, Form 20G, Form 200 and Form 20D are valid for the period of five years from the date of granting them.

License for Retail sale	License of Wholesale	Application Form	License fee	Additional fee per month
From 20 From 20- B	From 20 From 20- B	From 19	1500	500
From 21 From 21- B	From 21 From 21- B	From 19	1500	500
From 20-F From 20- G	From 20-F From 20- G	From 19 c	500	250
From 20-C From 20- D	From 20-C From 20- D	From 19-B	250	50

DUPLICATE LICENCES

- If the original licences defaced, damaged or lost, the duplicate licences may be issued on application given by the licensee accompanied by the prescribed fee. The fees for different

License for retail sale License of wholesale	License for retail sale License of wholesale	Fees for Duplicate License
From 20 From 20- B	From 20 From 20- B	150
From 21 From 21- B	From 21 From 21- B	150
From 20-F From 20- G	From 20-F From 20- G	150
From 20-C From 20- D	From 20-C From 20- D	50

LIST OF DRUG CATEGORIES

S. No	Schedules	Drugs
1.	SCHEDULES C	1. Sera, Vaccine, Toxoids, Antigen and Antitoxins 2. Insulin

		4. Sterilized ligatures and sutures 5. Ophthalmic preparations 6. Pituitary extract 7. Adrenaline and salt of adrenaline 8. Sterilized surgical ligature and sterilized sutures. 9. Bacteriophages 10. Various antibiotics and their parenteral preparations: Penicillin, Streptomycin, Tetracycline, Bacitracin, Vancomycin, Erythromycin, Polymyxin B, Aminoglycoside.
2.	**SCHEDULES C_1**	1. Digitalis group 2. Ergot and its preparation 3. Fish liver oil and its preparation 4. vitamins, hormones, antibiotics 5. Liver extract and its preparation 6. Non parenteral vaccines. 7. Hormones and preparations containing hormones not in a form to be administered parenterally. 8. Following drugs and preparation containing them not in a form to be administered parenterally: Penicillin, Streptomycin, Tetracycline, Bacitracin, Vancomycin, Erythromycin, Polymyxin B, Aminoglycoside
3.	**SCHEDULES G**	Aminopterin, Antazoline, Bleomycin, Carbutamide, Chlorothiazide, Chlorocyclizine, Chlorpropamide and its salts, Diphenhydramine, Glibenclamide, Hydantoin, Insulin all types, Meclozine, Metformin, Phenformin, Pheniramine, Primodine, Promethazine, Tolbutamide, Tripolidine etc.
4.	**SCHEDULES H**	ACTH, analgin, estrogenic and progestational substances, allopurinol, antibiotics, betamethasone, chloralhydrate, clonidine, dapsone, carbidopa, Thiotepa, Primidone, Ethacrynic acid, cyclophosphamide etc.
5.	**SCHEDULES Q**	Amaranth, tartrazine, eosine, indigo, erythrosine, alizarin, Curcumin, Cochineal, Napthol blue, Erythrosine yellow etc.
6.	**SCHEDULES X**	Amobarbital, amphetamine, meprobamate, Phenobarbital, methaqualone, Cyclobarbitol, Barbiturate, Gluthimide, Phencyclindine, Meprobromate etc.
7.	**SCHEDULES W**	Analgin, aspirin and its salt, chlorpromazine and its salt, ferrous sulphate, piperazine and its salt.
8.	**SCHEDULES J**	AIDS, Atheriosclerosis, Cancer, Diabletes, Disease and disorder of brain, Leprosy, Goiter, Tuberculosis, jaundice, Paralysis, Genetic disorder, Thypoid, Small pox, Ulcer, Obesity, Pneumonia, Epilepsy, blood poisoning, Plague, Syphillis, Gonorrhoea, Sterility in woman, Gangrene, etc.

PHARMACY INDIA

JOIN US

IF YOU ARE B.PHARMA STUDENT

GET IT ON Google Play

Download PHARMACY INDIA App from play store

WHATSAPP

TYPE "PINDIA"
& SEND US ON
8006781759 FOR PHARMA UPDATES

TELEGRAM

SCAN QR CODE
TO JOIN BIGGEST
PHARMA TELEGRAM GROUP
(10000+ STUDENTS)

Instagram

FOLLOW
PHARMAINDIA24
GET RECENT PHARMA JOBS UPDATES

WEBSITE

pharmacyindia.co.in
GET LATEST PHARMA
JOBS UPDATES

Download PHARMACY INDIA Mobile App From Play Store

GET B. PHARMA NOTES