

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 1 : Law and Acts Related to Pharmacy

Topics	Page No
General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	3



Chapter 1

Law and Acts Related to Pharmacy

- Law is a set of rules , which developed by government or authorities that say what things people may do and what may not do , to provide a balance in society and to protect the citizens.
- Ethics are the principles that guide a person or society to decide what is wrong or right , and bad and good .and what is just and unjust.

General Principles of Law

- Rule of Law
- Separation of power
- Ubi jus ibi remedium (for every wrong , the law should provide remedy)
- Ignorantia facti excusat - Ignorantia juris non excusat . (Ignorance of law is not an excuse)
- Volentia Non fit injuria (injury caused by consent is not a cause of action) If some one willingly placed himself in a position where harm may be result, and he became injured then he can not bring a claim against the other party.
- Res ipsa loquitur (the things speak for itself , and it is related to ignorance).
- Actus non facit reum nisi men sit rea (an act does not make anyone guilty , unless an intention found to commit that act).
- Nemo debet bis vexari pro una et eadem (a man should not given punishment twice or more for the same offence) for single offence , single punishment.
- Fiat justitia ruat coelum (let justice be done,though the heaven should fall)
- Principle of natural justice (no man can be a judge in his own case , and in case subjected to him).
 - Rules are not universally embodied and are not codified.
 - Rules have been created to secure justice and to prevent failure of justice.

History

- The first time in India a chemist shop was opened in about 1811 by Mr. Bathgate who come in India with East India company in Calcutta.
- After one hundred years this firm started manufacture of tincture and spirits.
- Another firm Smith stanistreet and Co. Started abothecar by shop in 1821 and commenced the manufacturing in 1918.
- Bengal chemical and pharmaceutical works a small factory was started in Calcutta in 1901 by Achary Prafulla Chandra Ray.
- In 1903 under the leadership of prof. TK. Gajjar a small factory at Parel was started which led to the development of other pharmaceutical units the alembic chemical wark Ltd at Baroda.

- These units were not sufficient to fulfill the requirements of Indian public in those days most of the medicines were being imported from abroad mainly from U.K, France and Germany.
- Then the situation was changed with the First World War cheaper drugs were imported from abroad. There were also increasing demands for indigenous drugs. The Indian and Foreign concern entered in competition grew up and the Indian market got flooded with inferior substandard and even harmful drugs.
- With this issue the public made the government to take notice of such situations of drug trade and industry and to think of introducing effective legislation to control the import manufacture, distribution and sale of the drugs.
- In those day opium Act 1878 poison Act 1919 and Dangerous Act 1930 where in existence.
- Thus as such there was no legal control on Pharmacy profession at the beginning of this century with rapid expansion in pharmaceutical industries and market more comprehensive legislation was required Hence to have a comprehensive legislation the Indian Government appointed a "Drug enquiry committee" (DEC) under the chairmanship of Lt. Col R.N. Chopra in 1931.
- The committee was asked to make enquiries in the said matter and then to make recommendations for smooth control of manufacture import distribution and sell of drugs in the interest of public health.

Various Acts Related to Drugs and Pharmacy Profession

- In the beginning of 20th century , there was no legislation control on drugs and Pharmacy Profession , although the Opium Act 1878 and Poison Act 1919 was present , but were not in effect.
- In 1927 council of states passed a resolution that government should take legislative efforts for drug and pharmacy profession.
- On 11th August 1930 Drug Enquiry Committee (DEC) was made under the chairmanship of Col. R.N. Chopda.
 - ✚ Pharmacy Act 1948 and rules
 - ✚ Drug and Cosmetic Act 1940 and Rules 1945
 - ✚ Narcotic Drugs and Psychotropic substances Act 1985.
 - ✚ Drugs and Magic Remedies Act 1954.
 - ✚ Prevention of Cruelty to Animals Act 1960
 - ✚ Poison Act 1919.
 - ✚ FSSAI Act and Rules
 - ✚ Medical termination of pregnancy Act 1971 and rules 1975.
 - ✚ Clinical Establishment Act and Rules
 - ✚ Consumer protection Act

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 2 : Pharmacy Act & Pharmacy Practice Regulation

Topics	Page No
Pharmacy Act-1948 and Rules : Objectives, Definitions,	3
Pharmacy Council of India ; its constitution and functions,	
Education Regulations,	
State and Joint state pharmacy councils,	
Registration of Pharmacists,	
Offences and Penalties	
Pharmacy Practice Regulations 2015	

FDSPharmacy
Learn and Educate

Chapter 2

Pharmacy Act & Pharmacy Practice Regulation Rules Pharmacy Act 1948 and

- Pharmacy Act 1948 And Rules is a set of rules in which Pharmacy profession ,practices , course , duration , qualification , penalties and things are related to pharmacy mentioned.
- Before independence there was no rule for the pharmacy practice and education.
- The drug enquiry committee recommend the Government that pharmacy practitioner should have a proper knowledge , in the same way Health Survey and Development Committee also recommended for that , and Government made Pharmacy Act and It came into force in 1948.

Objectives of Pharmacy Act, 1948

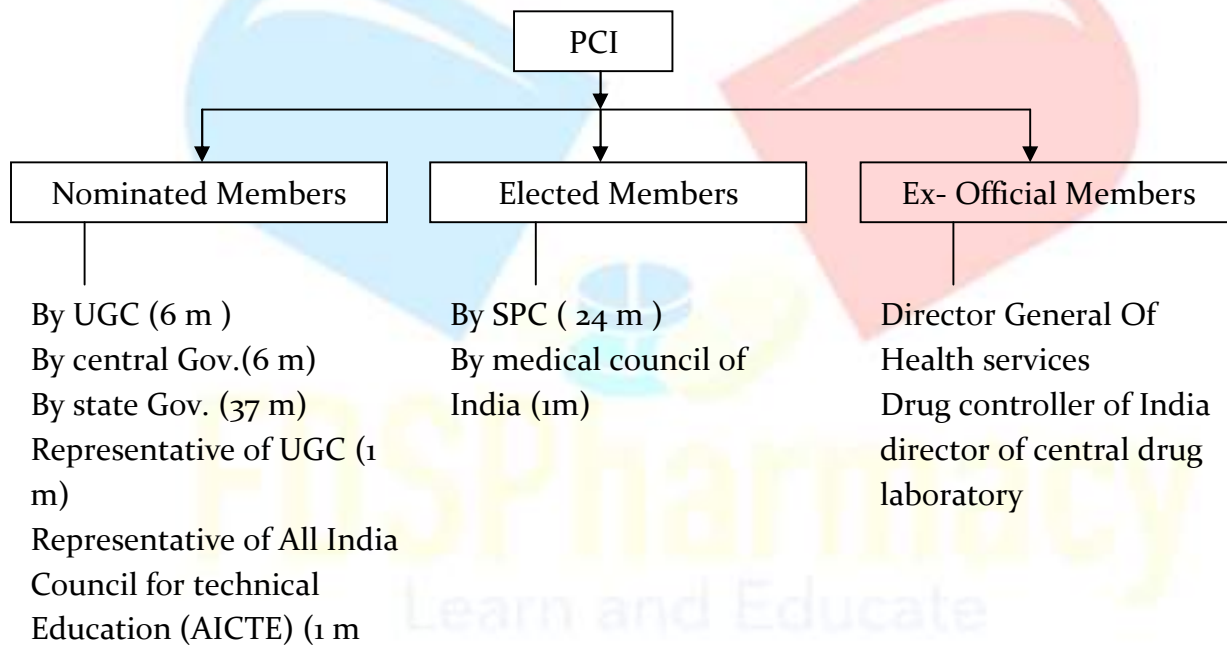
- The pharmacy act 1948 is passed with the main objects to regulate the profession and practice of pharmacy are as follows
 - To make better provisions for regulating profession and practicing of pharmacy.
 - To rise the status of "Profession of Pharmacy" in India.
 - To constitute "Pharmacy Council of India" For setting new standards in pharmacy education.
 - To regulate pharmacy institution specially "Diploma in Pharmacy" through education regulations with registration of pharmacist.

Definitions

- **Central Council** : It means PCI , it is created under Section 3 Of the Pharmacy Act 1948.
- **State Council** : It means State Pharmacy Council , created under section 19 , and also includes Joint State Pharmacy Council created under section 20.
- **Registered Pharmacist** : A person whose name is entered (written) in the Register of Pharmacists of the state in which he / she is living presently or doing his pharmacy practice.
- **First register** : It means the register of pharmacists prepared under chapter 5th of the Pharmacy Act , by the state government before constitution of State Pharmacy Council.
- **Central Register** : It means the register of pharmacists Maintained by the central Council.
- **Displaced Person** : It means a person who was living in that area of India which is now in Pakistan , He has left that area Because of any reason (civil disturbance , fear) after March 1947 , and now living in India.
- **Repatriate** : It means a person who was living in that area of India which is now in Burma ,Sri Lanka Or Uganda , He has left that area Because of any reason (civil disturbance , fear) after April 14, 1957 , and now living in India.
- **UGC (University Grant Commission)** : It is made up under the University Grant Commission Act 1956 . It gives approval the Universities and determine and maintain the standard of teaching , examination ,and research in universities.

PCI (Pharmacy Council Of India)

- PCI was constituted (created) under Section 3rd of pharmacy Act 1948. First time it was created by Central Government in 1949, to regulate Pharmacy practice and profession .
- It is reconstituted over every 5 years.
- It consist of Following types Of members.
 - 1) Nominated Member
 - 2) Elected Member
 - 3) Ex - Official Member



Constitution of PCI and methods used

1. Nominated Members (51)

- ❖ **By UGC** : 6 members are Nominated by UGC From among the teachers are working in Indian Universities or college affiliated (joined) to Indian universities . Out of 6 teachers at least one should be specialist of Pharmacology , Pharmaceutical chemistry , and pharmacognosy.
- ❖ **By Central Government** : 6 Members are nominated Central government , out of 6 at least 4 should have minimum qualification , diploma in pharmacy.
- ❖ **State Government** : 37 members are nominated by state government . One nominee of each state government . They should be registered pharmacist.
- ❖ 1 representative of UGC.
- ❖ 1 representative of AICTE (All India Council of Technical Education).

2. Elected members (25)

- ◇ **State Pharmacy Council** : 24 members are elected by SPC. Each state Pharmacy council select one registered Pharmacist from themselves.
- ◇ **MIC** : Medical Council of India select 1 member from themselves.

3. Ex - Official Members (3)

- ▲ The director general of health services.
- ▲ The Director of Central Drug laboratory.
- ▲ The Director of drug Controller of India.

Function of PCI

- ✓ To regulate pharmacy institution specially Diploma in Pharmacy through education regulation.
- ✓ To frame periodically "Education Regulation" with approval of central government for setting new standard for pharmacy education.
- ✓ To approve or disapprove course of study and examination in pharmacy.
- ✓ To recognise foreign qualification in pharmacy for purpose of registration.
- ✓ To maintain central register of pharmacist.

Education Regulation , 2020 for Diploma in Pharmacy

Chapter 1

- **Qualification for Pharmacist** : The minimum qualification required for registration as a Pharmacist is to be passed in D. Pharma Part 1st , Part 2nd and part 3rd (hospital training)
- or any other qualification approved by PCI

Chapter 2

- **Admission In D Pharmacy** : The minimum qualification for admission in D Pharmacy is 10+2 examination , with Physics , chemistry , biology or mathematics.
- **Duration of Course** : The duration of d pharma is 2 academic year , and each academic year should not be less than 180 working days , and 500 hours for Hospital training and it should not be less than 3 months.
- **Course Of Study** :

Subject	Number of Hours		
	Theory	Practical	Tutorial
Pharmaceutics	75	75	25
Pharmaceutical Chemistry	75	75	25
Pharmacognosy	75	75	25
Human Anatomy & Physiology	75	75	25
Social Pharmacy	75	75	25
Total	375	375	125

Subject	Number of Hours		
	Theory	Practical	Tutorial
Pharmacology	75	50	25
Community Pharmacy & Management	75	75	25
Biochemistry & Clinical Pathology	75	50	25
Pharmacotherapeutics	75	25	25
Hospital & Clinical Pharmacy	75	25	25
Pharmacy Law & Ethics	75	-	25
Total	450	225	150

→ **Approval of the authority / Institution conducting the course :**

- No one can conduct D Pharma course in a state without the approval of PCI . and PCI do not approve any Institution unless it provide appropriate arrangements for teaching like buildings , accommodation , equipment and teaching staff etc.

→ **Examinations :**

- Annual exam Theory and practical at end of the academic year.
- Supplementary exam (back paper)
- Sessional exam (theory and practical)

Subject	Maximum Marks for Theory			Maximum Marks for Practicals		
	Examination	Sessional	Total	Examination	Sessional	Total
Pharmaceutics	80	20	100	80	20	100
Pharmaceutical Chemistry	80	20	100	80	20	100
Pharmacognosy	80	20	100	80	20	100
Human Anatomy & Physiology	80	20	100	80	20	100
Social Pharmacy	80	20	100	80	20	100
			500			+ 500 = 1000

Subject	Maximum Marks for Theory			Maximum Marks for Practicals		
	Examination	Sessional	Total	Examination	Sessional	Total
Pharmacology	80	20	100	80	20	100
Community Pharmacy & Management	80	20	100	80	20	100
Biochemistry & Clinical Pathology	80	20	100	80	20	100
Pharmacotherapeutics	80	20	100	80	20	100
Hospital and Clinical Pharmacy	80	20	100	80	20	100
Pharmacy Law & Ethics	80	20	100	-	-	-
			600	+400	+100	= 1100

- **Eligibility for Appearing at the exam** : The percentage of presence in class should not be less than 75%.
- **Minimum Passing Marks** : Minimum 40% marks should be obtained in each subjects including sessional marks , separately in theory and practical.
- **Eligibility for Promotion to D pharma second year** : If a student is fail in more than two subjects he / she will not be promoted to second year.

Chapter 3

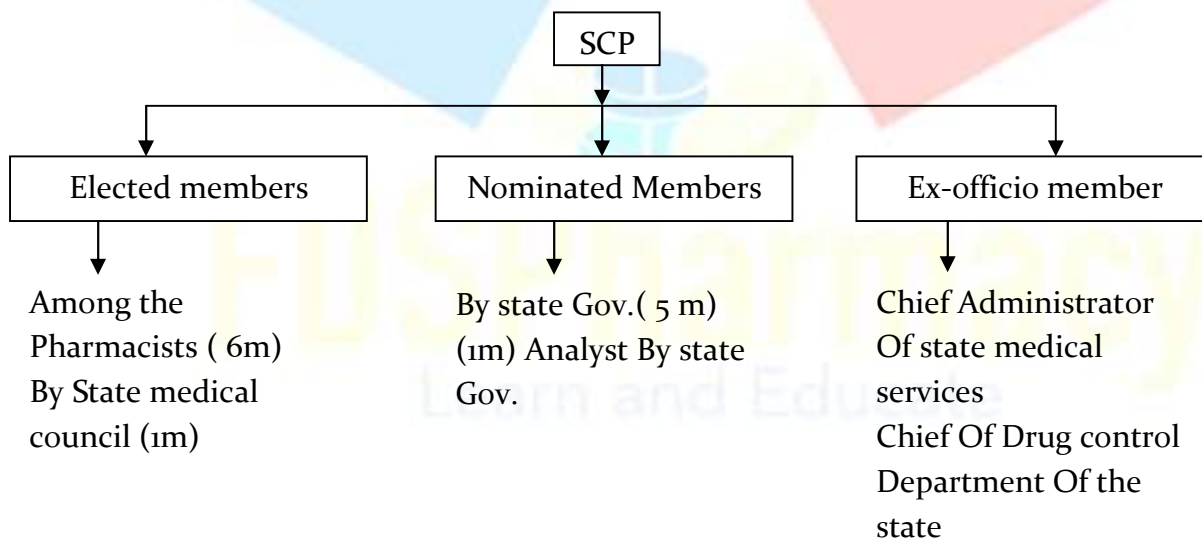
- Diploma In pharmacy Part 3rd (Practical training)
 - **Procedure for practical training** : The institution issue the Practical Training Contract Form , It will be in will in five sections.

Chapter 4

- **Certificate of Diploma In Pharmacy** : On completing successfully all the 3 Parts , the student granted a certificate of Diploma In Pharmacy
- Now he can apply for Exit Exam . after passing the exit exam he can apply for drug license.

State and Joint State Pharmacy Council (SPC)

- According to the Pharmacy Act , a State Pharmacy Council is constituted under each state government .
- This council Maintains a register for the Pharmacists of the state , and monitor their activities regarding the profession .
- These members hold their positions for five years , from themselves a president is nominated by Gov. and vice - President is elected by themselves.
- Section-19 of pharmacy Act 1948 provides for constitution and composition of state council. Every state government has to constitute state council accordingly which consists of following members.
 1. Elected members
 2. Nominated Members
 3. Ex-officio member



1. **Elected members** : Six members elected from among themselves by registered Pharmacist of state. One member elected by the state Medical council from amongst its member.
2. **Nominated Members** : Five members are nominated by the state government of whom atleast three should be degree are D.Pharma or pharmaceutical chemistry or should be registered Pharmacist.
3. **Ex-officio members** : The chief administrative medical officer of the state ex-officio.
 - The officer incharge of drug controller department of State.
 - The government analyst deputed by the state government.
 - President and Vice President of shall be elected by the members from amongst themselves.
 - Subject to membership they hold office for the five years and are also eligible for re-election

Joint State Pharmacy Council

- Under the Joint State Pharmacy Council , two or more states do an agreement , and according to this agreement , State Pharmacy Council of one state help and fulfill the needs of other state/ states.
- Member of Joint State Pharmacy Council are nominated by each state governments.
 - 3- 5 members from state Pharmacy council
 - 2-4 other members from each state (not from state council)
 - 1 member from medical council
 - and chief administrative medical officer , Government analyst ,drug controller.

Registration of Pharmacist

- The pharmacy act provides for registration of the pharmacist to regulate the entry of person in "Pharmacy professions" only person having requisite, qualifications, training, and experience are allowed to enter the professions. Name of registered Pharmacist are entered in the Register maintain by state council and central council.
- The register include particulars
 - Full name and residential address of registered Pharmacist.
 - Date of first admission to register.
 - Qualification for registration
 - Professional address,
 - Name of employer if employed.
 - Such other particulars are may be prescribed

First register :

- For preparation of 1st register the state government constitutes a "Registration Tribunal" by notification in the official gazette.
- The tribunal consists of three person and a register. The registered act as secretary of tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.

Qualification for entry on 1st register :

- A person above 18 years of age who resides or carries business or professions of pharmacy in the state on payment of prescribed fee is entitled for entry of the name in the 1st Register.
- Hold degree or diploma in Pharmacy of pharmaceutical chemistry or a "chemist" and "druggist" "Diploma of Indian University or state government". A qualification granted outside of India approved under section-14.
- Hold degree of and Indian University other than degree in pharmacy or pharmaceutical chemistry and has been engaged for a total period of time is more than than 3 years in compounding of drug in hospital or dispensary in other place.
- Passed an examination recognised as adequate by the state government for compounding or dispensing

Procedure for Registration of Pharmacist :

- Under provisions for section-33 of act state pharmacy council register name, Address, and, Qualifications of the Pharmacist in the state register an application in prescribed pro-forma is to be submitted to the register of respective State pharmacy council.
- The application should be accomplished by the prescribed fee and following document.

Document required for Registration of Pharmacist (P.C.I. Registration) :

- 5 recent passport size photo
- ID proof
- Address proof
- Hospital training certificate
- Mark sheet of 1st year and 2nd year D.Pharma, If you want to get the registration of B.Pharma then its complete mark sheet all year.
- Provision certificate
- 10+2 marksheet

Renewal of Registration :

- First registration continued till 31 December of year following the year in which it is granted there after registered Pharmacist should annually renew registration by the due date to retain his name on register of pharmacist.
- On failure to remit renewal fee before due date 1April of subsequent year.
- The name defalter pharmacist is remove from the registered on payment of renewal fee the register issues receipt therefore.
- This stand as a proof of renewal of Registration in order to avoid such situation, pharmacist may voluntarily remit advance renewal fee in Lump Sum (ARFL).

Offences and Penalties

- ❖ **Falsely claiming to be a registered Pharmacist** : If a person who is not a registered Pharmacist , and he claims to be registered pharmacist or uses such words which signify (show) that he is a reg. Pharmacist , he can be punished with a fine up to 500 rupees.
- ❖ **Dispensing drug without registration** : If a person is not reg. Pharmacist and dispensing prescribed drugs , he could be punished with a fine of Rs 1000 . or imprisonment up to six months or with both.
- ❖ **Failure to surrender the Certificate Of registration** : If some ones name has been removed , and he has not surrendered his certificate to the registrar without a reason ,he can be punished with Rs 50.

Pharmacy practice regulations , 2015

Chapter 1

Definitions

- Act : means Pharmacy Act 1948.
- Practice Of Pharmacy : Means
 - a) Interpretation , evaluation and implementation of medical orders , dispensing of prescriptions , drug orders.
 - b) Participation in drug and device selection , drug administration.
 - c) Provisions of patient counseling and the provision of those acts or services necessary for patients

Compounding

- Compounding means the preparation, mixing, packing or labeling of a drug or device.

Dispensing

- “Dispensing” Means delivery of drugs or devices to a patients or patients attendant , according to prescription or without prescription.

Patient Counselling

- It means the oral guidance by Pharmacist to the patient regarding drugs or devices.

Pharmaceutical Care

- It means to provide health care services with the help of Pharmaceuticals (drugs and devices).

Pharmacy Practitioner

- It means a registered Pharmacist which can be classified as :
 - **Community Pharmacist** : It is a registered Pharmacist who provides health care services in a community with the help of a community pharmacy.

- **Hospital Pharmacist** : It is a registered Pharmacist who provides health care services in a hospital.

Clinical Pharmacist

- ▲ It is a registered Pharmacist which provides health care services through his Clinical Pharmacy. Clinical Pharmacist provides his services with the help of physicians and other health care professionals.

Prescription

- It means a written or electronic direction from a registered Medical Practitioner to a Pharmacist to deliver drugs.

Chapter 2

Code of Pharmacy ethics

- 1) **Declaration** : When a person apply for the registration , he is provided a copy of declaration in which he declares with oath that I will follow all the rule and regulation.
- 2) **Displaying name of owner and registered pharmacist** :
 - (a) Name of the owner of pharmacy business shall be displayed.
 - (b) Name of the registered pharmacist along with his registration number and qualification along with his/her
 - (c) photograph shall be displayed adjacent to the area where dispensing is carried on in the pharmacy. Registered

Duties and responsibilities of the registered pharmacist in general :

- 1) **Character of registered pharmacist** :
 - The main objectives of Pharmacy profession is to provide services to humanity. financial Gain should not be main target.
 - A pharmacist should care about the dignity and honour of his profession.

Renewal of Registration

- It is the responsibility of pharmacist to renew his registration , after one year of registration and then after 5 years.

Dispensing against prescription of Registered Medical Practitioner only

- It is the responsibility of pharmacist to dispense only those medicines which are prescribed and will not substitute the prescription.

Practical training to student pharmacists

- The owner of pharmacy should get the approval of PCI before practical training to students. and during he should handle them with good manner and should pay best of his efforts.

Pharmacy Inspectors to Inspect the Pharmacists

- The owner / registered Pharmacist should allow co-operate with the inspectors are pointed by state Pharmacy council to inspect the premises where the drugs are compounded or dispensed.

Maintaining Good Pharmacy Practice

- 1) **Membership In Association** : For advancement of his profession he should join with association and society of allopathic pharmacy professions , and should attend their meetings.
- 2) **Maintenance of Patient record** : He should maintain the prescription record of patients for 5 years.
- 3) **Highest Quality Assurance in Patient Care** : The Pharmacist avoid those persons whose moral character and educational level is low.
- 4) **Exposure of Unethical conduct** : He should expose , without fear and favor, the corrupt , dishonest , and unethical things of the members of profession.
- 5) **Payment of professional services** : A Pharmacist should announce his fees before paying service not after.

Application of other Laws not Barred

- The registered pharmacist shall obey the laws of country and convinced others to follow them also.

Chapter 3

Duties of Registered Pharmacist to their Patients

Obligations to the Sick

- 1) It is not necessary for pharmacist to provide his services to every person asking his services , but he should pay his best of effort for those who are under his care.
- 2) A pharmacist should review the patient record and each prescription , for purpose of promoting appropriate therapeutic care by identifying :
 - Overutilisation or underutilization.
 - Drug -disease interaction
 - Drug - drug interaction
 - Incorrect dosage or duration of drug administration.

Patience , Delicacy and Secrecy

- A registered Pharmacist should have Patience and delicacy in his character , and defects of patient observed during medical attendance should never be reveal to anyone unless it is required by state gov

Prognosis

- A Pharmacist will neither exaggerate not minimize the real condition of a patient .

The patient must not be neglected

- A Pharmacist is free to choose whom he will provide services , but he should neglect anyone in emergency condition.

Chapter 4

Duties of registered Pharmacist

- a) **Dispensing / supply of drugs** : The actual dispensing of drugs to patients should only by a registered Pharmacist , if it is not possible , then the various activities be performed under super- vision of a registered pharmacist.
- b) **To promote rational use of drug** : It is also a duty of pharmacist to promote rational (appropriate) use of drugs (quality , safety , drug related information).

Patient Counselling

- At the time of delivery of drug the pharmacist should provide important information orally such as
 - Route of administration
 - Duration of administration
 - Dose
 - Drug storage

Chapter 5

Responsibilities of registered Pharmacists to each other

- 1) **Conduct In counseling** : A junior Pharmacist should get suggestion from a senior Registered Pharmacist , and should not be jealous , dishonesty and disrespect to each other.
- 2) **Appointment of substitute** : Whenever a registered pharmacist request another to attend his patients during his temporary absence, he should accept the request.

Chapter 6

Duties Of Registered Pharmacist to public and to the profession

- 1) **Registered Pharmacist as citizen** : He should play his role in enforcing the laws of community and should conduct the institution and programs that increase the humanity
- 2) **Public And Community Health** : It is a duty of pharmacist to promote the public health and try to prevent diseases . He should teach about diseases and their transmission , especially communicable diseases.

Chapter 7

Unethical Acts

- A registered pharmacist should avoid the unethical acts are following :
 - a) **Advertising** : A pharmacist should avoid Advertising for the purpose of attraction of patients to him, directly or indirectly , in the same way he should avoid printing of self - photograph or any such material of publicity.
 - b) **Rebates and Commission** : A registered pharmacist should avoid rebates (discount on buying) and commissions.
 - c) **Secret Remedies** : The prescribing or dispensing of drugs which ingredients are unknown is unethical.
 - d) **Human rights** : A pharmacist should care the human rights and should avoid mental and physical torture.

Chapter 8

Misconduct :

- A registered Pharmacist should avoid unacceptable and improper behaviour such as :
 - Violation of Regulations Of Pharmacy Act.
 - Substitution of prescription without approval of prescriber.
 - Giving His certificate to use a pharmacy owner without attending the pharmacy.
 - Giving the certificate to use to more than one pharmacy.
 - Not displaying the certificate in the pharmacy.
 - Not allowing the inspectors from inspection the pharmacy.
 - Disclosing (exposing) the secrets of patients which he observed during medical profession.
 - Using agents for seeking patients.
 - Working in pharmacy, to work in another place like industry , college etc is understood a misconduct.

Chapter 9

Punishment and disciplinary Action

- Any complaint regarding profession can be submit before the PCI or State Pharmacy council.
- In the case of removal from register for a limited time may also be restore by state pharmacy council.
- Any decision on complaint against a registered pharmacist should be taken within 6 months.
- During the pendency of decision the state pharmacy council may stop the pharmacist from pharmacy practice until the decision sdeclared.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics

Chapter 3 : Drugs and cosmetic act 1940 and Rules 1945 and New Amendments

Topics	Page No
Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments Objectives, Definitions,	3
Legal definitions of schedules to the Act and Rules	4
Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit.	7
Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug,	8
loan license and repacking license.	10
Study of schedule C and C ₁ , G, H, H ₁ , K, P, M, N, and X.	12
Sale of Drugs – Wholesale, Retail sale and Restricted license,	16
Records to be kept in a pharmacy Drugs	
Prohibited for manufacture and sale in India	17
Administration of the Act and Rules – Drugs Technical Advisory Board,	19
Central Drugs Laboratory, Drugs Consultative Committee,	20
Government analysts, licensing authorities, controlling authorities,	20
Drug Inspectors.	22

Chapter 3

Drugs and cosmetic act 1940 and Rules 1945 and New Amendments

- The main aim of The Drugs and Cosmetics Act, 1940 and Rules 1945 is to maintain the import, manufacture, distribution, and sale of drugs and cosmetics.
- Continuous use of cosmetics in luxury items prove to be harmful as they may contain harmful ingredients. Therefore, there is a need to control the cosmetics.
- This Act verifies that the drugs and cosmetics should be manufactured, distributed, and sold only by qualified persons having a licence for this purpose.
- The Central and State Drugs Control authorities are also recognised to control these actions. To this Act and Rules, timely amendments are made.
- The major amendment was made in 1982, in which Schedules E, I, and L were eliminated, Schedules G and H were revised and expanded, and Schedule X was added. Previously there were Schedule C and C₁ drugs, and drugs other than those specified in these schedules.
- At the present time, there are :
 - 1) Drugs not specified in Schedule C, C₁, and X,
 - 2) Schedule C and C₁ drugs, excluding Schedule X drugs, and
 - 3) Schedule X drugs.

Objectives

- ❖ For Preventing sub standard (Low quality) in drugs , ant for promoting high medical standards.
- ❖ For controlling the import , manufacturing , distribution and sale of drug and cosmetics by licensing.
- ❖ Ensuring that manufacturing , distribution, in sale of drugs and cosmetic is done by qualified persons only.
- ❖ For establishing Drug Technical Advisory Board(DTAB) in Drug consulting Committees (DCC) for allopathic drugs and cosmetics.

Definitions

- ❖ **Cosmetic** : Cosmetic means any articles or thing which is used for cleaning , beautifying , or promoting attractiveness.
- ❖ **Manufacture** : Any process for making, altering, ornamenting ,packaging or labeling with purpose of sale is called manufacture.
- ❖ **Import** : It means to bring any goods or services into a country from out of country for sale.

❖ **Drug Includes :**

- All medicines and devices intended for internal or external use of human being or animal for treatment or for preventing disease and diagnosis.
- All those substances intended for diagnostic purpose.
- All those substances intended used for destruction of vermin or insects.
- All those substances intended for use as a component of drug like empty gelatin capsule.

Legal Definition of Schedules to the Act

- ❖ **First Schedule :** In this schedule the list of the standard books of ayurveda , siddha, Unani and tibb are mentioned.
- ❖ **Second Schedule :** In this schedule those standards are mentioned which are required and requested for drugs are imported and manufactured for sale , or sold , stocked or exhibit for sale or distributed.

Legal Definition of Schedules to Rules :

A - Proforma (form) for application for the licences, issue and renewal of licences, for sending memoranda (a written message) under the Act.

B - Rates of fee for test or analysis by the Central Drugs Laboratory or the Government Analyst.

C - List of biological and special products (marine products which are obtained from sea) whose import, sale, distribution, and manufacture are governed by special provisions. (injectable)

C1 - List of other special products whose import, sale, distribution, and manufacture are governed by special provisions. (non injectable)

D - List of drugs exempted from the provisions of import of drugs.

E1 - List of poisonous substances under the Ayurvedic (including Siddha) and Unani systems of medicine.(Evil)

F

(i)- Space, equipment, and supplies required for a blood bank.

(ii)- Minimum requirement for grant of licence to procure blood components from whole human blood.

F1 –

Part I- Provisions applicable to the production of bacterial and viral vaccines.

Part II - Provisions applicable to the production of all sera from living animals.

Part III - Provisions applicable to the manufacture and standardisation of diagnostic agents (bacterial origin).

F2 - Standards for surgical dressings.

F3 - Standards for sterilised umbilical tapes.

FF- Standards for ophthalmic preparations. (focus , focus)

G- List of substances to be used only under medical supervision and which are to be labelled accordingly. (Guardian)

H - List of prescription drugs.

J - Diseases or ailments which a drug may not prevent . (Jaan leva)

K- Drugs Exempted from certain provisions of the manufacture of drugs.

M- Good Manufacturing Practices (GMP) requirements of factory premises, plants, and equipment.

M₁- Requirements of factory premises, etc. for manufacture of homeopathic preparations. (HCD)

M₂ - Requirements of factory premises for the manufacture of cosmetics.

M₃ - Requirements of factory premises for the manufacture of medical devices.

N- List of minimum equipment for efficient running of a pharmacy. (need for pharmacy)

O- Standards for disinfectant fluids. (Dettol Lizol)

P- Life periods of drugs.

P₁- Pack sizes of drugs.

Q-

Part I - List of dyes, colours and pigments permitted in cosmetics and soaps.

Part II- List of colours permitted in soaps.

R - Standards for condoms made of Rubber latex intended for single use and other mechanical contraceptives.

R₁- Standards for medical devices. (other than Rubber)

S- Standards for cosmetics. (sundar)

T - Requirements of factory premises and hygienic conditions for Ayurvedic (including Siddha) and Unani drugs. (Tree Preparation)

U- Particulars (items) to be shown in manufacturing, raw material, and analytical records of drugs. (Utilization Record)

U₁ - Particulars to be shown in manufacturing, raw material, and analytical records of cosmetics.

V- Standards for patent or proprietary medicines.

W- List of drugs to be marketed under generic names only.

X - List of drugs whose import, manufacture, sale, labelling, and packaging are governed by special provisions. (X = dangerous)

Y - Requirements and guidelines on clinical trials for import and manufacture of new drugs. (Yield)

Import of Drugs

- The Central Government exercises regulatory control over these drugs and cosmetics imported into country through (CDSCO) Central Drugs Standard Control Organisation headed by the (DCG) Drugs Controller General of India
- The manufacture, sale, and distribution of drugs are primarily regulated by the State Drug Control Authorities appointed by the State Government.
- The objective of the drug regulatory system in the country is to ensure availability of safe, effective, and quality drugs, cosmetics, and medical devices based on scientific excellence and best possible regulatory practices.
- Drug is defined in Section 3 of the Drugs and Cosmetics Act 1940. The Central Government has the power to declare any drugs, cosmetics, or medical devices as useful Drugs by giving notification in the official gazette.
- By virtue of the said power the Central Government has Notified Disposable Hypodermic Syringe, Disposable Hypodermic Needle, and Orthopedic Implant, Catheter, as drugs in 1989.

Classes of Drugs and Cosmetics Prohibited from Import

- Any drug or cosmetic of non-standard quality.
- Any misbranded or spurious or adulterated drug.
- Any misbranded or spurious cosmetic,
- Any drug or cosmetic which requires a licence for import,
- Any patent or proprietary medicine, till the true formula or list of active ingredients contained in it, along with the quantities are displayed on the label or the container.
- Any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed,
- Any cosmetic containing an ingredient which may be unsafe or harmful for use,
- Drugs which claim to prevent or cure any of the diseases or ailments specified in Schedule J,
- Drugs whose manufacture, sale and distribution are prohibited in the country of origin, except when required for the purpose of examination, test or analysis,
- Drugs not labelled and packed in the prescribed manner,
- Biological and other special products specified in Schedule C and C 1 after their expiry date or those not complying with the standards of strength, quality and purity .
- Any new drug except with express permission of the licensing authority.
- Any drug or cosmetic whose import is prohibited.

Import under Licence or Permit

- The licensing authority grants a licence for the import of the following classes of drugs:
 - 1) Drugs specified in Schedule C and C1.
 - 2) Drugs specified in Schedule X.
 - 3) Small quantities of drugs imported for examination. test, or analysis
 - 4) Drugs for personal use prescribed by a Registered Medical Practitioner.
 - 5) Any new drug.

Manufacture of Drugs

- The manufacture of drug under this Act include the processes of making, altering, ornamenting, finishing, packing, labelling, breaking up, or adopting drugs for their sale or distribution (except compounding or dispensing or packing of drug).

Prohibition of Manufacture and sale of Certain drugs

Following type of drugs are prohibited from manufacturing and sale :

- 1) Any Non standard quality , or misbranded or adulterated or spurious drug or cosmetic.
- 2) Any patent or proprietary medicines whose formula is not disclosed on label or container.
- 3) Any drug which claim to prevent , cure or decrease the disease specified in schedule J.
- 4) any cosmetic containing any unsafe or harmful ingredient.
- 5) any cosmetic or drug which is in contravention of drug and cosmetic Act and Rules.
- 6) Any drug and cosmetic which has been imported or manufactured in contravention of Act or Rules , Or in contravention of the conditions of a license.

Conditions for grant of license and condition of license for manufacture of drugs

- Schedule C and C₁ drugs are manufactured under a licence obtained from the Licensing Authority after paying the prescribed fee. A licenced person can manufacture Schedule C and C₁ drugs under the following conditions:
 - 1) The licensee should provide adequate space, plant, and equipment for manufacture of drugs
 - And the licenced premise should comply with the requirements of Good Manufacturing Practices specified in Schedule M (Schedule M III for devices).
 - Separate laboratories and utensils should be provided for culture and manipulation of spore bearing pathogenic micro-organisms which should not be used for other purpose .
 - 2) The licensee should provide adequate arrangements for testing the strength and quality of drugs in the licenced premises
 - And the testing unit should be separate from the manufacturing unit with an independent head, who should possess a degree in Medicine or Science or Pharmaceutical Chemistry and should have experience in testing of drugs considered adequate by the Licensing Authority.
 - 3) The drugs should be manufactured under the direction and supervision of technical staff, one of whom should be either:
 - a) Graduate in pharmacy or pharmaceutical chemistry with an experience of at least 18 months' in the manufacture of drugs (6 months training is allowe d during graduation) to which this licence applies, or
 - b) A graduate in medicine with an experience of at least 3 years' in the manufacture and pharmacological testing of drugs to which the licence applies, or

- c) Graduate in science with chemistry or microbiology as the principal subject or graduate in chemical engineering with an experience of at least 3 years' in the manufacture and testing of the drugs to which the licence applies, or
 - d) Hold any foreign qualifications which are comparable to those prescribed under (a), (b), and (c). Further, any person who was approved by the Licensing Authority as an expert responsible for the manufacture of drugs immediately before June 29, 1957 shall also be deemed to be technical staff.
- 4) Schedule C and C₁ drugs used for animal treatment should be manufactured by or under the supervision of graduates in veterinary science or general science or medicine or pharmacy with an experience of at least 3 years in the manufacture and testing of veterinary biological products.
- The devices specified in Schedule C should be manufactured under the supervision of a graduate in pharmacy or science with physics or chemistry or microbiology as one of the subjects or should possess a degree/diploma in mechanical, chemical, or plastic engineering.
- 5) The licensee should have adequate facilities for storing the drugs manufactured by him.
- 6) The licensee should maintain detailed records of the manufacture and testing of each batch of drugs. The records for those drugs which have date of expiry should be preserved for a period of 2 years from the date of their expiry and for other drugs for a period of 5 years from the date of their manufacture.
- 7) The licensee should allow an authorised inspector to inspect the premises, processes of manufacture, testing of drugs, records required to be maintained under the Act and the Rules, and to take samples of any drug manufactured by him.
- 8) The licensee should inform the Licensing Authority about any changes in the expert staff and also about any material changes in the plant or premise used for the manufacture.
- 9) The licensee should provide the Licensing Authority with samples of drugs either from each batch or from batches demanded by the Licensing Authority.
- Along with the samples, full details of the test applied by him should also be provided.
 - The licensee should not sell or offer for sale any batch from which a sample has been supplied to the Licensing Authority, until a certificate authorising the sale has been issued by the Licensing Authority.

Conditions of Licence to Manufacture of Drugs for Examination, Test or Analysis

- The manufactured of drugs for examination, test, or analysis should be manufactured under a licence obtained from the Licensing Authority.
- The person have license to manufacture this type of drugs should satisfy following conditions :
 - 1) The drugs should be used for the purpose for which they are manufactured.
 - 2) Licensee should maintain a record of the names and quantities of drugs manufactured and the names of persons to whom they have been supplied.
 - 3) The licensee should allow an authorised inspector to inspect the licenced premises and satisfy himself that only examination, analysis or test work is being done.
 - 4) The licensee should comply with other requirements for which a notice has been given to him one month before by the Licensing Authority.

Conditions of Licence for Manufacture of New Drugs

- If any one wants to may new drugs he should satisfy the conditions are mentioned in schedule Y , Some important conditions are following
 - 1) Application for permission.
 - 2) Clinical trials (4 phases)
 - 3) Study of new drug in special population.
 - 4) Post marketing surveillance.
 - 5) Special Study should be done Like B.A . and B.E.(Bioavailability & Bioequivalence).

Loan License and Condition

- This type of license is issued to the person who used other's Premises to manufacture the drugs . Except those drugs are specified in Schedule X can be manufactured under this license.
- The licensee and premises should comply all the conditions and requirements are necessary for manufacture of drugs.
- He Should submit the consent document of owner of the premises to the Licensing authority along with the Application for grant of Loan License.
- The licensee is required to test each batch of raw material and finished goods and should maintain the record of test for at least 5 years from the date of manufacture (2 years in the case of expiry of drug).

Repacking License

→ **Repacking** : It is a process in which someone take the products from manufacturing unit and packs on his brand name and Market the products . This type of license is required for repacking the other than drugs are specified in Schedule C and C₁

Conditions are related to repacking :

- 1) For repacking operations sufficient space and equipment should be provided and should be carried out under hygienic conditions and under the supervision of a person approved by the Licensing Authority as a Competent Person
 - a) Who passed intermediate with chemistry. or
 - b) passed diploma in pharmacy. or
 - c) A registered pharmacist. or
 - d) A person have 4 year experience in manufacturing , dispensing , or repacking of drugs.
- 2) The licensee should have sufficient arrangements for analysis and testing of each batch of raw materials and repacked drugs or should get them analysed and tested by an approved institution. He should also maintain records of such tests for 3 years from the date of manufacture and in case of drugs with expiry date at least for 3 months from such date.
- 3) The licensee should make suitable arrangements for storage of drugs and should allow an authorised Inspector to inspect the premises and take samples. The factory premises should meet the requirements specified in Schedule M.
- 4) The licensee should maintain proper records for repacking of drugs and should allow an inspector to check them.
- 5) The licence should be kept on the licenced premises and should be produced before an authorised Inspector on demand.
- 6) The drugs repacked should bear the number of the licence preceded by the words Rpg. Lic. (Repackaging Licence). No. , on their label.
- 7) The licensee should comply with the provisions of the Act and the Rules and other requirements, a notice for which has been given for not less than 4 months by the Licensing Authority

Study of Schedules

Schedule C and C₁

→ These are Biological and special products . A license on Form 28 is required for manufacture , sale and distribution of these drugs , and a License on Form 21 is required for retail sale , and Form 21-B is required for wholesale sale.

Schedule C (they are used parenterally)

- 1) Sera
- 2) toxin
- 3) antigen
- 4) antitoxin
- 5) Insulin
- 6) Serum Protein
- 7) vaccine
- 8) Hormones
- 9) Antibiotics etc.

Schedule C₁ (they are not used Parenterally)

- 1) Ergot and Ergot containing preparation.
- 2) Adrenaline and Adrenaline containing preparation.
- 3) Fish liver oil and fish liver oil containing preparation.
- 4) Vitamins and Vitamins containing preparation.
- 5) Hormones and hormone containing preparation.
- 6) Vaccines are not administered intravenously.

Schedule G

→ These are the drugs which are toxic in nature and a caution is labeled on drugs as " It is dangerous to take this preparation except under medical supervision " .

→ some **examples** : Aminopterin , Bleomycin , Busulphan , Clorthiazide , Glibeclamide.

Schedule H

- There is a list of 551 drugs which are called prescription drugs . these drugs are labeled with " Rx " and Warning " To be sold by retail on the prescription of a registered medical practitioner Only " . If the any drug come under Narcotic drugs and Psychotropic substances it will be labeled with " NRx " and warning .
- **Examples** : acyclovir , Diclofenac , baclofen , Terazosine , verapamil , repaglinide etc.

Schedule H₁

- Schedule H₁ includes sensitive antibiotics , Habit forming medications and drugs produce severe side effects . These are also labeled like Schedule H and sold by retail on prescription only .
- **Examples** : Isoniazid , Levofloxacin , zolpidem , Gemifloxacin etc

Schedule K

- These are the drugs exempted from certain provision of the manufacture of drugs .
- Following drugs are exempted :
 - 1) Drugs are not for medicinal use.
 - 2) Antimalarial drugs
 - 3) The substances are used for as food and medicine
 - 4) Mechanical and chemical contraceptive.
 - 5) Household medicines which are commonly used like Aspirin , Paracetamol, analgesic balms, antacids, cough and cold medicine skin ointment, lozenges etc.
 - 6) Normal Cosmetics.

Schedule P

- Schedule P deals with life period of Drugs and the Storage conditions of drugs and serial number . These things should be mentioned on the drugs . for
- Example

SN	Drugs	Life periods	Storage
25832	Ampicilin	36 months	In a cool place

Schedule P₁

- This Schedule deals with pack size of drugs , and dosage form .
- for example

Drugs	Dosage form	Pack Size
paracetamol	tablets	15 tabs

Schedule M

- This Schedule deals with Good Manufacturing Practice and requirements for that . this Schedule is divided into M M₁ M₂ M₃.
- M (requirements of premises , factory, plant for Allopathic drugs)
- M₁ (requirements of premises , factory, plant for Homeopathic drugs)
- M₂ (requirements of premises , factory, plant for cosmetic items)
- M₃ . (requirements of premises , factory, plant for medical devices)

Requirements

- 1) **Location** : The factory should not be located in public and dirty place .
- 2) **Buildings** : The building used for manufacturing should clean and hygiene , should not be used for sleeping and other purpose . and walls should be 6 feet high and smooth and easily cleanable .
- 3) **Water supply** : There should be proper facility of water supply , to drain used water .
- 4) **Waste Disposal** : There should be proper facility of Waste disposal .
- 5) **Staff** : All staff should be free from transmissible disease , and their clothes should be clean .
- 6) **Equipments For Manufacturing Ointments , emulsions , Lotion etc** : like Mixing tank , Mixer , emulsifier etc.
- 7) **Equipments For Manufacturing Syrup , elixirs etc.** : like Mixer , filter equipments etc.
- 8) **Equipments For Manufacturing pills compressed tablets** : Like Powder mixer , Granulator , tablet machine , tablet counter etc.
- 9) **Equipments For Manufacturing powder** : Ball mill . hammer mill , size separators .
- 10) **Equipments For Manufacturing surgical dressing** : like Cutting equipment , folding pressing machine , Sterilizer etc.

Schedule N

- This schedule deals with minimum requirement for the proper running the pharmacy.
- A pharmacy should be under the supervision of a registered pharmacist.
 - 1) **Entrance** : There should be written " Pharmacy " or Medical Store " in the front of a pharmacy.
 - 2) **Premises** : The premises should be build properly , and should dry and well ventilated . the pharmacy should not be less than 6m².
 - 3) **Furniture and Apparatus** : The furniture and apparatus of a pharmacy should be according to need . A pharmacy should have cupboard with lock and key for storing poisons and narcotic substance.
 - 4) **Books** :
 - IP
 - The National Formulary of India
 - The Drug and Cosmetic Act 1940 and Rules 1945.
 - The Pharmacy Act 1948
 - The narcotic drugs and Psychotropic substances Act etc

Schedule X

- This Schedule deals with Narcotics and Psychotropic substances , these are habit forming drugs , if someone takes without the supervision of a RMP , can lead to addiction if used for a long time.
- These drugs should be kept under lock and key.
- These drugs are labeled with NRx and Warning " To be sold by retail on the prescription of a Registered Medical practitioner " .
- **Examples** : Phenobarbital , secobarbital , mepromate , Diazepam , alprazolam.
- **Dispensing** : these drugs are dispensed only on valid prescription.
- They should be dispensed according dose size prescribed. should not be refilled without permission of physician.

Sale of drugs

- The process of passing drugs from manufacturers to consumers is termed "sale".
- Before 1940, there was no restriction / prohibition for selling, compounding, and dispensing of drugs.
- but after implementation of D& C Act 1940, selling, compounding, dispensing of drugs became a prohibited work, and only licensed persons can involve in these works.

Types of Sale

- 1) Wholesale of Drugs
- 2) Retail Sale of drugs

Wholesale of Drugs :

- A wholesale licensee can directly contact to manufactures for supplying of drugs to retailers .

Conditions for wholesale of drugs :

- ◆ Separate licenses are required for the drugs of Schedule C and C₁ and the drugs are other than Schedule C and C₁.
- ◆ The Licensee must have adequate premises, and premises should not be less than 10 square meters.
- ◆ There should be facilities for storage of drugs that can preserve the potency of drugs.
- ◆ these drugs should not be sold to whom, who don't have preservation facilities.
- ◆ The wholesale Licensee sell the drugs to persons who have a license to retail them, and drugs also can be sold to hospital, educational and research institutes, but the records of the drugs should be maintained for 3 years with their names, quantity, batch no., date manufacturer name and cash memo (bill)
- ◆ The license should be displayed in premises.

Retail Sale of drugs

Conditions For retail sale of drugs :

- 1) Facility according to Schedule N.
- 2) Purchase only from Licensed wholesalers.
- 3) Separate license for Schedule C and C₁ drugs, Schedule X and for the drugs other than schedule C and C₁ and X.
- 4) Schedule H and X drugs will not be sold without valid prescription.
- 5) All the registers and records should be maintained for at least 2 years from the date of the last entry.
- 6) The licensee should allow the inspectors for inspection of premises, registers and records.

Restricted License

→ This is a type of license , and issued to sale the drugs other than specified in schedule C , C 1 and X , . and the drugs are sold under this license don't require the supervision of a Qualified person. This license is issued under Forms 20A and 21 A.

Conditions :

- a) Well- equipped premises.
- b) Display license in premises.
- c) Purchase from a licensed dealer.
- d) Drugs should be sold in their original container.

Some Examples of drugs permitted to be sold under this license :

- Aspirin Tab. , Paracetamol Tab . , Analgesic Balms , Antacids , Antiseptic cream etc.

Records to be Kept in Pharmacy

All the sale of drugs on prescription should be recorded in a register with :

- Serial no. of Entry.
- Date of supply.
- prescriber's name and address.
- patient 's name and address.
- name and quantity of drugs.
- Manufacturer name , batch no.
- Credit Bill

Records of Purchases of Drugs

Records should be maintained by Retailer and wholesaler :

- Purchase date
- Name and address of Licensee from whom drugs are purchased.
- Drugs name , Batch no. and quantity.
- manufacturer 's name.
- Purchase bill (cash credit).

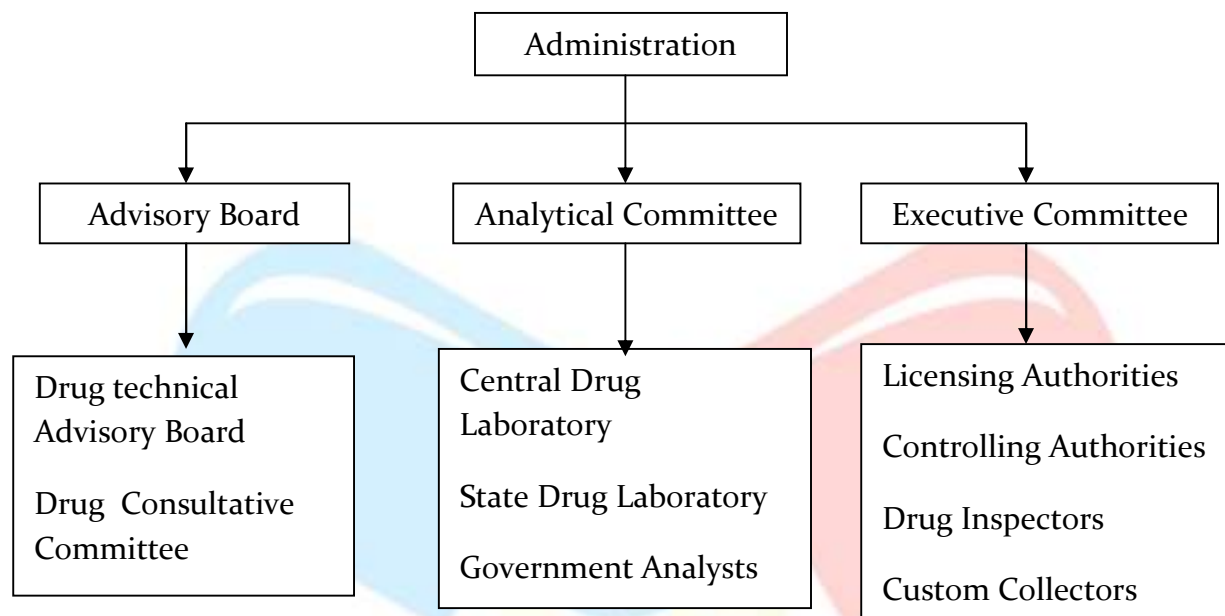
Drugs Prohibited For manufacture and Sale

- 1) Misbranded , spurious , adulterated and non- standard quality drugs.
- 2) Patent drugs with unclosed Formulation.
- 3) Drugs Claiming by any way to cure any disease are mentioned in schedule J.
- 4) Expired Drugs.
- 5) Drugs are provided by government freely.
- 6) "Physician 's sample , not to be sold " is written on container.
- 7) The drugs manufactured or imported in contravention of D and C Act.

Offences and penalties regarding Sale of Drugs

Offences	Penalties
Sale , stocking , exhibition , or offer for sale of drugs which may cause death or serious hurt.	Imprisonment from 5 years to life and fine of not less than 10,000 rupees
Sale , stocking , exhibition , or offer for sale of spurious drugs	Imprisonment of 1-3 years and fine of up to 5,000 rupees on first conviction , and for 2-6 years Imprisonment and fine 10,000 rupees on next conviction.
Sale , stocking , exhibition , or offer for sale in Contravention of any other provisions.	Imprisonment of 1-2 years and for subsequent offence 2-4 years , or 5000 fine.
Failure to keep records or disclose required Information	Imprisonment for 1 year or fine up to 1000
False warranty to purchase	Imprisonment for 1 year or fine up to 5,000 on first conviction , and imprisonment for up to 2 years or fine or both on subsequent convictions

Administration of The Drug and Cosmetic Act and Rules



Drug Technical Advisory Board (DTAB)

→ DTAB is constituted the Central Government to advise the Central and State Governments on technical matters arising out of the administration of this Act.

→ It consists of 18 members, of whom are ex-officio, 5 nominated and 5 elected members, as follows:

I. Ex- officio members :

1. Director General of Health Services (chairman)
2. Drug Controller of India.
3. Director, Central Drug laboratory, Kolkata
4. Director, Central Research Institute, Kasauli
5. Director, Indian Veterinary Research Institute, Izatnagar
6. President, Pharmacy Council of India g. President, medical Council of India
7. Director, Central Drug Research Institute, Lucknow

II. Nominated members

- Two Persons nominated by the Central Government from amongst persons who are incharge of drugs Control in states.
- One person from the Pharmaceutical industry, nominated by the Central Government
- Two Government analyst, nominated by the Central Government.

III. Elected members

- A teacher in Pharmacy or Pharmaceutical Chemistry or Pharmacognosy on the staff of an Indian University or an affiliated - College, elected by the Executive Committee of the Pharmacy Council of India.
- A teacher in medicine or therapeutic on the staff of an Indian University or an affiliated college, elected by the Executive Committee of the medical Council of India.
- One Pharmacologist elected by the Governing body of the Indian Council of medical Research.
- One Person elected by the Council of the central medical Association.
- One Person to be elected the Council of the Indian Pharmaceutical Association.

Drug Consultative Committee (DCC)

- The drugs Consultative Committee is constituted by the Central Government. It is an advisory committee for the Central and State governments and the DTAB
- It Consists of two representatives nominated by the central Government and one nominee of each of state Governments.
- The Committee meets when required by Central Government to do so and is empowered to regulate its own procedure.

Central Drug Laboratory

- ▲ The Act provides for the establishment of a Central Drug Laboratory under the Control of a director appointed by Central Government. This laboratory established in Kolkata has been entrusted with the following functions.
- ▲ To analyse or test samples of drugs or Cosmetics send to it by the Customs Collectors or Courts.
- ▲ To carry out such other duties as entrusted to it by the Central Government or with its permission by the State Government after Consultation with the DTAB.
- ▲ The functions of the laboratory in respect of sera, Solutions of serum proteins for injection, vaccines, toxins antigens, antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out at the Central Research Institute Kasauli.

Government Analysts

- The Analysts analyse and test the drugs and cosmetics samples sent by the drug Inspectors or other persons , and prepares reports . they do other works given by the government.

Qualification of Government Analysts

- A graduate in medicine/ science / Pharmacy / Pharmaceutical Chemistry of a recognized university and have five years past graduate experience in the testing of drugs in a laboratory under the Control of

- a) A Government Analyst:
- b) Head of an approved institution or testing laboratory or has completed two years training testing of drugs, including items stated in Schedule C in Central Drugs Laboratory.
- c) A post graduate in medicine | science / Pharmacy / Pharmaceutical Chemistry of a recognised University or Associate ship Diploma of the Institution of Chemists (India) obtained by Passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years' experience in the testing of drugs in a laboratory under the Control

Duties of Government Analysts

- To cause to be analysed or tested sample of drugs or cosmetics sent to under the act and to furnish reports of the results of test or analysis.
- Forward to the Government from time to time, reports giving the results of analysis work and research with a view to their publication at the discretion of Government

Licensing Authorities

- The Central Government appoints the licensing authorities to issue license for Import of Drugs.
- The state Government appoints the licensing authorities to issue licenses for manufacture and sale of drugs and cosmetics.
- The Licensing authority has choice to issue the license or refuse.
- If licensee does not follow the conditions , the licensing authority can cancel the license.
- The decision of Licensing authority can be challenged in court.

Controlling Authorities

- These are persons who control the Drug Inspectors . They send them for inspection of premises for manufacture of drugs or sale of drugs .

Qualification

- Graduation in Pharmacy , Pharmaceutical Chemistry or medicine with specialization in clinical Pharmacology or microbiology . and has 5 years experience in manufacturing of drugs or enforcement of provisions of the Act .

Drugs Inspectors

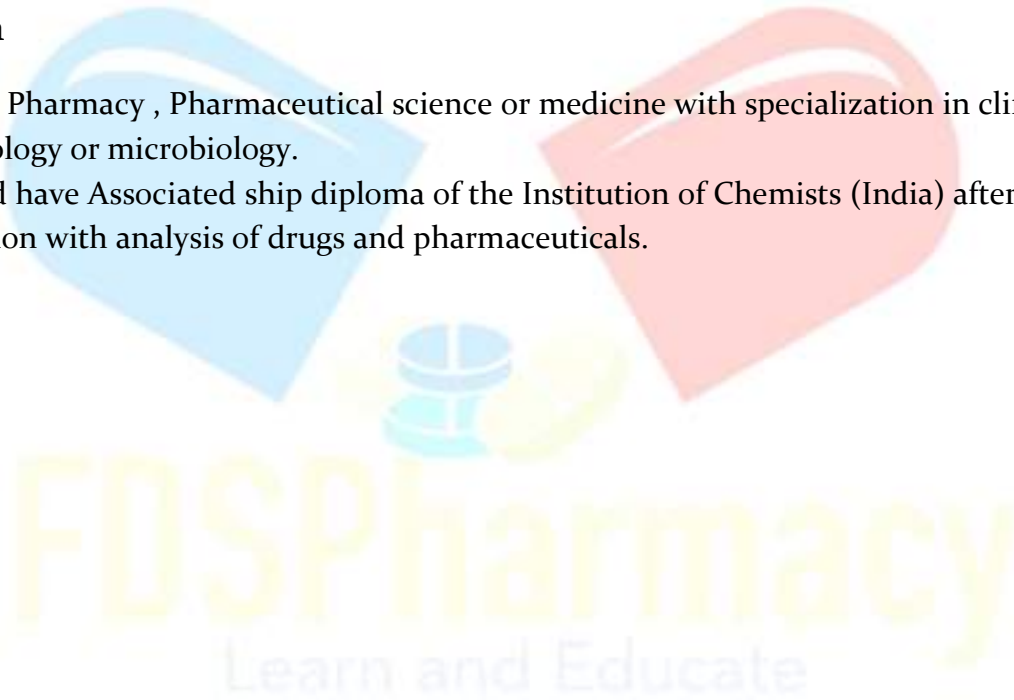
→ Drug Inspectors are appointed by Central government or by State government as much required,

Functions

- Inspection Of Premises licensed for the Sale of Drugs.
- Inspection Of Premises licensed for the Manufacture of drugs.

Qualification

- Degree in Pharmacy , Pharmaceutical science or medicine with specialization in clinical Pharmacology or microbiology.
- He should have Associated ship diploma of the Institution of Chemists (India) after passing examination with analysis of drugs and pharmaceuticals.



Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

**Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics**

**Chapter 4 : Narcotic Drugs and Psychotropic Substances Act 1985
and Rules**

Topics	Page No
Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties	3

FDSPharmacy
Learn and Educate

Chapter 4

Narcotic Drugs and Psychotropic Substances Act 1985 and Rules

- The central acts like Opium Act 1857, the opium Act, 1878 & the Dangerous Drugs Act, 1930 were enacted a long time ago.
- With the changing circumstances and the developments in the field illicit drugs traffic and drugs abuse at national and International level many drawbacks have come to notice in the said Acts.
- The government of India has repealed these old Acts passed the:
- These Acts established in 14 November 1985.
- It also provides the licensing system for both central & state government.

Objectives

- To amend and consolidate the law related to narcotics drugs.
- To control , prohibit and regulate the operations related to NDPS.
- To make stringent provisions to control and regulate the operations/ activities related to narcotic drugs and psychotropic substances.
- To provide licensing system to regulate cultivation ,manufacturing, import, export , sale , transportation of narcotic drugs and psychotropic substances.
- To provide a mechanism for the implementation of the Provisions of the International Conventions on NDPS.

Definitions

- 1) **Edict** : means a person has addiction of narcotic drugs and psychotropic substance or a person is habitual to regular use of any narcotic drug and psychotropic substances
- 2) **Cannabis** : means ;
 - a) **Charas** : that is the separated Resin in whatever form ,(whether crude or purified) obtained from cannabis plant.
 - b) **Ganja** : that is the flowering or floating tops of the cannabis plant (excluding seeds and leaves)
 - c) Any mixture with or without any natural material of any of the above forms of cannabis.
- 3) **Coca plant** Means the plant of any species of Erythroxylon Coca
- 4) **Opium** : Means
 - a) The coagulated juice of the opium poppy
 - b) Any mixture with or without any natural material of the coagulated juice of the opium poppy. But does not include any preparation containing no to more than 0.2% of the morphine.

- 5) **Opium poppy** : Means
 - a) The plant of the Species papaver Somniferum L.
 - b) The plant of other species of Papaver from which the opium is obtained.
- 6) **Opium Derivatives** : Means medicinal opium which has undergone the process necessary for medicinal use . Some derivatives are : Morphine , Codeine , Thebaine , Di-Morphine.
- 7) **Narcotic drugs** : Means coca leaf , cannabis , opium , poppy straw and includes all manufactured drugs.
- 8) **Essential narcotic drugs** : Means a narcotic drug notified by the central government for medical and scientific use.
- 9) **Commercial quantity** : In relation to narcotic drugs and psychotropic substance means any quantity greater than the quantity specified by the central government by notification in the Official Gazette.

Authorities and Officers

A) Measures Taken by the Central Government for preventing abuse of NDPS and illicit traffic .(to buy or sell illegally)

- It helps Various officers , state Government and other authorities under this act .
- It carries out obligations under International Convention (agreement)
- It coordinates authorities are related to NDPS in other countries .
- It pays attention on treatment , education and rehabilitation of addicts .

B) Officers of Central Government

- It appoints Narcotic Commissioner and other Officers as needs .

Function of Commissioner and other Officers :

- The supervision of cultivation of opium poppy .
- production of opium according to needs

C) NDPS Consultative Committee

- The Central Government Constitutes (make) this committee.
- this committee consists of a chairman and other members not exceeding 20

Functions

- The committee shall advice the Central Government on the matters relating to the administration of the Act
- The Committee will meet when required and have power to regulate its own procedure.
- The committee can constitute one or more sub-committees to perform their functions.

Prohibition , Control and Regulation of NDPS

Prohibition of Certain Operations

- Cultivation of any Coca plant or gathering of any portion of Coca.
- Cultivation of opium Poppy or any Cannabis plant.

- Production , Manufacture , Possess , sell , Purchase , transport , store , use , Import Inter-state , export inter-state , import into India , Export from India any narcotic drug or psychotropic substances.
- And activities related to these things.

Control And Regulation

- The Central and State Government provides permit , license and regulate :
- The cultivation and collection of Coca and opium plant and possession , sale ,purchase Import , export manufacture etc

Offences and Penalties

Offences	Penalties
a. Contravention of Act and rules related to NDPS	Rigorous Imprisonment for 10-20 years .
a.) illegal import or export into or out of India or dealings in NDPS . b.) Allowing use of premises , vehicles etc. For doing offences under the act . c.) Embezzlement of opium by licensed Cultivators . d.) Contravention relating to cannabis plant and cannabis other than ganja .	1-2 lacs Rs. or more
Contravention relating to cannabis plant and cannabis related to ganja	Rigorous Imprisonment for up to 5 years and fine up to 50, 000 rupees
Failure to keep accounts submit returns as required or keeping false accounts or making false statements	Rigorous Imprisonment for up to 5 years and fine up to 50, 000 rupees
a) failure to produce license , permits etc . on demand by authorities . b) willful breaking of any provision of Act , for which no penalty is mentioned	Rigorous Imprisonment for up to 3 years or fine or both
Illegal possession for personal use or consumption of NDPS	Rigorous Imprisonment for up to 1 year or fine or both
Offences for which no punishment is separately provided .	Rigorous Imprisonment for up to 6 months or fine
Attempt of above offenses	Rigorous Imprisonment for up to 6 months or fine

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 5 : Drugs and Magic remedies (Objectionable
Advertisements) Act 1954

Topics	Page No
Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	3

FDSPharmacy
Learn and Educate

Chapter 5

Drugs and Magic remedies (Objectionable Advertisements) Act 1954

- It is seen in India that some person are selling magic remedies such as Kavach as mantras, talisman etc and claiming them as unive of treatment for any disease etc.
- Likewise advertisement in magjine new paper and premises of same doctors, Hakim or vaidhs or also found claiming to cure disease not cured by any other drugs or treatment.
- The drugs and Magic remedies act 1954 is passed for regulating the advertisement of same drugs and the advertisement of remedies having qualities of magic.

Objectives

- To control certain type of advertisement related to drugs
- To control certain kinds of advertisement relating to magic remedies which falsely claim to treat and mislead public.

Definition

- **Advertisements** : These are all notice, circular, label, wrapper or other documents and all announcement made orally or by means of producing or transmitting light sounds or smoke.
- **Drugs** : drugs are substance use for the diagnosis, cure, mitigation, prevention or treatment of disease in human beings or animals for the alternation of any function of the body of human beings.
- **Magic Remedy** : It Includes Mantra , Talisman , Kavacha and any other thing which claims a miraculous powers for treatment , prevention , mitigation , and diagnosis of diseases in human beings or animals .

Prohibition of Certain Advertisement

Following are the classes of advertisements prohibited under this Act:

- 1) Advertisement of drugs for :
 - ▲ The procurement of miscarriage(Birth of a child before fully developed and causes death) in women or prevention of conception in women;
 - ▲ The maintenance or improvement of the capacity of human beings for sexual pleasure; or
 - ▲ The correction of menstrual disorder in women
 - ▲ For diagnosing, preventing, or curing appendicitis, arteriosclerosis, blindness, blood poisoning, cancer, cataract, deafness, diabetes, brain disorders, uterus disorders,

disorders of menstrual flow, disorders of nervous system and prostatic gland, dropsy (oedema), epilepsy, female diseases (in general), fevers (in general), fits, form and structure of female bust, gall stones, kidney and bladder stones, gangrene, glaucoma, goitre, heart diseases, high or low blood pressure, hydrocele, hysteria, infantile paralysis, insanity, leprosy, and leucoderma.

- 2) Advertisements providing false impression about any drug or making false claims for it, or if the advertisements are false and misleading, and
- 3) Advertisement of magic remedies, claiming to be efficient in any conditions produced by the person, who wants to carry on the profession of administering magic remedies.

Classes of Exempted Advertisements

- Any advertisement relating to the drugs printed by the government or any other person who has taken permission of Government.
- Any advertisement sent to RMPs directly.
- Advertisement including any book which dealing with any matters relating to a disease.
- Any Sign board or Notices displayed by the RMPs on the ir premises , which claiming to treat certain disease , whose advertisement is forbidden.
- Leaflets accompanying packing of drugs.
- Advertisement of drugs in medical , pharmaceutical , scientific and technical journals (newspaper , magazines etc.)
- Price lists or therapeutic indexes published by the drug manufacturers Importers or distributors under license.

Offences and Penalties

- ◆ If anyone disobeys the provisions of the Act and Rules He/ she will be punished with Imprisonment for 6 months or a fine or both on first conviction . And imprisonment for 1 year or a fine or both on next convictions.
- ◆ If a company disobeys the provisions of the Act , every single person will be responsible who are involved for the conduct of the business , at the time when the offence was committed , and punished accordingly, if they unable to prove that the offence was committed in their unawareness.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 6 : Prevention of Cruelty to Animals Act 1960

Topics	Page No
Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	3

FDS Pharmacy
Learn and Educate

Chapter 6

Prevention of Cruelty to Animals Act 1960

→ This act has been made to prevent humans from cruelty to animals and to prevent animals from needless pain and suffering.

Objectives

- To promote animal welfare generally
- To prevent the infliction of unnecessary pain or suffering on animals as well to prevent cruelty to animals.
- To provide guideline for housing, care breeding and maintenance source of experimental animals and acceptable experimental procedures for anaesthesia and euthanasia.
- The goal of these guidelines is to promote the human care of animals use in biomedical and behavioral research and testing

Definitions

- "Animal" means any living creature other than a human being;
- "Board" means the board established under section 4, and as reconstituted from time to time under section 5a
- **Captive Animal** : Means any animal not being a domestic animal which is held by human and preventive from escaping , weather permanent or temporary .
- **Captive Animal** : Means any animal not being a domestic animal which is held by human and preventive from escaping , weather permanent or temporary .
- "Local authority" means a municipal committee, district board or other authority for the time being invested by law with the control and administration of any matters within a specified local area;

CPCSEA

- CPCSEA (The Committee for the Purpose of Control and Supervision of Experiments on Animals) was established under section 15 of this Act , under the Ministry of Environment Forest & Climate Change .
- This was made to Administrate the Act

IAEC (International Animal Ethics Committee)

- IAEC is a Committee Consists of a group of Persons recognized and registered by CPCSEA . And the individuals of this committee work under guidance of CPCSEA .

Functions

- It give approval for all research projects are related to animals
- Every member of IAEC has right to question or disapprove any project
- It can't approve any research project on large animals like dogs hats goats etc
- It monitors the research experiments before during and after experiment performed.
- The committee ensure that all the required equipments are available before experimentation
- It provides research based proposal to prevent unnecessary pain to animals during experimentation and after

Breeding of Animals

- No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered.
- Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall, apply for registration within sixty days from the date of commencement of these rules and, stop breeding of animals if registration is subsequently refused to it by the Committee.

Stocking Of Animals

- The animals should be stocked by the registered breeders or establishments in the following manner :-
 - Animal Houses should be located in a quiet place and places should be tidy , hygienic and protective for animals from weather prob lems.
 - Animal Cages for small animals and stables for large animals should have sufficient space so they can live in comfort.
 - Animals should be looked after before and after the experiment by a trained and experienced person.

Performance of Experiment

- In conducting experiment on animals following conditions should be considered :
 - 1) Experiments should be performed in every case under the supervision of a qualified person.
 - 2) Experiments should be performed with humanity.
 - 3) animals should be looked after before and after the experiment.
 - 4) the Experiments involving operative procedure , should be performed under influence of anaesthetic to prevent pain perception.
 - 5) If animals are so injured that their recovery is pain full or suffering they should be destroyed humanly , under the influence of anaesthetic.

- 6) When there is a reason to believe that an animal is suffering from severe pain at any stage of a continuing Experiment , it should be painlessly destroyed at that stage without the proceeding the Experiments.
- 7) Experiments should not be performed for illustration.
- 8) Experiments should not be performed for public show.

Transfer and Acquisition of Animals for Experiment

- A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these rules.
- An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment.
- Every establishment after acquisition of a animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment.
- The animals used for experimentation in a production/ breed improvement programme may be given out by the breeder' institution for domestic use.
- No animal shall be imported by a breeder or an establishment which is available in the country
- A breeder or establishment shall comply, with the directions given by the Committee for the purpose of controlling and supervising experiments of animals.

Records

- 1) Every, establishment/Institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody in the specified format.
- 2) Every establishment/Institutional Animals Ethics Committee shall furnish such information, as the Committee may from time to time require in the specified format.
- 3) All laboratories shall inform the exact number/ species of animals to the Member Secretary or any officer authorised in this regard by the Committee as per the specified format.

Power to suspend or revoke Registration

- The committee has power to suspend and revoke (cancel) the registration if they found someone not following the Provisions of Act , They can give an opportunity to registered person for mending his faults , and if the committee satisfy they can reissue the license.

Offences and Penalties

- If he / she:
 - Exhibits or trans any animal without registration
 - Does not allow any authority to inspect the place where experiment is performed.
 - Hides any animal to avoid inspection
 - Despite of being registered , fails to produce certificate with no genuine reason.
 - He / she will be punished with imprisonment of 3 months or fine of 500 rupees ,or both



Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

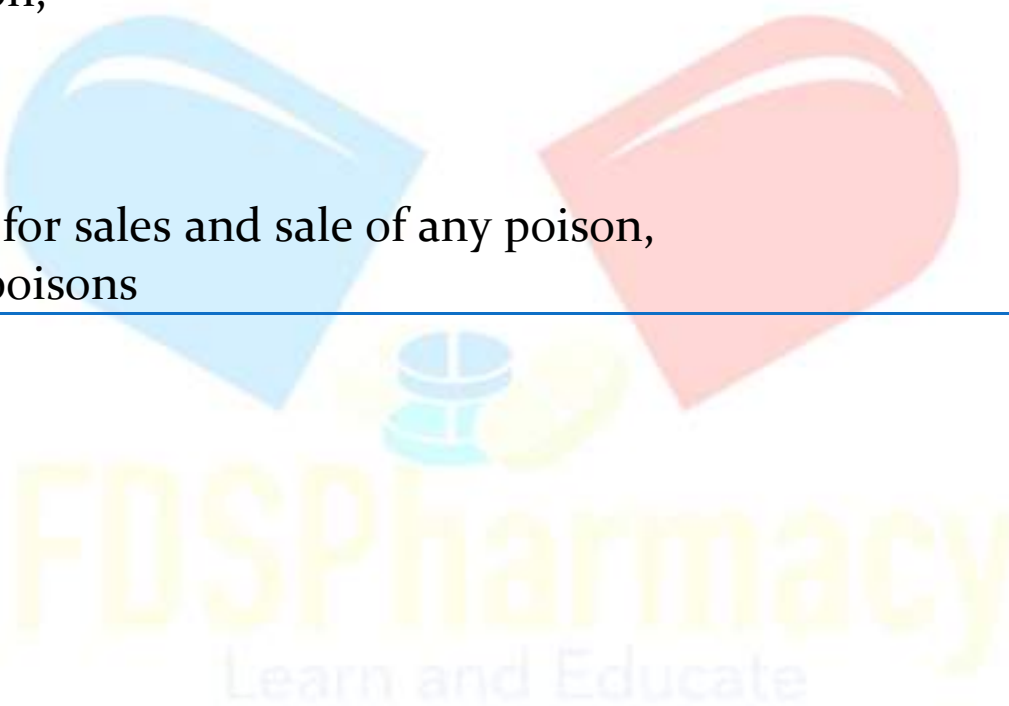
Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 7 : Poison Act 1919

Topics	Page No
Poisons Act-1919 Introduction, Objective, Definition, Possession, Possession for sales and sale of any poison, Import of poisons	3



Chapter 7

Poison Act 1919

- The Poison Act , 1919 was passed to regulate the import , possession and sale of poisons in India.
- The central government regulate the import of poisons in India
- The state government regulate and make rules for a possession and sale of poisons in their areas.

Objective of Poisons Act-1919

- To regulate the sale and possession of poisons in the country and to prevent the illegal use of these substances.
- To ensure that certain poisons are labeled and sold only by licensed dealers, in order to protect the public from the dangerous effects of toxic substances.
- To establish penalties for the illegal sale or possession of poisons, as a deterrent against such activities.
- To require that a register be kept of all poisons sold, including the name and address of the purchaser, in order to track the sale and use of these substances.
- To protect the public from the dangerous effects of toxic substances and to prevent the misuse of poisons.

Definition

- Poison" The act defined a poison as any substance which, if used or applied in a certain way, would be likely to cause death, injury or damage to health.

Possession

- Possession refers to the act of having control over or owning something. In legal terms, possession can refer to physical possession of an object, such as a piece of property or a weapon, or to constructive possession, which means that an individual has control or authority over something, even if they do not physically have it in their possession.
- In the context of the Poisons Act 1919 in India, possession would refer to an individual or organization having physical or constructive control over a poison, regardless of whether they own it or not.

Possession for sale and sale of poison

- The State Government may by rule regulate within the whole or any part of the territories under its administration the possession for sale and the sale, whether wholesale or retail, of any specified poison.
 - The grant of licences to possess any specified poison for sale, wholesale or retail, and fixing of the fee (if any) to be charged for such licences.
 - The classes of persons to whom alone such licences may be granted.
 - The classes of persons to whom alone any such poison may be sold.
 - The maximum quantity of any such poison which may be sold to any one person.
 - The maintenance by vendors of any such poison of registers of sales, the particulars to be entered in such registers, and the inspection of the same.
 - The safe custody of such poisons and the labelling of the vessels, packages or coverings in which any such poison is sold or possessed for sale.
 - The inspection and examination of any such poison when possessed for sale by any such vendor.

Import of Poisons

- Import of specified poison is allowed only under and in accordance with the conditions of a license, the central government may regulate the grant of such licenses

Offences and Penalties

- ◇ If someone violates the Act , He or She will be punished with imprisonment for 3 months or a fine of 500 rupees or both on first conviction , and on subsequent conviction imprisonment of 6 months and or a fine of 1000 Rs , or both.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 8 : FSSAI (Food Safety and Standards Authority of India)
Act and Rules

Topics	Page No
FSSAI (Food Safety and Standards Authority of India) Act and Rules Brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements	3



Chapter 8

FSSAI (Food Safety and Standards Authority of India) Act and Rules

- Fssai (Food Safety and Standards Authority of India) was established in 2008 under the Ministry of Health and Family Welfare.
- It was made to set down science based standards for articles of foods and to regulate their manufacturing , storage , sale and import.
- To ensure that availability of safe and wholesome(good) food and food supplements for consumers.
- This act aims to establish a single reference point for all matters relating to food safety and standards.

Role and Functions of FSSAI

- ✓ It provides standards and guidelines of food safety.
- ✓ Fssai and State Food Safety Suthorities grant licence and certificate and guidelines for manufacturing , storage ,sale and labelling of food articles.
- ✓ It collect data regarding contamination in foods from all parts of the country.
- ✓ It conducts training programs for persons involves in food businesses.
- ✓ It promote general awareness about food safety.
- ✓ It specify limits for additives, contamination , pesticides , heavy metals etc. in foods.

Manufacture of Food Supplements

- The manufacture of food supplements is a regulated industry, with strict standards in place to ensure the safety and quality of these products for human consumption. The regulations vary from country to country, but in general, the following are some of the key aspects of food supplement manufacturing
1. **Good Manufacturing Practices (GMP)** : Food supplement manufacturers must comply with Good Manufacturing Practices (GMP) standards, which lay down guidelines for the production, control, and storage of food supplements to ensure their safety and quality.
 2. **Raw Material Sourcing** : Food supplement manufacturers must source high-quality raw materials from reputable suppliers and ensure that the materials meet the required standards for purity, potency, and quality.
 3. **Production Processes** : Food supplement manufacturers must follow strict production processes to ensure that the supplements are made in a clean and hygienic environment and are free from contamination and deterioration.

4. **Testing and Quality Control** : The manufacture of food supplements must be accompanied by regular testing and quality control measures to ensure that the finished product meets the required standards for safety and quality.
5. **Packaging and Labeling** : The packaging and labeling of food supplements must comply with the regulations set by the relevant authorities, including the use of appropriate warning and caution statements, if necessary

Storage of Food Supplements

- ◊ The aisles (space between rows) should be clear and not used for temporary material storage.
- ◊ Pallets should be placed in a systematic manner.
- ◊ Appropriate distance should be maintained between pallets for ventilation.
- ◊ All materials and products should be correctly tagged with their identification or lot number.
- ◊ The product should be stored in such way that loading of material should be convenient.
- ◊ Proper stoke rotation should be maintained like first in , first out.

Sale of Food Supplement

- A Licence is required for a food business operator (FBO) who wants to manufacture or sell food supplements.
- Powder ,capsule , tablets and syrup are forms of food supplements.
- Plants or serials or fruits in their natural state are not considered as food supplement . as well as their juices also .
- food supplements must be formulated according to the established medical principles
- hormones, steroids and psychotropic substances are prohibited to be used in the food supplements.

Labelling of Food Supplements

- ⇒ Every pre packaged product shall be labelled with the following information
- The food name
 - Ingredients list
 - Information of nutrients present in it
 - Declaration of Veg. or Non-Veg.
 - Declaration of food additives used
 - Manufacturers name and complete address
 - Total quantity
 - Identification of the Lot or batch number
 - Manufacturing or packaging date
 - Expiry date best before
 - Imported food's country of origin

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

**Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics**

Chapter 9 : National Pharmaceutical Pricing Authority (NPPA)

Topics	Page No
National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	3

FDSPharmacy
Learn and Educate

Chapter 9

National Pharmaceutical Pricing Authority (NPPA)

Drugs Price Control Order (DPCO) - 2013

- The Drugs Price Control Order (DPCO) 2013 is an order issued by the Government of India under the Essential Commodities Act, 1955, which regulates the prices of essential and life-saving drugs in the country.
- Under the DPCO 2013, the National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the prices of drugs under price control and monitoring the prices of decontrolled drugs.
- The order covers all formulations that are specified in the National List of Essential Medicines (NLEM), and the prices are revised periodically based on changes in the wholesale price index.
- The DPCO 2013 has helped in ensuring the availability and accessibility of essential medicines at affordable prices for the general public and reducing the burden of out-of-pocket expenditure on healthcare.
- It also promotes the growth of the domestic pharmaceutical industry by creating a fair and competitive market for bulk drugs and formulations.

Objective

- Fixing the maximum prices of essential and life-saving drugs and formulations to ensure affordability for the general public.
- Regulating the prices of bulk drugs and formulations that are specified in the National List of Essential Medicines (NLEM).
- Monitoring the prices of decontrolled drugs to prevent them from becoming too expensive.
- Encouraging the domestic pharmaceutical industry to promote growth and innovation while ensuring a fair and competitive market.
- Reducing the burden of out-of-pocket expenditure on healthcare for the general public.

National pharmaceutical Pricing Authority (NPPA)

- National pharmaceutical Pricing Authority is a department of Ministry of Chemicals and Fertilisers , It was established in 1997.
- It regulates the DPCO Rule , and fix the price cap for drugs are listed in National List of Essential medicines (NLEM) . all the powers of government of pricing , according to Essential Commodity Act Has been given to it.

Functions

- ✓ To implement and enforce the provisions of the DPCO.
- ✓ To appoint the officers and other staffs members of the authority.
- ✓ To deal with the legal matters arising against the decision of the authority.
- ✓ To collect data on production , export , import market share of individual companies and their profitability.
- ✓ To monitor the availability of essential drugs , and management in case of shortage.

Definitions

- **Active Pharmaceutical Ingredients (APIs) or Bulk Drug** : is a pharmaceutical chemical , biological or plant product and which is used as an ingredient in any formulation.
- **Brand** : is a name, design, symbol, trademark or any other things that identify one seller's drug from other sellers.
- **Ceiling Price** : The maximum price fixed by government for Scheduled Formulations.
- **Generic Version of a medicine** : is a formulation sold in Pharmacopoeial name or in name of Active Pharmaceutical Ingredients used in formulation , without any brand name.
- **Maximum Retail Price** : it is the maximum price mentioned on pack for retail sale , it may includes ceiling price , taxes , and labor charge etc.
- **Scheduled Formulation** : it is a formulation , included in first schedule , whether it is formulated in generic or brand name.

Sale prices of bulk drugs

- ⇒ The sale price of bulk drugs is an important aspect of the pharmaceutical industry, as it determines the cost of raw materials used in the manufacture of formulations. The sale price of bulk drugs can be influenced by several factors, including supply and demand, production costs, government regulations, and market competition.
- ⇒ In India, the sale price of bulk drugs is regulated by the Drugs Price Control Order (DPCO) 2013, which is an order issued by the Government of India under the Essential Commodities Act, 1955. Under the DPCO 2013, the National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the prices of essential and lifesaving drugs in the country.
- ⇒ The sale price of bulk drugs under price control is determined by the NPPA based on various factors, including the manufacturing cost, market price trends, and wholesale price index. The NPPA takes into account the cost of raw materials, labor, and other production costs, as well as the prevailing market conditions, to determine the maximum sale price of a bulk drug.
- ⇒ In addition to price control, the NPPA also monitors the prices of decontrolled drugs to ensure that they do not exceed the ceiling price fixed by the government. If a company is found guilty of overcharging customers for decontrolled drugs, it may face penalties and fines imposed by the NPPA.

⇒ The regulation of the sale price of bulk drugs helps in ensuring the affordability and accessibility of essential medicines, and reducing the burden of out-of-pocket expenditure on healthcare for the general public. It also promotes the growth of the domestic pharmaceutical industry by creating a fair and competitive market for bulk drugs and formulations.

Retail Price of Formulation

- The retail price of formulations is the price that a consumer pays for a finished dosage form of a drug, such as a tablet, capsule, syrup, etc.
- The retail price of formulations is influenced by various factors, including the cost of raw materials, production costs, marketing and distribution expenses, and government regulations
- The following formula is used to calculate the retail price of formulation .

$$RP = \left(\frac{MC + CC + PM + PC}{100} \right) \times (1 + MAPE) + ED$$

Where :

RP= Retail Price.

MC= Material cost.

CC= Conversion Cost , the cost comes in converting raw material into final product e.g. labour cost , Manufacturing cost etc.

PM= Cost of packing material.

PC= Packing charge.

MAPE = Maximum allowable Post manufacturing Expenses (it includes ex factory cost , trade margin , and manufacturing margin , and it should not exceed 100%).

ED= excise duty . it is a local tax applied on domestically production of goods.

Ceiling Price of scheduled Formulation

- Ceiling Price is a maximum price of goods fixed by the government to protect Consumer, and any one can not sell a product at more price than price fixed by the government.
- Following Formula is used to fix a ceiling price :

$$P(c) = P(s) \times (1 + M/100)$$

Where

P (c) = Ceiling price.

P(s) = average price to retailer (sum of prices to retailer of all the brands and generic drugs , having a market share more than or equal to 1%).

M= % Margin to retailer and its value = 16%

Pharmaceutical Policy 2002

- Pharmaceutical policy, 2002 is a set of plans chosen by Indian government for establishing and promoting Indian pharmaceutical industries,
- This policy was made considering many of objectives some of them are :
 - To available good quality of essential drug at reasonable price
 - to promote and make capable the Indian pharmaceutical industries for cost effective quality production .
 - To reduce the barriers to trade at global level
 - To encourage for research and development (R&D) etc.

Under this policy government focused on many of targeted fields such as

- enragement for research and development and for this purpose the government Promoted and strengthened the PRDC (pharmaceutical Research and Development Committee ,1999) to identify the needs of Indian pharmaceutical companies for R&D . and government decided :
 - To invest at least 5% of Its Turnover per annum in R&D.
 - To invest at least Rs. 10 crore per annum in innovative research including new drug development and new drug delivery system etc.
- Foreign technology agreement.
- To minimize import and export related barrier.
- Margin for imported drugs.
- Pricing of formulation.
- Fixation of ceiling pricing.
- Pricing of scheduled bulk drugs.
- Pharmacy education and training.

National List of Essential medicines (NLEM)

- ◆ The National List of Essential Medicines (NLEM) is a list of essential medicines that are considered necessary for meeting the basic health needs of the population. It is a comprehensive list of drugs and medicines that are considered essential for public health, and is updated periodically to reflect the changing needs of the population.
- ◆ The NLEM is prepared and maintained by the Ministry of Health and Family Welfare, Government of India, and is based on the World Health Organization's (WHO) Model List of Essential Medicines. The list is reviewed and updated every two years to keep pace with the changing needs of the population and the advances in medical science.
- ◆ The NLEM includes a wide range of essential medicines, including those used for the treatment of common illnesses, life-threatening conditions, and chronic diseases. The list includes both generic and branded drugs and covers a wide range of therapeutic categories, such as anti-infective agents, cardiovascular drugs, and anti-cancer drugs, among others.
- ◆ The NLEM plays an important role in the regulation of drug prices in India and is used as a reference for fixing the maximum retail price of essential and life-saving medicines. The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the maximum prices of drugs included in the NLEM, based on the manufacturing cost, market price trends, and wholesale price index.
- ◆ The NLEM is an important tool for ensuring the availability of essential medicines to the public, and helps in promoting access to quality healthcare and reducing the financial burden on patients and their families. The list helps in promoting rational use of medicines and ensures that the most essential and life-saving drugs are available and accessible to the public
- ◆ The first National list of essential medicines of India was prepared and released in 1996.
- ◆ This list was revised many times and last was in 2022.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 10 : Code of Pharmaceutical Ethics

Topics	Page No
Code of Pharmaceutical Ethics Definition, Ethical principles, Ethical problem solving, Registration, Code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	3

FDSPharmacy
Learn and Educate

Chapter 10

Code of Pharmaceutical Ethics

- **Ethics** : It means good treat or behaviour to other which is not compulsory by any act or rule. in other words we can say ethics is help or to give benefits to other.
- **Pharmaceutical Ethics** : The ethics are related to pharmacy profession are called Pharmaceutical ethics.
- **Code of Pharmaceutical ethics Code** : Rule and discipline . or moral rule and discipline The code of pharmaceutical ethics is formulated by the PCI for guidance of Indian Pharmacists, which helps a pharmacist to commit moral activities.

Ethical Principles

- **Consumer**
 - Recognizing the consumer's Health and well Being as the first priority.
 - Respecting the consumer's Autonomy and Rights and encouraging them to participate in Decision- Making.
- **Community**
 - Upholding the reputation and public trust on the Profession.
 - Acknowledging the Professional Roles and Responsibilities to wider Community
- **Pharmacy Profession**
 - Demonstration a Commitment(giving time and attention) to the development and enhancing the profession
 - Maintaining a Contemporary (latest, recent) Knowledge of Pharmacy practice and ensuring health.
- **Business Practice**
 - Conducting the pharmacy ethically and professionally
- **Other healthcare Professionals**
 - Working Collaboratively with other health professionals for optimising the health Outcomes of the Consumer.

Ethical Problem Solving

- The techniques are used to solve Ethical problems are called ethical problem Solving.
- The process typically involves the following steps:
 - ▲ **Identify the ethical issue** : The first step in ethical problem-solving is to identify the ethical issue or dilemma at hand. This may involve analyzing a particular situation, reviewing relevant policies and guidelines, and consulting with colleagues or other experts as needed.
 - ▲ **Gather information** : Once the ethical issue has been identified, the pharmacist should gather all relevant information and data to help understand the problem and evaluate possible solutions.

- ▲ **Analyze the ethical issue** : The pharmacist should then analyze the ethical issue, taking into account all relevant factors, including patient rights, professional obligations, legal requirements, and any other relevant considerations.
- ▲ **Consider possible solutions** : Based on the analysis of the ethical issue, the pharmacist should consider possible solutions to the problem. This may involve brainstorming with colleagues, reviewing relevant guidelines and policies, or seeking advice from experts in the field.
- ▲ **Evaluate the solutions** : The pharmacist should evaluate the potential benefits and risks of each proposed solution, taking into account the interests of all stakeholders, including the patient, other healthcare providers, and the public.
- ▲ **Choose and implement the solution** : After evaluating the possible solutions, the pharmacist should choose the most appropriate solution and implement it in a timely and effective manner.
- ▲ **Monitor and review** : Finally, the pharmacist should monitor the situation and review the results of the chosen solution, making any necessary adjustments or modifications as needed.

Pharmacist in relation to his job

1. Pharmaceutical services

- Pharmacy premises (medicine shops) should be registered.
- Emergency medicines and common medicines should be supplied to the patient without any delay.

2. Conduct of pharmacy

- Error of accidental contamination in the preparation, dispensing and supply of medicines should be checked in a pharmacy.

3. Handling of prescription

- A pharmacist should receive a prescription without any comment on it that may cause anxiety to the patient.
- No part of the prescription should be changed without the consent of the prescriber. In case of changing the prescription should be referred back to the prescriber.

4. Handling of drugs

- A Prescription should always be dispensed correctly and carefully with standard quality drug or excipients. Drugs that have abusive potential should not be supplied to any one.

5. Apprentice pharmacist

- Experienced pharmacist should provide all the facilities for practical training of the apprentice pharmacists.
- Until and unless the apprentice proves himself or herself certificate should not be granted to him/her.

Pharmacist in Relation to his Trade

- In relation to his trade Pharmacist Should follow the following :
- **Price** : The pharmacist should charge a reasonable price for drugs , which should not be a burden for consumers.
 - **Fair trade Practice** : Any type of gift , prizes or any other attractive thing should not be offered and also the Pharmacist should not lower the prices than Charged by the other pharmacist in that area to capture the market.
 - **Purchase of Drugs** : He should buy the drugs only from registered dealers.
 - **Advertisement** : The pharmacist should avoid every type of advertisement to increase his income.

Pharmacist in Relation to his Medical profession

- ◇ **Prescribing** : The pharmacist avoid Medical Practice like(Prescribing , diagnosis) as Physician avoid pharmacy practices.
- ◇ **Commission** : The pharmacist should not make a secret agreement with physician to send patients to his store on commission.

Pharmacists in Relation to his profession

- Extend help to fellow pharmacist in emergency need.
- Should Maintain Standard of the profession.
- Should try to weed out corruption in profession and society.
- He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession.
- Should have up to date Knowledge of Professional matters.
- Should have fair knowledge of laws related to his profession Pharmacists in Relation to his medical profession.

Pharmacist's Oath

→ Given below is the Pharmacist's Oath which should be taken without hesitation by a pharmacist:

- I swear by the Code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of healthcare team.
- I shall uphold the laws and standards governing my profession.
- I shall strive (try very hard) to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
- I shall follow the system, which I consider best for pharmaceutical care and counselling of patient.
- I shall endeavour (try hard) to discover and manufacture drugs of quality to alleviate (to decrease the effect) sufferings of humanity.
- I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge (expose the secret) unless compelled to do so by the law.
- I shall associate with organisations having their objectives for betterment of profession of pharmacy and make contribution to carry out the work of these organisations.
- While I continue to keep this oath inviolate, may it be granted to me to enjoy life and practice of pharmacy respected by all, at all times! Should I trespass and violate the oath, may the reverse be my lot.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics

Chapter 11 : Medical Termination of Pregnancy Act and Rules

Topics	Page No
Medical Termination of Pregnancy Act and Rules Basic understanding, salient features, and Amendments	3



Chapter 11

Medical Termination of Pregnancy Act and Rules

→ The Medical Termination of pregnancy Act 1971 and Rules 1975 and regulations 1975 set standards for certain cases of Pregnancy termination by the registered medical Practitioners and related matters

Objectives

- To prevent unsafe abortion , which causes death of women.
- to prevent unnecessary abortion.
- to legalise abortion services.

Conditions in which Termination of pregnancy is allowed are Following :

- ▲ A woman can medically terminate her pregnancy if there is a risk to her physical or mental health.
- ▲ or if there are foetal malformation (body parts not formed correctly).
- ▲ or if she became pregnant due to failure of any contraceptive method or device.
- ▲ or if she became pregnant as a result of rape.

Opinion required for termination of pregnancy

- ◇ Pregnancy termination up to 20 weeks of gestation the opinion of one Registered medical practitioner is required.
- ◇ Two register medical practitioner 's opinion are required for termination of a pregnancy between 20-24 weeks of gestation.
- ◇ State level medical board 's opinion is required for termination of a pregnancy after 24 weeks of gestation if there are significant foetal abnormalities.

Place where pregnancy may be terminated

- A hospital established or maintained by government.
- or a place for the time being approved for the purpose of termination of pregnancy by government.

Salient features of Medical Termination of Pregnancy Act and Rules :

→ The Medical Termination of Pregnancy Act, 1971 is an Indian law that regulates the conditions under which a pregnancy can be terminated. Here are some of the salient features of the MTP Act, 1971 :

- **Legalization of Abortion** : The MTP Act legalized abortion in India, subject to certain conditions.
- **Conditions for Abortion** : The MTP Act allows for abortion if the pregnancy poses a risk to the physical or mental health of the mother, if there is a risk of the child being born with physical or mental abnormalities, or if the pregnancy is a result of rape or failure of contraception.
- **Time Limit for Abortion** : The Act permits abortion up to 20 weeks of pregnancy. However, in certain cases, such as when the woman's life is in danger or in case of fetal abnormalities, abortion can be carried out beyond the 20-week limit.
- **Who can Perform Abortions** : The Act permits only registered medical practitioners to perform abortions. In addition, the Act requires that certain qualifications and experience be met by the medical practitioner performing the abortion.
- **Consent** : The Act requires that the woman seeking an abortion must give her informed consent, and the consent of the spouse, if married, is also required in certain cases.
- **Confidentiality** : The Act ensures confidentiality for women seeking an abortion, and prohibits disclosure of the identity of the woman seeking an abortion, except in certain circumstances.
- **Establishment of Committees** : The Act mandates the establishment of committees to oversee the implementation of the law and to ensure that the procedure is being carried out safely and legally.
- **Penalties** : The Act provides for penalties for non-compliance with the provisions of the law, including imprisonment and fines.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 12 : Government Pharma Regulator Bodies

Topics	Page No
Role of all the government pharma regulator bodies Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	3



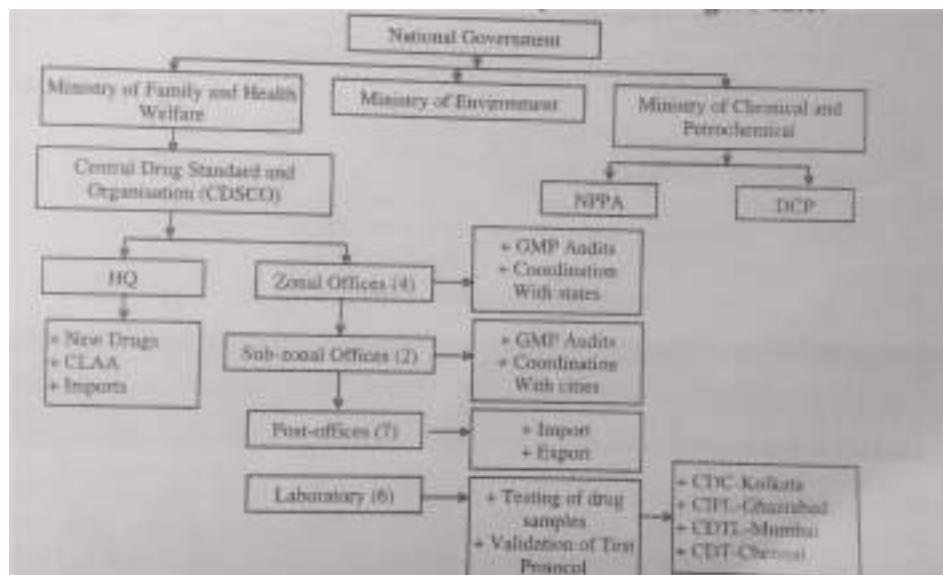
Chapter 12

Government Pharma Regulator Bodies

Central Drugs Standards Control Organization (CDSCO)

- They Control and Regulates Drug related matters at National and International Level , and also cooperate the State Drugs Controllers
- The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.
- The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.
- It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.
- Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
- Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

Structure



Functions and Roles of CDSCO

- ✓ It makes policies and procedures for uniform implementation of the provisions of Drugs and Cosmetics Act and Rules.
- ✓ It Sets Standards for drugs and Cosmetics and medical Devices.
- ✓ It Controls the import of Drugs , approval of new drugs and clinical trials.
- ✓ It acts as license Providing Authority for approval of certain Licences . like license for import of drugs , blood bank.
- ✓ it checks the quality of imported drugs through the port offices.
- ✓ It maintains drugs testing laboratories for sample testing.
- ✓ Amendment of D and C Act and rules.
- ✓ It Bans Drugs and cosmetics.
- ✓ It Conducts Meetings with International Organizations like WHO , US FDA , European Medical Devices Agency of Japan etc.
- ✓ It grant Test license for Drugs.

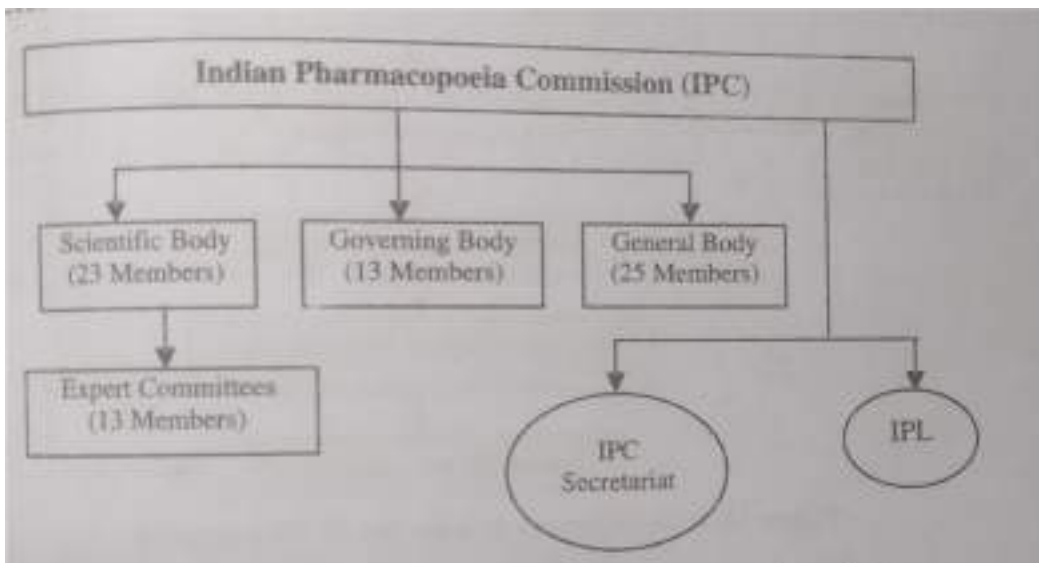
Indian Pharmacopoeia Commission (IPC)

- Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India.
- The set of standards are published under the title Indian Pharmacopoeia (IP) which has been modelled on and historically follows from the British Pharmacopoeia.

Vision

- To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis

Structure



Function of IPC

- It issues Official Documentation in the form of IP.
- It improves the quality of Drugs by adding the new monographs and updates old monographs.
- It publishes National Formulary of India.
- It conducts Meetings with national and international institutions for better performance.
- Planning education programmes, skill development initiatives, and research activities.



Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 13 : Good Regulatory Practices

Topics	Page No
Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices	3



Chapter 13

Good Regulatory Practices

- Good Regulatory Practices (GRP) is processes, systems, tools, and methods for improving the quality of regulations that are internationally recognised.
- Before government initiatives are implemented, GRP systematically implements public consultation and stakeholder involvement, as well as impact analysis of government proposals to ensure they are fit for purpose and will achieve the goals set out.

Good Regulatory Practice in Community and Hospital Pharmacy (Retail and Whole sale)

Documentation

- Constitution of the entity, Memorandum of Association (MOA), Articles of Association (AOA) for a company, partnership deed, LLP agreement in case of partnership and LLP.
 - ID proof of partner/director/proprietor.
 - Documents related to premises – Copy of ownership documents of property or rental agreement and NOC (No Objection Certificate) from the owner of the rented premises as the case may be.
 - Site plan and key plan of the premises.
 - Copy of Board resolution permitting obtaining of a license.
 - Proof of availability of storage space as cold storage, refrigerator, etc.
 - Copy of challan as proof of depositing fee.
 - Affidavit regarding non-conviction of proprietor/partner/director and the firm.
 - The affidavit from the registered pharmacist/competent person.
 - Cover letter with name and designation of the applicant.
 - Declaration form in a prescribed format.
 - Applicant's qualification certificate.

For a pharmacist at a retail sale

- Proof of qualification
- Registration of local pharmacy council
- Appointment letter

For a pharmacist at a wholesale sale:

- Proof of qualification
- Experience certificate
- Appointment letter

Prerequisites for Obtaining a License

- **Pharmacist/ Competent Individual:** The pharmacist must be qualified in the case of a retail business. In the case of a wholesale business, the individual must be a graduate with 1-year experience or an undergraduate with 4 years of experience.
- **Space Requirement:** The other important requirement is space, that is the area of the pharmacy/unit. For both wholesale and retail licenses the area of the pharmacy/unit should be 15 square meters. In the case of a retail and medical shop, it should be 10 square meters. The clear height of the sales premises shall be as per the guidelines laid down under the National Building Code of India, 2005.
- **Storage Facility:** The other important requirement is storage facility since some drugs require to be stored in low temperatures, refrigerators and air conditioners are a must.
- **Technical Staff:** The retail pharmacy staff must be experienced with in-depth knowledge. The staff of the wholesale pharmacy must be a graduate with a minimum of 1-year experience or an undergraduate having four years of experience

Types of Drug License

- **Manufacturing License :** License issued to a business that manufactures drugs inclusive of allopathic/homoeopathy medicines.
- **Sale License :** License issued for the sale of drugs. It has the following bifurcations: –
Wholesale Drug License – Retail Drug License
 - **Wholesale License :** A drug wholesaler must obtain a wholesale licence. Wholesale means the sale of the drug to a person/retailer to further sell it.
 - **Retail License :** A retail license is required for the retail sale of drugs. A retail sale means the sale of drugs or cosmetics for the consumption of the end consumer. Retailers can sell it to a dispensary, hospital, educational, medical, or research institute. Retailers engaged in pharmaceuticals, cosmetics, stand-alone pharmacists, ayurvedic shops, etc need this license.
- **Loan License :** License issued to a business that does not own the manufacturing unit but uses the manufacturing facilities of another licensee.
- **Import License :** License is issued to any dealer importing the products for the manufacturing of drugs or is engaged in the business of importing drugs in India.
- **Multi-Drug License :** License issued to businesses that own pharmacies in multiple states with the same name.

Renewal of Drug Sales License

- Renewal of Sale license should be made on the application form same as the form submitted during the grant of the new license along with the necessary fee. The Fee for the renewal of the license is same as the grant of license. The late fee for the renewal of the license is as follows that is applicable up to six months.

Late fee for Renewal Per month

- Rs. 500+500= Rs. 1000.00
- Rs. 500+500= Rs. 1000.00
- Rs. 250+250= Rs 500..00
- Rs. 250.00
- Rs. 250.00

Documents Required for Renewal

- Copy of last renewal.
- Affidavit of Pharmacist and current rent agreement.
- Address proof of the authorised proprietor/applicant.
- Affidavit of the liable person for day-to-day working and for any violation of drug laws.

GRP in Pharma Manufacturing

1. Document related to licensing authorities :

- Copies of all documents are submitted for grant of licence.
- Copies of licence related to manufacture of drugs like premises licence , Licences of manufacturing of schedule X schedule C and C₁ etc.
- Inspections record : copies of all inspections done by licensing authorities.
- NOC (No Objection Certificate) from pollution control board.

2. Registration and qualification records of chemist

- Qualification record
- Registration certificate
- Address proof
- In case of change of chemist and other trained staff the copies of all document of new registered chemist and staffs .

3. Analytical laboratory records

- All approval letters copies of analytical laboratories.
- Educational and experience certificate of analyst.
- Approval letter of analytical chemist by State drug controller.

4. **Equipment Cleaning and Use Record**
5. **Records of Raw Materials, (Intermediates, API Labelling and Packaging Materials)**
 - All transaction records related to raw material used.
 - Signature of person in charge cash memo or credit memo.
6. **Records of production including**
 - Drug Name and batch number.
 - The manufacturing date.
 - Quantity of raw material used.
 - Quantity of finished product.
7. **Laboratory Control Records**
8. **Batch Production Record Review**

Licenses For Drugs Manufacturing

Type of Manufacturing License	Application Form to be Submitted
For drugs other than those mentioned in Schedules C , C (1) and X	Form 24
For Homeopathic Medicines	Form 24C
For drugs mentioned in Schedule X and not specified in Schedules C & C(1)	Form 24F
For drugs mentioned in Schedules C and C (1) excluding those specified in Schedule X	Form 27
For loan license for drugs mentioned in Schedules C and C (1) excluding those specified in Schedule X	Form 27A
For drugs mentioned in Schedules C, C(1) and X	Form 27B
For the manufacture of drugs for the purposes of examination, test or analysis	Form 30
For approval for carrying out tests on drugs/cosmetics or raw materials used in the manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics	Form 36

Renewal of Manufacturing Licenses

- Licenses are valid for 5 years Renewal of license should be made on the application form same as the form submitted during the grant of the new license along with the necessary fee. The Fee for the renewal of the license is same as the grant of license.

Import / Export of Drugs and Medical Devices

Documents

- Copies of Documents submitted for grant of registration certificate for import or export of drug.
- Registration certificate.
- Copies of document submitted while application for import license.
- License.
- Challan evidence.
- Registration and IEC No.
- records of drugs and cosmetics imported and distributed.
- list of products are approved.
- list of countries from where products exported.

Renewal of License

- License for drugs and medical devices are valid for 3 years and application for renewal should be made before 9 months of expiry . IEC is valid for life time.

Inspection

- Inspection of Pharmacies Drug Inspectors are appointed by Central government or by State government as much required,

Functions

- Inspection Of Premises licensed for the Sale of Drugs to confirm whether the Condition are being followed or not . and he can investigate

1) Records related to Licensing Authority :

- License Retention Fees records , Records of Premises , record of Change in premises if any , Record of Suspension if Any,
- Copies of all documents submitted while grant of license , Copies of retail sale or Whole sale license.
- Copies of all inspections done by licensing authority.

2) Registered pharmacist

- Record of Certificate of qualification , pharmacist registration certificate , address proof, in case of change registered pharmacist the copies of all document regarding change of registered pharmacist.

3) Purchase record of drugs

- The date of Purchase.
- The name , address and the number of license of the person from whom purchased.
- The name of the drug , quantity and batch number.
- The name of manufacturer.
- All the purchases invoice ,payment record including purchase bill with cash or credit memo and transactions record of drugs for tow 2 years.

4) Sale record of drug

5) **Prescription feeling records** : The record of the drugs has been sold on prescription should be maintain with (this is only for retail sale)

- Serial number of entry
- Date of supply
- Name and address of prescriber
- The name and address of patient
- Name of drug and strength

6) Expiry drug Records

Inspection of Pharmacies of Manufacturing Drug

→ Inspectors are appointed by Central government or by State government as much required Inspection Of Premises licensed for the Manufacture of drugs to confirm whether the Condition are being followed or not , and he can investigate

E- Governance In Good Regulatory Practice

- Electronic governance or e-governance is the application(Use) of information technology for delivering government services, exchange of information, communication transactions, between government to citizen (G2C), government-to-business (G2B), government-to-government .
- Government of India wants to replace the traditional paper system with Information and Communication Technology (ITC) for good regulatory practices . and ICT is better than paper system.

Some benefits

- It takes less time than paper system.
- It provide transparency.
- It reduce cost.
- It is easy.
- Increase the satisfaction of public on government services.
- It reduce chances of Commission , unnecessary charges by greedy authorities.

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 14 : New Drug Development

Topics	Page No
Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	3

FDSPharmacy
Learn and Educate

PHARMACY LAW & ETHICS
Chapter 14
New Drug Development

Introduction to BCS system of classification

→ The Bio pharmaceuticals Classification System (BCS) is a scientific framework developed to predict the behavior of a drug product in the human body based on its physicochemical properties.

The BCS classifies drugs into four categories (BCS Class I to IV) based on their solubility and permeability.

1. BCS Class I drugs are highly soluble and highly permeable, meaning they dissolve readily in the gastrointestinal tract and are easily absorbed into the bloodstream.
 - Examples of BCS Class I drugs include caffeine and ibuprofen.
2. BCS Class II drugs are poorly soluble but highly permeable, These drugs may have difficulty dissolving in the gastrointestinal tract, but once absorbed, they can pass through cell membranes easily.
 - Examples of BCS Class II drugs include ketoconazole and danazol.
3. BCS Class III drugs are highly soluble but poorly permeable, meaning they dissolve easily in the gastrointestinal tract but may have difficulty passing through cell membranes.
 - Examples of BCS Class III drugs include atenolol and cimetidine.
4. BCS Class IV drugs are poorly soluble and poorly permeable, meaning they have difficulty dissolving in the gastrointestinal tract and passing through cell membranes.
 - Examples of BCS Class IV drugs include griseofulvin and diazepam

Simple method

1. BCS Class I (High solubility , High permeability drugs)
2. BCS Class II (Low solubility , High permeability drugs)
3. BCS Class III (High solubility , Low permeability drugs)
4. BCS Class IV (Low solubility , Low permeability drugs)

Basic Concepts of clinical trials

- Clinical trials are research and studies performed with volunteer people,
- Clinical trial is done to test safety and efficacy of new drugs or new surgery procedure.

Types of clinical trial

- **Treatment trial** : This is performed for experimental treatments , test of new combination of drugs, or for new surgery procedure.
- **Preventions trial** : This is performed test a drugs foe prevention of disease , like vaccines , vitamins etc.
- **Screening trails (early detections)** : This trail is performed for detection of certain disease or health condition.
- **Diagonstic trail** : This is performed for diagnosing a particular disease or condition, of people have sign and symptoms.
- **Quality of life trail** : This performed to explore the ways which can improve comfort and quality of life in chronic illness.

Phases of Clinical Trials

- 1) Phase I trials test the safety and tolerability of a new intervention in a small group of healthy volunteers.
- 2) Phase II trials test the effectiveness and safety of the intervention in a larger group of patients.
- 3) Phase III trials test the effectiveness and safety of the intervention in an even larger group of patients, and compare the intervention to standard treatment or placebo.
- 4) Phase IV trials are conducted after the intervention has been approved for use, and evaluate its long-term safety and effectiveness

Abbreviated New Drug Application (ANDA)

- ANDA is an application submitted to FDA for the review and approval of a generic drug for production , this application contains necessary data of related drugs.
- Once FDA approved the application , the applicant can manufacture and market that generic drug, to offer a safe , effective and lower cost alternative drug to the brand name drug.
- Generic drug application are not required to provide pre clinical(on animal) and clinical (on human) data to prove safety and effectiveness of drugs , that is why they are called "abbreviated applications ".

New Drug Application (NDA)

→ NDA is an application submitted to U.S. FDA to get permission for marketing a new drug product in United States . If FDA satisfied with provided data (safety , effectiveness , strength , quality etc) , approved for marketing.

NDA required following document to provide the information about the drug

- Procedure of clinical test
- Ingredients of the drug
- Result of animal studies
- Pharmacokinetics
- Manufacturing , processing and packaging of drug

New Drug development:

- New drug development is the process of discovering, designing, and testing new medications for treating specific diseases or health conditions.
- It involves a long and complex process of research and development, which begins with identifying potential drug targets and compounds that can modify those targets.
- The process includes various stages, such as pre-clinical testing, clinical trials, regulatory approval, and post-marketing surveillance.
- New drug development is a complex and time-consuming process, often taking several years or even decades to bring a new drug to market.
- However, it is a critical component of modern medicine, as it allows researchers to identify new treatments for previously untreatable diseases, and improve existing treatments to better meet the needs of patients

New drug and clinical trial rules 2019

- The ministry of Health and family welfare has released the latest drug and clinical trial rules in 2019
- The new rules promote the Clinical research and provide easy explanation of difficult subjects like orphan drugs , Post trial access, pre and post submission meeting.
- The new drug and clinical trials rules 2019 are organised in 13 chapters and every chapter has many of rules . (107)

Generic Drugs vs Brand Name Drugs

Features	Generic Drugs	Brand Name Drugs
Definition	A generic drug is an off-patent pharmaceutical product that is manufactured by a pharmaceutical company in the same strength, dosage form, route of administration, safety, quality, performance characteristics, and intended use after expiring the patent of the relevant brand name drug (Innovator drug).	A Brand name drug is a pharmaceutical product that is developed and marketed under a patent or registered trademark by a pharmaceutical company. But it is approved after establishing the drug's safety and effectiveness through animal and clinical (human) studies. Also, brand name drugs known as innovator drugs.
Patents	Off patent.	Patent protected.
Trade Name	Marketed under the Generic name of the drug.	Marketed under a unique proprietary name given by the company.
Application	ANDA required for USFDA approval.	NDA required for USFDA approval.
Manufactured by	Manufactured by several pharmaceutical companies after patents expiration of the relevant brand name drug.	Developed and manufactured by an innovator company.
Animal & Clinical study	Not required to perform.	Essential to perform.
Price	Cheaper.	Costly than generic drugs.
Appearance (Color, Shape, Size)	Look different from relevant brand name drug.	Unique look as design during product development.
Name variation	Same Generic drug name in any country.	Same or different brand names in different countries.
Excipients	May contain the same or altered but acceptable excipients from relevant brand name drug.	Uses acceptable excipients by the innovator company during development.
Availability	After expiration of patents and exclusivities	From product launch after proving the safety and effectiveness.
Examples	Paracetamol tablet	Tylenol, Para, NAPA, Mapap, Nortemp,

Trade name concept

- ◆ A trade name is a term used to refer to a company or business entity's name, often used to identify and distinguish it from other similar entities in the market. It is also sometimes referred to as a "business name" or "doing business as" (DBA) name.
- ◆ Trade names can be registered with the government to protect the name from being used by other businesses in the same industry, but this is not always necessary.
- ◆ A trade name is a name used by a business or company to identify itself and distinguish it from others in the market. It can be registered or unregistered, and is often used interchangeably with the terms "company name" or "business name".
- ◆ Trademark, which is a legal protection for a specific symbol, word, or phrase used to identify a particular brand, a trade name is simply the name that a company uses to conduct business.

Introduction to Patent law

- Patent Law is defined by various provisions of the patent Act 1970 . According to this law , Patent rights are given for inventions , which includes a new process , product or anything used in manufacture , and they should have patent eligibility .

Patent eligibility (Patentability conditions)

- Novelty.
- Non - Obvious (the invention should not be previously recognised , documented , or used in any form).
- Useful and Industrially Applicable.

Intellectual Property

- Intellectual properties refers to creation of mind such as invention , literary and artistic works , design, symbols , name and image used in commerce (businesses) examples of intellectual property Patent , trademark, copyrights, and trade secret.

Intellectual property rights

- It is a legal right given to the inventor or creator to protect his invention or creation for a certain period of time , in this time period no one can use that properties for creating wealth without permission of owner and utilising intellectual property without permission is illegal and punishable.

Type of Intellectual Property rights

- **Patents** : It is used for protecting new inventions, ideas, or processes. Patent holders need to pay periodic government renewal fees. An approved patent is for a limited time period. Know more about Patents Act in India.
- **Copyrights** : It protects the ideas, examples would be written works, music, art, etc.
- **Trademarks** : It is something that protects the symbols, colors, phrases, sounds, design etc.
- **Trade Secrets** : It may be strategies, systems, formulas, or other confidential information of an organization that provides them a competitive advantage in the market.

Emergency use authorisation (EUA)

- Emergency use authorisation is an authorisation(Permission) issued for use of unregistered drugs and vaccines in a public health emergency by FDA even in the lake of complete information about the safety and efficacy of the product The FDA determine that , it is appropriate to give permission for use of a drug or vaccine in a declared emergency

Conditions for issuing EUA

- FDA may determine (confirm) before issuing emergency use authorisation the
 - The agent mentioned in the emergency condition may be serious life threatening illness or not ?
 - The available scientific evidence indicates that the product may be useful in diagnosing , treating or preventing a serious life threatening illness
 - The known and potential (which may be occur) benefits must be more than the known and potential risk of the product . (Risk reward ratio)

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 15 : Blood bank

Topics	Page No
Blood bank Basic requirements and Functions	3



Chapter 15

Blood bank

- A blood bank is a facility that collects, stores, and provides blood for transfusions.
- Blood banks play a crucial role in modern medicine, as they provide a vital resource for patients who require blood transfusions due to medical conditions, surgeries, and accidents.
- Blood banks collect blood donations from volunteer donors, which are then screened, processed, and stored for future use.
- The blood is typically separated into various components, including red blood cells, plasma, and platelets, which can be used to treat different medical conditions.
- Blood banks also maintain a database of blood types and the antibodies present in the donated blood, which helps match blood products with patients in need.
- This helps ensure that patients receive safe and compatible blood transfusions.
- Blood banks may also conduct research into new blood products and transfusion techniques, as well as provide education and training to healthcare professionals and the public on the importance of blood donation and transfusion safety.

Basic Requirements for a Blood Bank

- **Premises** : a 10 m² square space is enough for blood bank which should be clean and air conditioned .
- **Manpower** : there must be a well educated healthcare professional , and he should have training and experience.
- **Electricity** : A consistent 24 hours electricity supply should be available , and a generator also should be available for emergency condition .
- **Equipments** :
 - A Refrigerator which have a storage capacity of 50 units of blood .
 - Cold Boxes , Ice Pack , Deep Freezer , Centrifuge Machine .
- **Consumable things** : Pasteur Pipette (Dropper) Glass tube ,glass slides , Test tube rack , gloves , marker pen etc.
- **Reagents** : Anti-A , Anti-B , Anti-AB , Anti-D , These are used for determination of antigens present on RBCs to Determine Blood Groups .
- **Disinfectant** : This is used for cleaning the skin to prevent infection Like Sprit , or Sodium Hypochlorite etc.
- **Transportation Facility** : Blood should be stored and transported between 2-6 ° C temperature. Blood Should be transported in Cold chain , a refrigerator or Cold Boxes can used.

Function

- ❖ **Blood collection** : The blood bank collects blood from voluntary blood donors through blood drives or at the blood bank itself. The blood is collected using sterile techniques and appropriate collection equipment.
- ❖ **Blood processing** : Once the blood is collected, it undergoes processing to separate the various components of blood such as red blood cells, white blood cells, platelets, and plasma.
- ❖ **Blood testing** : All donated blood must be tested for various infectious diseases such as HIV, Hepatitis B and C, and syphilis to ensure that the blood is safe for transfusion.
- ❖ **Blood storage** : The blood bank stores the various blood components at appropriate temperatures to maintain their viability and potency.
- ❖ **Blood transfusion** : The blood bank provides blood and blood products to hospitals and medical facilities for transfusion to patients who require them due to various medical conditions such as surgery, trauma, and cancer treatments.
- ❖ **Blood inventory management** : The blood bank maintains an inventory of blood and blood products and ensures that an adequate supply is available to meet the demands of the community.
- ❖ **Donor recruitment and retention** : The blood bank actively promotes blood donation and encourages donors to donate regularly.
- ❖ **Research and development** : The blood bank may conduct research to improve transfusion therapy and develop new blood products to meet the evolving needs of the medical community

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 16 : Clinical Establishment Act and Rules

Topics	Page No
Clinical Establishment Act and Rules Aspects related to Pharmacy	3



Chapter 16

Clinical Establishment Act and Rules

- The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.
- The Act has taken effect in the four States namely; Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories except the NCT of Delhi since 1st March, 2012 vide Gazette notification dated 28th February, 2012.
- The States of Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Assam and Haryana have adopted the Act under clause (1) of article 252 of the Constitution.
- The Clinical Establishment Rules are a set of guidelines and regulations issued by the government of India to regulate the functioning of clinical establishments across the country.

Objectives

- To improve the quality of healthcare by creating the standards of Health care facilities which are required for all types of Health care establishment.
- To prevent unqualified practitioners by an obligatory registration system.
- To create a national state and district level digital registration of clinical establishment.

Procedure for registration

- The owner of Establishment is responsible for registration
- The registration can be done in following ways:
 - In person by visiting office of District CMO (Chief medical Officer)
 - By post by sending filled in application along with proof of payment of fee
 - Online by visiting website www.clinicalestablishments.nic.in

Information required during registration for clinical establishment

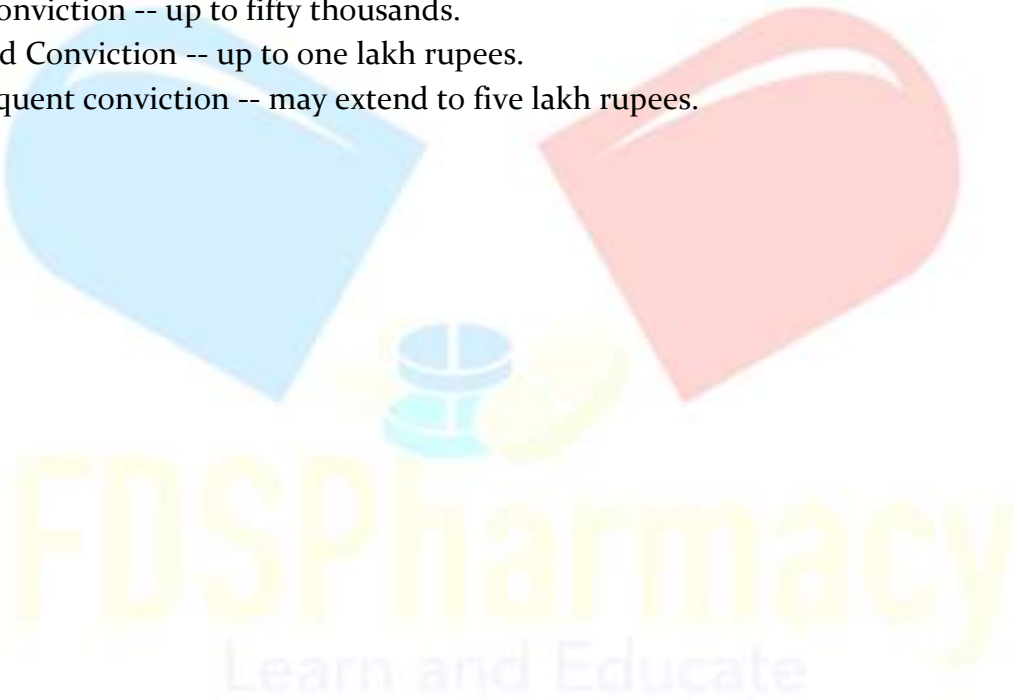
- ▲ Details of establishment categories
- ▲ Address
- ▲ Medical facilities
- ▲ Details of owner
- ▲ Details of person in charge (registration number)
- ▲ Details of other medical and paramedical staffs with registration number
- ▲ Types of facilities are provided
- ▲ Facilities for disposal of medical wastes
- ▲ Fire fighting system

Renewal of Registration

- Provisional Registration is valid for 1 year and renewal application should be applied before 30 days of expiry.
- Permanent Registration is valid for 5 years and renewal application should be applied before 6 months of expiry.

Penalties for Non registering a clinical establishment

- ◇ On first conviction -- up to fifty thousands.
- ◇ On Second Conviction -- up to one lakh rupees.
- ◇ On subsequent conviction -- may extend to five lakh rupees.



Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

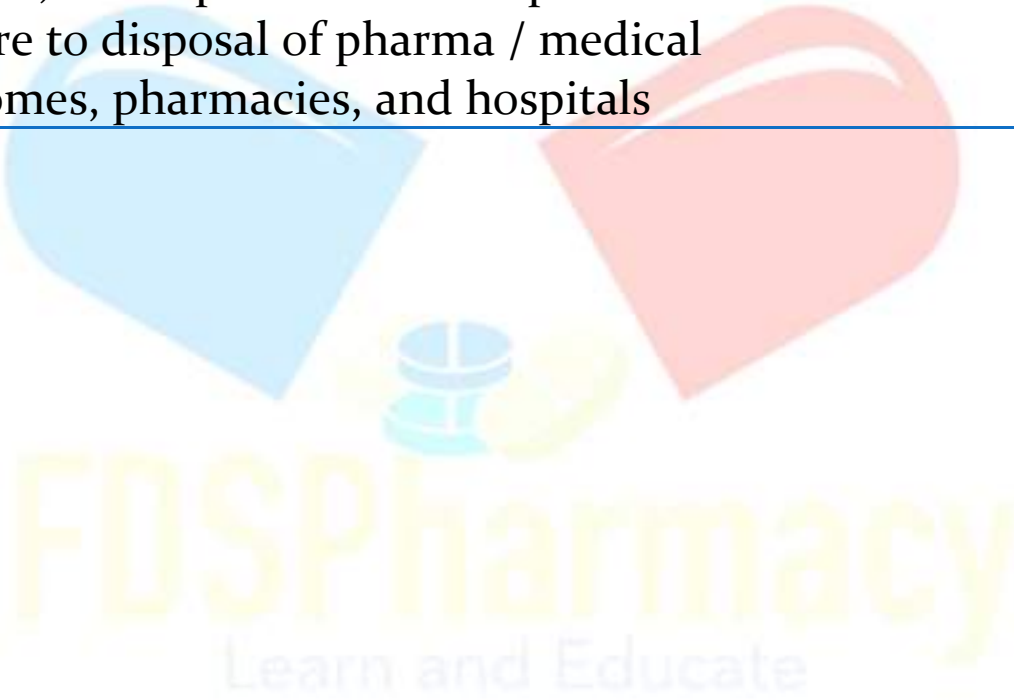
Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 17 : Biomedical Waste management rules 2016

Topics	Page No
Biomedical Waste Management Rules 2016 Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	3



Chapter 17

Biomedical Waste management rules 2016

- Biomedical waste refers to any waste generated during the diagnosis, treatment, or immunization of humans or animals or research activities pertaining thereto or in the production or testing of biological products. Proper management of biomedical waste is crucial to protect the environment and prevent the spread of infections.
- The Biomedical Waste Management Rules 2016 are a set of regulations that provide guidance on the safe handling, segregation, transportation, and disposal of biomedical waste. These rules are applicable to all persons who generate, collect, store, transport, treat, dispose of or handle biomedical waste in any form.

Basic Aspects of Biomedical Waste Management Rules 2016

- **Segregation** : Biomedical waste should be segregated at the point of generation into different color-coded containers as per the type of waste. For example, yellow for anatomical waste, red for infectious waste, blue for glassware, and white for waste sharps.
- **Storage** : Biomedical waste should be stored in leak-proof and puncture-resistant containers that are properly labeled and securely fastened. The containers should be kept in a separate area designated for biomedical waste storage.
- **Transportation** : Biomedical waste should be transported in closed vehicles with appropriate markings indicating the type of waste being transported.
- **Treatment and Disposal** : Biomedical waste should be treated and disposed of in an environmentally sound manner as per the guidelines provided in the rules. The treatment and disposal methods may include autoclaving, incineration, microwave treatment, chemical disinfection, or any other method approved by the regulatory authority.

Aspects Related to Pharma Manufacture to Disposal of Pharma / Medical Waste

- Pharmaceutical manufacturing facilities generate a significant amount of biomedical waste. The waste generated may include expired or unused drugs, contaminated packaging, and production-related waste
 - ◆ **Segregation** : Pharmaceutical waste should be segregated from other types of biomedical waste and stored separately in dedicated containers.
 - ◆ **Disposal** : Pharmaceutical waste should be disposed of by incineration or through authorized recyclers or collectors. The waste should not be disposed of in open landfills or dumped in water bodies.
 - ◆ **Reverse Logistics** : The pharmaceutical industry must establish a system for the collection and disposal of unused and expired medicines. The system must ensure the safe and secure transport of the waste to the designated disposal facility.

Pharmacies

- Pharmacies generate a significant amount of pharmaceutical waste in the form of expired or unused medicines, packaging material, and syringes.
 - **Segregation** : Pharmaceutical waste should be segregated from other types of waste and stored separately in designated containers.
 - **Disposal** : Pharmaceutical waste should be disposed of by incineration or through authorized recyclers or collectors. The waste should not be disposed of in open landfills or dumped in water bodies.

Hospitals

- Hospitals generate a large volume of biomedical waste in the form of sharps, infectious waste, and anatomical waste.
 - ▲ **Segregation** : Biomedical waste should be segregated at the point of generation into different color-coded containers as per the type of waste.
 - ▲ **Storage** : Biomedical waste should be stored in designated areas that are secure, inaccessible to unauthorized persons, and equipped with appropriate safety measures.
 - ▲ **Transportation** : Biomedical waste should be transported in closed vehicles with appropriate markings indicating the type of waste being transported.
 - ▲ **Treatment and Disposal** : Biomedical waste should be treated and disposed of in an environmentally sound manner as per the guidelines provided in the rules.
 - ▲ **Home Care** : Patients who generate biomedical waste at home, such as used syringes or bandages, should be provided with clear instructions on how to store and dispose of the waste. The waste should be stored in puncture-resistant containers and disposed of through authorized collectors or recyclers

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

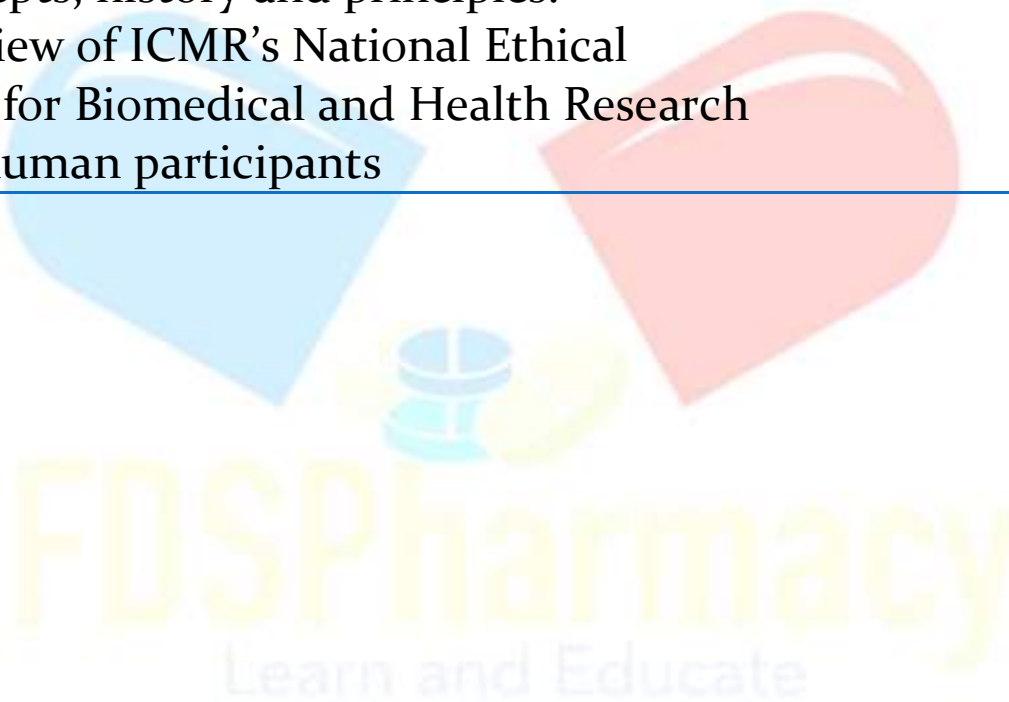
Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 18 : Bioethics

Topics	Page No
Bioethics Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	3



Chapter 18

Bioethics

Basic Concepts of Bioethics

- Bioethics is the study of ethical issues that arise in the fields of healthcare, medicine, and biotechnology. It is concerned with the biological research and application about what is right or wrong, good or bad, just or unjust, in relation to human life and health.
- Bioethics seeks to provide a framework for addressing ethical issues that arise in the fields of healthcare, medicine, and biotechnology, and to ensure that these issues are addressed in a way that is respectful of human dignity, promotes justice and equity.

History of bioethics

- The history of bioethics dates back to ancient times, where moral and ethical considerations were given to medical practices. However, modern bioethics began to emerge in the midtwentieth century, as the result of advances in medical technology and research that raised ethical issues.
- One of the most significant events in the development of bioethics was the Nuremberg Trials, which took place after World War II. The trials exposed the horrific medical experiments conducted by the Nazi regime, which highlighted the need for ethical guidelines in medical research.
- In the late 1960s, the concept of brain death was introduced, which raised questions about the definition of death and the ethics of organ donation. This led to the development of the first bioethics committees, which were established in hospitals to address ethical issues in patient care.
- In the 1970s, the field of bioethics expanded to include issues such as reproductive rights, genetic testing, and end-of-life care. The famous case of Karen Ann Quinlan, a woman in a persistent vegetative state, sparked (started) national debate about the right to die and the ethics of life-sustaining treatment.
- In the 1980s and 1990s, advances in biotechnology raised new ethical issues, such as cloning and genetic engineering. The Human Genome Project, which mapped the entire human genome, led to discussions about the ethics of genetic testing , based on genetic information
- Today, bioethics remains a rapidly evolving field, as advances in medical technology continue to raise ethical questions. The field now encompasses a wide range of issues, including stem cell research, assisted reproductive technologies, and the use of artificial intelligence in healthcare.
- Bioethicists continue to grapple (engage) with complex ethical questions and work to develop guidelines to ensure that medical practices are conducted in a way that respects human dignity and autonomy.

Principals of bioethics

The four main principles of bioethics are:

- 1) **Respect for autonomy** : This principle emphasizes the importance of respecting the decisions and choices of individuals. It involves providing patients with information to make informed decisions about their medical care, and respecting their right to make decisions about their own lives.
- 2) **Beneficence** : This principle requires that healthcare providers and researchers act in the best interests of their patients or research subjects, and seek to promote their well-being.
- 3) **Non-maleficence** : This principle requires that healthcare providers and researchers avoid causing harm to patients . It involves minimizing the risks associated with medical treatments or research, and ensuring that the benefits outweigh the potential harms.
- 4) **Justice** : This principle emphasizes the need to treat individuals fairly and equitably, and to distribute benefits and burdens of healthcare and research in a just manner. It involves ensuring that resources are allocated (distribute) fairly, and that vulnerable populations (minorities) are not exploited.

These four principles are often referred to as the "principles of biomedical ethics" and provide a framework for analyzing and resolving ethical issues in healthcare, medical research, and biotechnology.

Brief overview of ICMRs

- The Indian Council of Medical Research (ICMR) is the apex (highest) body in India for the formulation, coordination, and promotion of biomedical research. It was established in 1911 and operates under the Department of Health Research, Ministry of Health and Family Welfare, Government of India
- ICMR's National Ethical guidelines for biomedical and health research involving human participants The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants is a document developed by the Indian Council of Medical Research (ICMR) that sets the ethical principles and procedures that must be followed in conducting medical research in India involving human participants.

Some of the key principles and procedures the guidelines include

- **Informed consent** : The guidelines emphasize the importance of obtaining informed consent from participants before they are enrolled in a research study. The consent process must be voluntary, based on adequate information provided to the participants.
- **Risk-benefit assessment** : Before conducting any research involving human participants, the potential risks and benefits must be assessed. The benefits must outweigh the potential harms, and steps must be taken to minimize any risks to participants.
- **Privacy and confidentiality** : The guidelines emphasize the importance of protecting the privacy and confidentiality of participants in research studies. Researchers must take steps to ensure that participant data is secure and protected from unauthorized access.
- **Ethical review** : All research studies involving human participants must undergo ethical review by an independent ethics committee, which will assess the scientific validity and ethical implications of the study.
- **Vulnerable populations** : Special consideration (care or reward) must be given to vulnerable populations, such as children, pregnant women, and persons with disabilities, who may be at greater risk of harm in research studies.
- **Data sharing** : Researchers are encouraged to share data generated in research studies in a responsible manner, taking into account issues such as confidentiality, privacy, and intellectual property rights.

These guidelines provide a framework for ensuring that ethical standards are maintained in medical research involving human participants in India

Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting

WELCOME TO



This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site <http://www.fdspharmacy.in/>

You tube <https://www.youtube.com/c/FDSpharmacy>

What app <https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z>

Telegram <https://t.me/Fdspharmacy>

Face book <https://www.facebook.com/61550107538313/>

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 19 : Consumer Protection Act

Topics	Page No
Introduction to the Consumer Protection Act	3



PHARMACY LAW & ETHICS
Chapter 19
Consumer Protection Act

- The Consumer Protection Act of 2019 is a law passed by the Indian government to protect the interests of consumers and to ensure fair trade practices. It replaces the old Consumer Protection Act of 1986.
- The law is applicable to all products and services sold in India, whether they are manufactured in India or imported from abroad. The law aims to protect consumers from unfair trade practices, false advertising, and defective products.

Consumer

- Consumer means any person who : "Consumer" means any person who: 1) Buys any goods for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any user of such goods.
- Hires or avails of any service for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any beneficiary of such service.

Consumer Rights and Responsibilities

The Rights of the Consumer

- **Right to Safety** : Before buying, a consumer can insist on the quality and guarantee of the goods. They should ideally purchase a certified product like ISI or AGMARK.
- **Right to Choose** : Consumer should have the right to choose from a variety of goods and in a competitive price.
- **Right to be informed** : The buyers should be informed with all the necessary details of the product, make her/him act wise, and change the buying decision.
- **Right to Consumer Education** : Consumer should be aware of his/her rights and avoid exploitation. Ignorance can cost them more.
- **Right to be heard** : This means the consumer will get due attention to express their grievances at a suitable forum.
- **Right to seek compensation** : The defines that the consumer has the right to seek redress against unfair and inhumane practices or exploitation of the consumer

The Responsibilities of the Consumer

- **Responsibility to be aware** : A consumer has to be mindful of the safety and quality of products and services before purchasing.
- **Responsibility to think independently** : Consumer should be well concerned about what they want and need and therefore make independent choices.
- **Responsibility to speak out** : Buyer should be fearless to speak out their grievances and tell traders what they exactly want
- **Responsibility to complain** : It is the consumer's responsibility to express and file a complaint about their dissatisfaction with goods or services in a sincere and fair manner.
- **Responsibility to be an Ethical Consumer** : They should be fair and not engage themselves with any deceptive practice



Hello

Friends

**If you Get Any Help From This Notes /
Videos**

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940



Amir Khan

Thank You

Keep Supporting