CHAPTER

# PHARMACEUTICAL JURISPRUDENCE

## [PHARMACIST-EXAMS-2018]

# PHARMACY ACT

- 4th March 1948 Act was passed.
- It contain 5 Chapter's and 46 Section.

Chapter - 1 :- Introduction
Chapter - 2 :- PCI
Chapter - 3 :- State Pharmacy council
Chapter - 4 :- Registration of Pharmacist
Chapter - 5 :- Miscellaneous
Chapter 1 & 2 came into force immediately.

**Two objectives:-** ( 1) Uniform education and training Program for would be pharmacist.
(2)To control the other qualified persons entry in the profession of pharmacy.

**Note:-** Pharmacy council of india constituted in 1949.

- As per act P.C.I .reconstituted after every five year.

**Members-** (1)Elected (2) Nominated (3) Ex-officio

**Ex-officio member**

1) Director general health service
2) Director central drug laboratory
3) Drug controller of india

- Besides this council have appointed president,vice-president and Registrar. Registar act as secretary as well as treasurer.

**Functions :-** 1. Education Regulation
2.Approval/Withdrawal of approval of institutions
3.Approval of other Qualification
4.Maintenance of Central Register for Pharmacist.

**Special Provision :-** Pharmacy Act (Amendment) act 1959,1976 .

**State Pharmacy Council :-** **Members-** (1)-Elected (2) -Nominated (3)- Ex-officio

**Ex-officio member :-**

1 Director Medical & health services
2 Drug controller of state
3 Govt. analyst

**Functions :-** Registration of Pharmacist (Maintenance of first register)

- State Govt. constitute registration tribunal which have 3 persons + registrar

♦ If any persons unsatisfied than he can appeal with in 60 days to the govt.

**Repatriate :**- Displace persons from Burma, Srilanka, Uganda displace after 14 march 1957 to 25 march 1976.

♦ State pharmacy council sent 5 copies of first register after Ist april to PCI every year also sent $\frac{1}{4}$ of fees.

**DRUG AND COSMETIC ACT & RULES**

(1) Drug and Cosmetic Act 1940

(2 ) Drug and Cosmetic Rules 1945

♦ Main object of the act is to prevent substandared in drugs.

♦ D &.C. Act divided in to 18 parts. These are 2 schedule to act and & more than 30 schedule to the rules.

**Substandard drugs are 3 types:-** (1) Misbranded (2) Adultered (3) Spurious

(1)**Mis Branded-**

♦ It is so coloured, coated powdered, polished that damage is concealed. Made to appear better therapeutic value.

♦ Not lable in prescribe manner.

♦ Lable bear any false claimed.

(2)**Adultered-**

♦ It is consist in whole in part of decomposed substances.

♦ Packed, prepared or stored under in sanitary condition.

♦ Container is composed of any poisonous substances.

♦ Coloured other than prescribed.

♦ Toxic substances.

(3)**Spurious**

♦ Imported under a name which belong to another drug.

♦ Substitute for another drug or resembles another drug.

♦ Name of company or individual which is fictious.

## Sch. to the Act.

(1)**First Schedule to the act-** Name of books ayurvedic, unani and Sidha system.

(2)**Second Schedule** - Standard to be complied for import, manufacturings and sale.

♦ Major amendment in D&C. Act 1982

♦ E,I & L deleted

♦ G and H revised and expanded 1982

♦ X- Added

♦ M & Y introduce in 1988

♦ T- introduce in 2000

## Sch. to Rule -

♦ **A**- Proforma for application for the license issue and renewal of license.

♦ **B**- Fee for test or analysis by CDL

♦ **C**- List of biological and other special produce whose import sale distribution and manufacturing are Govern by the special provision.

**$C_1$**- List of biological products.
**D**- Drug exempted provision of import.
**F**- Space equipment and supply for blood bank.
**$F_1$**- (I)- Standard of vaccine
**$F_1$**-(II)-Standard for sera
**$F_1$**-(III)- Diagnostic Agent
**$F_2$**- Standard for surgical dressing
**$F_3$**- Standard for sterlized umblical tapes
**FF**- Std. for Ophthalmic preparation
**G** - List of Substances used only under medical supervision.
**H** - List of prescription drugs.
**J** - Disease which a Drug may not prupose to prevent or cure.
**K**- Drug exempted from certain provision which are applicable to the manufacture of drug.
**$L_1$**- G.L.P.
**M** G.M.P.
**M**-1 Requirment for factory premises of Homeopathic medicine
**M**-2 .....for cosmetic
**M**-3 ..... for medical devices
**N**- List of minimum equipment for running pharmacy
**O**- Standard for disinfectant fluid.
**P**- Life period of drug.
**P**-1 Pack size of drug.
**Q**- List Coal tar Colour dyes which are permitted for used in cosmetics
**R**- Standard for Mechanical contraceptives.
**$R_1$**- Std. for Medical devices
**S**- Std. for Cosmetics
**T**- Requirement for factory premises and hygenic condition for Ayurvedic and unani drugs.
**U**- Particular to be shown in manufacturing Raw Material and analytical records of drug
**U**-1 Record for cosmetics
**V**- Standard for patent & propreietary medicine
**W**- Generic drugs
**X**- List of drugs whose import manufacturing and sale levelling governed by special provision.
**Y**- Clinical trial

**Form of No. :-**

| **Sale** | **Retails** | **wholesale** | **Motor Vehicle** |
|---|---|---|---|
| C&$C_1$ - excluding X | 21 | 21B | 21 BB |
| Other than C,$C_1$ and X | 20 | 20B | 20 BB |
| X | 20F | 20G | |

| **Manufacturing** | **Apply** | **Given** |
|---|---|---|
| C&C1 | 27 | 28 |
| Loan licence of C,$C_1$ excluding X | 27A | 28A |
| $CC_1$, and x | 27B | 28B |
| Blood bank (Processing whole blood) | 27C | 28C |

| | | |
|---|---|---|
| Blood products | 27E | 28E |
| Other than C,$C_1$&X | 24 | 25 |
| Loan licence Other than C,$C_1$&X | 24A | 25A |
| Repacking Other than C,$C_1$& X | 24B | 25B |
| X | 24F | 25F |

- 11 Drug can be imported for examinant, Test & Analysis
- 11A Drug import for govt. dispensery for patient treatment
- 12A Applying for import for personal use
- 12B Permission given. (only 100 doses.)
- 29- For Manufacturing any drug in small quantity for purpose of Examination test Analysis

# Administration of acts and rule

| | | |
|---|---|---|
| 1. | **Advisory** | 1.Drug Technical Advisory Board (DTAB)<br>2.Drug Consultative Committe (DCC) |
| 2 . | **Analytical** | 1.Central Drug Laboratory<br>2.Drug Control Laboratory in State<br>3.Govt. Analyst |
| 3. | **Executive** | 1.Licensing Authorities<br>2.Controlling Authorities<br>3.Drug Inspector<br>4.Custom Collector |

1. **DTAB** Constitute by central Govt.
To
Advise Central and State Govt's on Technical matters

## 18 Members →

**(I) Ex office → 8**

1. Director General of Health service (Chairman)
2. Drug Controller of India (Member secretary)
3. Director CDL
4. Director Central Research Institute Kasauli
5. Director Indian veterinary Research Institue Izat Nagar
6. President PCI
7. President Medical council of India
8. Director Central Drug Research Institute Lucknow

**(II) Nominated- 5** For

**(III) Elected- 5** 3 years

**DCC (Drug Consultative Comittee) :-** Advise Central and State Govt's and DTAB on Technical matters
Two representative from central govt. + 1 from each state

2. Cental Drug Laboratory Kolkata
    1. Samples of Vaccine, Sera Toxin, Suture ⟶ CRI Kasauli
    2. For veterinary use ⟶ VRI Izat Nagar
    3. Sample of Condoms ⟶ Central Pharmacopocial Lab Gaziabad.
    4. Polio vaccine ⟶ Pasteure Institue Conoor, ICMR Bombay and National Institute of Biologicals Noida
    5. VDRL Antigen ⟶ Lab. of serologist Kolkatta
    6. Homeopathic medicine ⟶ Homeopathic pharmacopoeia Lab Ghaziabad.
    7. Intra uterine devices ⟶ Central drug testing lab Thane
    8. Human blood and blood product ⟶ National Institute of communicable disease Delhi, National Institute of virology Pune
    9. Diagnostic kit for HIV virus & Hepatitis B ⟶ National Institute of Biologicals Noida

# Important points

**DRUG STORAGE TEMP :-**

1 Cold Temp. $2^0$ to $8^0$C
2 Cool Temp. $8^0$C to $25^0$C
3 Room Temp. Actual Temp. of working area (Not exceed $25^0$C)
4 Warm Temp. $30^0$C to $40^0$C

**CONTAINER**

1 **Well closed conainer -** Protect from extraneous solids and loss during handling shipment and stroage.
2 **Light resistance container -** Protect the content from light
3 **Tightly closed container -** Protect from contamination by liquid solid and Vapours from the loss of articles
4 **Hermetically sealed container -** Protect from air and gases.

**Solubility-**

| | | | |
|---|---|---|---|
| 1 | Very soluble | - | In less than 1 part of solvent |
| 2 | Freely Soluble | - | In 1 to 10 part of solvent |
| 3 | Soluble | - | 10 to 30 part |
| 4 | Sparingly Soluble | - | 30 to 100 parts |
| 5 | Slightly soluble | - | 100 to 1000 parts |
| 6 | Very slightly soluble | - | 1000 to 10000 Parts |
| 7 | In soluble | - | In more than 10000 parts |

**H.L.B :-**

| | | |
|---|---|---|
| 1-3 | - | Antifoaming agent |
| 3-8 | - | W/o emulsifying agent |
| 7-9 | - | Wetting Agent |
| 8-16 | - | O/w emulsifying agent |
| 13-16 | - | Detergent |
| 16- --- | - | Solublizer |