Program	B. Pharmacy
Semester	1st semester
Subject /Course	Pharmaceutics-1
Subject/Course ID	BP 103T
Module No.	01
Module Title	Historical background and development of profession of pharmacy
Course coordinator	Dr. Neelam Sharma

Learning Outcome of Module-

LO	Learning Outcome (LO)	Course Outcome Code
LO1	To know the historical background and profession of pharmacy and basics of pharmaceutical dosage forms.	BP103.1
LO2	To understand the importance of prescription and posology.	BP103.2

Module Content Table

No.	Topic
1.	**Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
2.	**Dosage forms:** Introduction to dosage forms, classification and definitions
3.	**Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
4.	**Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

PRESCRIPTION

Definition

A medical prescription is an order (often in written form) issued by a qualified health care professional (e.g. physician and dentist) to a pharmacist or other therapist for a treatment (medicine or device) to be provided to their patient.

There are two broad legal classifications of medications:

- The medications which can be obtained only by prescription which are referred as prescription drugs or legend drugs.
- The medications which may be purchased without a prescription, which are termed non-prescription drugs or over-the-counter (OTC).

COMPONENTS OF PRESCRIPTIONS

Generally, a prescription consists of the following parts

(1) Prescriber's name, degree, address and telephone number. In the case of prescriptions coming from a hospital or a multicenter clinic, the hospital or clinic's name, address and telephone numbers appear at the top. In such a case, the physician's name and degree would appear near his/her signature.

(2) Patient's name, address, age, and the date of prescription.

(3) The Superscription, which is represented by the Latin sign. (℞). This sign represents ''take thou'' or ''you take'' or ''recipe.'' Sometimes, this sign is also used to denote the pharmacy itself.

(4) The Inscription is the general content of the prescription. It states the name and strength of the medication, either as its brand (proprietary) or generic (nonproprietary) name. In the case of compounded prescriptions, the inscription states the name and strength of active ingredients.

(5) The Subscription represents the directions to the dispenser and indicates the type of dosage form or the number of dosage units. For compounded prescriptions, the subscription is written using English or Latin abbreviations. A few examples are provided as follows:

- ✓ M. et ft. sol. Disp vi (Mix and make solution. Dispense six)
- ✓ Ft. ung. Disp ii (Make ointment and dispense two)
- ✓ Ft. cap. DTD xii (Make capsules and let twelve such doses be given)

(6) The Signa, also known as transcription represents the directions to the patient. These directions are written in English or Latin or a combination of both. Latin directions in

prescriptions are declining, but since they are still used, it is important to learn them. A few examples are present:

- ✓ ii caps bid, 7 days (Take two capsules twice daily for seven days)
- ✓ gtt. iii a.u. hs (Instill three drops in both the ears at bedtime)
- ✓ In rect. prn pain (Insert rectally as needed for pain)

(7) The prescriber's signature.

(8) The refill directions, in which the information about how many times, if authorized, a prescription can be refilled is provided.

(9) Other information, such as ''Dispense as Written.''

Types of prescription

1- ***Simple prescription***: Those written for a single component or prefabricated product and not requiring compounding or admixture by the pharmacist.

2- ***Compound or complex prescription***: Those written for more than a single component and requiring compounding.

3- ***e-prescriptions (electronic prescription):*** The use of electronic means for the generation and transmission of prescriptions is used and accepted in some countries.

4- ***In-patient prescription:*** a medication order form used in the hospital setting. In addition, other forms may be used within a hospital by specialized units such as infectious disease, cardiac care, pediatrics, and others. Drug-specific forms also may be used, as for heparin dosing, electrolyte infusions, and morphine sulfate in patient-controlled anesthesia.

5- ***Narcotic prescription***: contains a narcotic substance or other habit forming drugs. It must contain in addition to the contents of the simple prescription, the address of the patient, the narcotic registry number of the prescriber. Such prescription should be written by ink or typewriter. The quantities of the narcotic substance must be written in words and numbers.

LABEL ON THE CONTAINER

It is a legal requirement to affix a prescription label on the immediate container of prescription medications. The pharmacist is responsible for the accuracy of the label. It should bear the name, address, and the telephone number of the pharmacy, the date of dispensing, the prescription number, the prescriber's name, the name and address of the patient, and the directions for use of the medication. Some states require additional information. The name and strength of the medication, and the refill directions are also written frequently.

PRESCRIPTION PROBLEMS

A pharmacist or a nurse has to perform some simple mathematical computations related to the dosage form strength, the quantity of medication, dates for the refills, and the medication costs, etc. As a few examples, very often, the prescribing authority writes the dosage regimen for a particular strength of a medication but doesn't write the total units of the medication. The pharmacist or the nurse then calculate the number of dosage units and dispenses them. Sometime the medication available in the pharmacy is of a different strength than the one prescribed. The number of dosage units and the directions for administration have to be modified by a few calculations. The following are a few examples of the prescription problems.

Example 1: R_X

Amoxicillin 125 mg/5 mL

Sig: ii tsptid, 7 days

How many fluidounces of amoxicillin suspension would the patient receive?

2 × 5 mL = 10 mL, each dose

10 × 3 = 30 mL per day

30 × 7 = 210 mL for seven days

Answer: 7 fluidounces

Example 2: R_X

HCTZ 50 mg

#XC

Sig: i tab q AM for HPB

Re: 1

If this prescription was filled on April 15, when would the refill be due?

Ninety tablets were dispensed with instructions to take one tablet every morning for high blood pressure. The medication would last for 90 days.

Answer: the refill would be due on July 15

Example 3: R_X

Keflex caps 500 mg

Sig: i cap bid. 10 days

If the pharmacist has only 250 mg capsules in the inventory, how many

capsules should be given to the patient?

20 capsules of 500 mg can be substituted with 40 capsules of 250 mg.

Answer: 40 capsules

Practice Problems

R_X

Insulin 100 units/cc

#10 cc

Sig: 10 units bid, sc

How many days would the medication last?

R_X

Dr. Zogg'sotic drops

15 cc

Sig: 0.1 cc au tid, prn pain

If a calibrated dropper delivers 40 drops per 2 mL, how many drops should the patient instill in each each every time?

R_X

Aspirin gr v

Caffeine gr i

Lactose qs

Ft. cap. DTD #xx

R/ 4

Chloral hydrate elixir

Sig: i dose of 250 mg, pohs

How many teaspoonful's of chloral hydrate with strength of gr viiss/5 mL should be administered to the patient and at what time of day?

ERRORSANDOMISSIONS

Prescription errors are unintentional mistakes in the prescription, transcription, dispensing, and administration of medications. Some prescription errors include wrong patient, incorrect medication, inappropriate dose, wrong time, wrong route of administration, and wrong rate of administration.

To prevent this, it is a good practice to follow the ‘‘five rights principle’’ as a check: the right medication—in the right dose—to the right patients—at the right time—by the right route of administration.

The following guideline may be helpful to a pharmacist for filling prescriptions:

(1) Make sure all the information required to fill the prescription is present. A systematic, step-by-step checking would be very helpful.

(2) Make sure that the information is correctly transferred to the prescription label.

(3) Make sure that the correct drug is being dispensed, whether generic or brand.

A few examples of prescription errors are provided as follows:

Example 1:

Errors

1. Patient’s address is wrong.
2. Number of capsules = 4 × 7 = 28 and not 40.
3. Prescription shows no refill, and the label shows one refill.

Example 2:

Errors

1. Wrong date on the label.
2. The doctor meant Vantin suspension (100 mg/5 mL) which is clear fromthe signa. Tablets are a wrong choice for an infant.
3. Signa should be one-half teaspoonful twice daily for seven days.
4. No refills. The label shows one.

POSOLOGY

Posology Latin term means Posos: How much; Logos: Science

Definition: Posology is a branch of medical science which deals with dose or quantity of drugs which can be administered to a patient to get the desired pharmacological action.

Factors Influencing Dose

- Age
- Gender
- Body weight
- Route of administration

- Time of administration
- Environmental factors
- Emotional factors
- Presence of disease
- Accumulation
- Additive effect
- Synergism
- Antagonism
- Idiosyncrasy
- Tolerance
- Tachyphylaxis
- Metabolic disturbances

1) Age:

a) New Born:

- Chloramphenicol cause grey baby syndrome because of inadequate metabolism resulting drug accumulation.
- Absorption of Amoxicillin is higher because of less gastric acidity.

b) Children (Pediatrics):

- Need lesser dose than the normal adult dose, because of their pharmacokinetic profile (metabolism & excretion).
- Children can tolerate relatively larger amounts of belladonna, digitalis and ethanol whereas, elderly patients are more sensitive to hypnotics and tranquillizers which may produce confusion states in them.
- The blood brain barrier (BBB) of children are not well developed so more sensitive to CNS

c) Adults: Age (18 yrs.), weight (70 kg) and BSA (1.7-1.8 m2)

d) Old people (Geriatrics, age > 60 yrs.):

- Need lesser dose because of their pharmacokinetic profile
- More sensitive to diazepam and morphine

2) Gender:

- Morphine and barbiturates produce more excitement before sedation in women. Special care must be taken when drugs are administered during menstruation, pregnancy and lactation.
- Drugs which may stimulate the uterine smooth muscles e.g. drastic purgatives, antimalarial drugs and ergot alkaloids are contraindicated during pregnancy.
- During lactation drugs like antihistamines morphine and tetracycline are excreted in milk, should be avoided or use cautiously.
- Alcohol, barbiturate, narcotic drugs acts on fetus through placenta

3) Body weight:

- The average dose is mentioned either in terms of mg/kg body wt or as total single dose for an adult weighing between 50-100 kg.
- However, in cases of obese patients, children and malnourished patients the dose differs. It should be calculated according to t:he body weight.

4) Route of administration

- Route of administration affects therapeutic efficacy of drug
- Intravenous dose of drugs are usually smaller than the oral doses, because drug administered directly into blood stream.
- The onset of action is quick and there may be chances of drug toxicity is higher in IV route.

5) Time of administration:

- Food in the stomach delays the absorption of drugs.
- The drugs are more rapidly absorbed on empty stomach.

So the amount of drug which is effective when taken on empty stomach may not be as effective after meals.

- The irritating drugs are better tolerated if administered after meals e.g. Iron, Arsenic and cod liver oil should always be given after meals
- Antacid drugs taken before meal

6) Environmental factors:

- Daylight is stimulant, enhancing the effect of stimulating drugs and diminishing the effect of hypnotics.
- Darkness is sedative. Hypnotics are more effective at night.

E.g. the amount of barbiturate required to produce sleep during daytime is much higher than the dose required producing sleep at night.

7) Emotional Factors:

- Females are more emotional than males and require fewer doses of certain drugs.
- Inert dosage forms called placebos which resemble the actual medicament in the physical properties are known to produce therapeutic benefit in diseases like angina pectoris and bronchial asthma.

8) Presence of disease:

- Drugs like barbiturates and chlorpromazine may produce unusually prolonged effect in patients having liver cirrhosis.
- Streptomycin which is excreted mainly by kidney may prove toxic for patients having kidney failure.

9) Accumulation:

- The drugs which are slowly excreted may build up a sufficient high concentration in the body and produce toxic symptoms if it is repeatedly administered for prolonged time**. E.g.** digitalis, emetine and heavy metals.

10) Additive effect:

- When the total pharmacological action of two or more drugs administered together is equivalent to the sum of their individual pharmacological action. This phenomenon is called as additive effect
- **E.g.**Ephedrine & aminophylline in the treatment of bronchial asthma.

11) Synergism:

- When two or more drugs are used in combination form, their action is increased. This Phenomenon is called synergism.
- E.g. Procaine and adrenaline combination increases the duration of action of procaine.

12) Antagonism:

- When the action of one drug is opposed by the action of other drug on the same pharmacological system is known as drug antagonism.
- The use of antagonistic response to drugs is valuable in the treatment of poisoning e.g. milk of magnesia is given in acid poisoning where alkaline effect of milk of magnesia neutralizes the effect of acid poisoning.

a) Competitive/Reversible antagonism: Both agonist and antagonist have same binding site.E.g. Acetylcholine and atropine

b) Noncompetitive/Irreversible antagonism: Antagonist inactivates receptor so that effector complex with agonist can't be formed. Phenoxybenzamine and adrenaline at α-receptor.

c) Physiological antagonism: Binding of agonist and antagonist to two different receptors but their action is opposite. Adrenaline (bronchodilatation) and histamine (bronchoconstriction).

13) Idiosyncrasy (Allergy):

- Extraordinary pharmacological response to a drug. The word idiosyncrasy has been replaced by allergy.
- E.g. Small quantity of aspirin may cause gastric haemorrhage.
- Penicillin sensitivity is observed in many individuals.

14) Tolerance:

- When unusually large dose of drug is required to produce pharmacological action which could have been otherwise produced by normal dose, is termed as tolerance.
- E.g., Smokers can tolerate nicotine etc.
- True tolerance is produced by oral and parenteral administration of drug, while Pseudo is produced only by oral route of administration.

15) Tachyphylaxis:

- It is observed that when certain drugs are administered repeatedly at short intervals, the cell receptors are blocked up and pharmacological response to that particular drug is decreased.
- E.g., Ephedrine when given in repeated dose at short interval in the treatment of bronchial asthma may produce very less response due to tachyphylaxis.

16) Metabolic disturbances:

- Changes in water electrolyte balance and acid base balance, body temperature and other physiological factors may modify the effects of drugs.
- E.g. Salicylates reduce the body temperature only in case an individual has risen in body temperature. They have no antipyretic action

17) Drug dependence/ Addiction:

- Euphoria; Tolerance; Dependence/Habituation

a) Physical Dependence: Tea, Nicotine

1. Depend on drug to function normally
2. Occurrence of withdrawal syndrome
3. When stop taking drug abruptly

4. Vary from one class of drug to another
5. Compensating mechanisms produce imbalance

b) Psychological Dependence: LSD, Marijuana, Opiates

1. Behavioural dependence
2. High rate of drug use, craving for the drug & tendency to relapse after stopping use
3. Related to drug reinforcing properties

Dose Calculation for Child

1) Young's formula: - Child below 12 years

$$\frac{Age\ (years)}{Age\ (years)\ +12} \ x\ Adult\ dose$$

2) Fried's rule: Infant max up to 2 years

$$\frac{Age\ (months)}{150} \ x\ Adult\ dose$$

3) Dilling's Formula: 4-20 years

$$\frac{Age\ in\ Years}{20} \ x\ Adult\ dose$$

4) Catzel's rule:

$$\frac{Body\ surface\ area\ of\ child}{Body\ surface\ area\ of\ adult} \ x\ Adult\ dose$$

$$\frac{Body\ surface\ area\ of\ child\ (m^2)}{1.73\ m^2} \ x\ Adult\ dose$$

5) Clark's formula: When weight is given in kg or pounds

$$\frac{Child's\ weight\ in\ kg}{70} \ x\ Adult\ dose$$

$$Child's\ weight\ in\ pounds\ +20$$

$$\frac{\text{Age of child in month}}{150\ \text{lbs}} \times \text{Adult dose}$$

150

Dose from Body Surface Area

No	Weight (kg)	Surface Area (m2)	Approx % of Adult Dose
1.	2	0.15	9
2.	4	0.25	14
3.	6	0.33	19
4.	8	0.40	23
5.	10	0.46	27
6.	15	0.63	36
7.	20	0.80	46
8.	25	0.95	55
9.	30	1.08	62
10.	35	1.20	70
11.	40	1.30	75
12.	45	1.40	81
13.	50	1.51	87
14.	55	1.58	91

Example: 1

Calculate the child dose for 1-year-old baby, if the adult dose of the medicine is 400 mg.

Solution: Given

Age of child in month = 12 months

Average adult dose = 400 mg.

Child dose = (Age of child in month /150 lbs) x Average adult dose

= (12/150lbs) x 400 mg

= 32mg

Example: 2

A 10 year old girl weighing 60 lbs. Average adult dose given for the girl is 300 mg Calculate the child‘s pediatric dose.

Solution: Given, age of child = 10 year, average adult dose = 300 mg.

Child's pediatric dose = [Age of child/Age of child+12] x Average adult dose

= [10 / (10 + 12)] x 300 mg

= (10/ 22) x 300 mg

= 0.4545 x 300 mg

= 136.36 mg

WHAT IS PHARMACY AND SCOPE OF PHARMACY?

Definition:

- Pharmacy is the profession, which is the concern with the art and science of preparing from natural and synthetic sources, suitable and convenient material for distribution and use in the treatment and prevention of disease.
- Pharmacy provides knowledge of identification, selection, synthesis, pharmacological action. Pharmacy is also included their proper and safe distribution and use of drugs.
- Pharmacy is the art and science of preparing and dispensing medication and the provision of drug-related information to be public.

Scope of Pharmacy

Pharmacy is a profession there is a wide scope.

Pharmacist is a specialist in medication, custodian of medical information, companion of the physician, counsellor to the patient and guardian of the public health.

1. Community Pharmacy:

A pharmacist having an aptitude for business can open a retail drug store to serve the community.

Some big drug store engages a number of pharmacists, So as to run them smoothly.

2. Wholesale Pharmacy:

The wholesale offers opportunities to a limited number of pharmacists to run a wholesale business of drug and medicines.

3. Industrial Pharmacy:

Pharmaceutical industry offers the opportunity to the pharmacist to all educational leaves.

Industrial pharmacy provide job to a pharmacist in the following fields.

i. Production
ii. Analytical and Quality Control
iii. Research and Development
iv. Marketing and Sales

Production

In production sector, the pharmacist work as manufacturing chemist, he has to supervise to the production of various types of pharmaceutical formulations, packing, labeling, and storage.

Analytical and Quality Control

A manufacturing unit needs the service of an analytical chemist in its analytical laboratory to the testing of raw materials and finished goods manufactured by it.

Normally pharmacist with a bachelor degree in pharmacy gets the job of an analytical chemist.

Research and Development

A pharmacist has a doctorate degree or master degree in pharmacy is ideally suited for product development in pharmaceutical industry.

a. The synthesis of a new compound to be used as drugs, cosmetics, excipients, industrial chemicals, and preservatives.
b. Research on the cultivation of the medicinal plant.
c. The isolation and purification of the active principle of plant and animal tissue, the determination of their chemical composition and further its synthesis.
d. The preparation of drug in suitable dosage forms designed and its testing to find the bio-availability of the drug.
e. The physical, chemical and biological standardization of drugs.

f. Research on the pharmacodynamics and toxicology of new drugs.

g. The stability of dosage form during its storage and finding its date of expiry.

h. The investigation of the suitability of proposed packing materials and container.

Marketing and Sales

Marketing and sales are the performance of services from producer to the consumer.

Health System Pharmacy

It is the practice of pharmacy in private and government-owned hospitals, health maintenance organization (HMOs), clinics, walk-in health centres and nursing homes.

In these, pharmacists dispense medication, prepare the sterile solution, advise other professionals and patients on the use of the drug, monitor drug regiment and evaluate drug use.

5. Nuclear Pharmacy

Nuclear pharmacy applies the principles and practice of pharmacy and nuclear chemistry to produce radioactive drug used for diagnosis and therapy.

6. Pharmaceutical Education

Due to a rapid growth of pharmaceutical industry and expansion of health service in the country, the demands of pharmacist have increased many a time.

7. Pharmaceutical Journalism

Pharmaceutical journalism offers rewarding experiences for a limited number of pharmacists with editing skills.

8. Drug Control Administration

Run both at the level of central government as well as the state governments.

The drug and control act provides for the establishment of following agency to maintain drug control administration.

i. **Advisory agency-** The advisory agency includes drug technical advisory board and drug consultative communities, to advise the government on technical matters related to drug and cosmetics.

ii. **Analytical agency-** Includes central drug laboratories and state drug control laboratories. The main function of these laboratories is to do the analysis and testing of drug and cosmetics or sold within their respective areas.

iii. **Licensing authority-** Licensing authorities are appointed by the central government to issue licenses for the import of drug.

9. Organization Management

This management available for those with pharmacy education who wish to serve in national and state association and on board of pharmacy.

Pharmacy Council of India (PCI) and All India Council for Technical Education(AICTE) are other bodies where service of the experienced pharmacist are needs at various levels.

PHARMACOPOEIAS

1. Pharmacopoeia

- Derived from Greek word 'Pharmakon' means drug and 'Poiea' means to make.
- It is a legal and official book issued by recognized authorities usually appointed by Government of each country.
- It comprises list of pharmaceutical substances, formulae along with their description and standards.

List of Pharmacopeias: a) Argentine b) Austrian c) Belgian d) Brazilian e) British f) Chinese g) Egyptian h) European i) French j) German k) Hungarian l) Indian m) International n) Italian o) Japanese p) Yugoslavian q) Mexican r) Netherlands s) Nordic t) Polish u) Portuguese v) Rumanian w) Russian x) Spanish y) Turkish z) United state.

2. Indian Pharmacopoeia

- First official Pharmacopeia of India appeared in 1868 which was edited by Edward John Waring.
- In preindependence days, British Pharmacopeia was used in India.
- The colonial addendum of BP 1898 was published in 1900 appeared as Government of India edition in 1901.
- In 1946 Government of India issued one list known as ‚The Indian Pharmacopeial list"
- Committee under chairmanship of Sir R. N. Chopra along with other nine members prepared „The Indian Pharmacopeial list"
- It was prepared by Dept. of Health, Govt. of India, Delhi in 1946.
- In 1948 Government of India appointed an Indian Pharmacopeia committee for preparing Pharmacopeia of India"
- Tenure of this committee was five years.

1. Indian Pharmacopeia committee under chairmanship of Dr. B. N. Ghosh Published **first edition of IP in 1955.**
   - It is written in English & official titles of monographs given in Latin.
   - It covers 986 monographs.
   - Supplement to this edition was published in 1960.
2. **Second edition of IP** was published in 1966 under the chairmanship of Dr. B. Mukkerji.
   - Official titles of monographs given in English.
   - Dose were expressed in Metric system.
   - For Tablets and Injections "USUAL STRENGTH" have been given.
   - Formulations of the drugs were given immediately after the monograph of drugs.
   - 274 monographs from IP 55 & their supplement were deleted.
   - 93 new monographs were added.
   - Supplement to this edition was published in 1975.
   - 126 new monographs have been included & 250 monographs have been amended.
   - Cholera vaccine has been deleted.
3. **Third edition of IP** was published in 1985 with two volumes & nine appendices.
   - 261 new monographs have been added.
   - 450 monographs were deleted.
   - Addendum I to IP was published in 1989 were 46 new monographs added and 126 amended.
   - Addendum II was published in 1991 were 62 new monographs added and 110 amended.
4. **Fourth edition of IP** was published in 1996 under the chairmanship of Dr. Nityanand.
   - It has been made effective from 1st December 1996.
   - It covered 1149 monographs and 123 appendices.
   - It includes 294 new monographs & 110 monographs have been deleted.
   - Addendum I has been made effective from 31st December 2000 were 42 new monographs have been added.
   - Addendum II has been made effective from 30th June 2003 were 19 new monographs have been added.
   - The veterinary supplement to IP 1996 contains 208 monographs & four appendices.
5. **Fifth edition of IP** was published in 2007 & addendum to this edition was published in 2008.

- IP 2007 is presented in Three Volumes.
- Volume One contains general notices & general chapters.
- Volume Two & Three contains general monographs on drug substances , dosage forms & Pharmaceutical aids.

6. **Sixth editionof IP** is published in 2010.

6th edition of the Indian Pharmacopoeia 2010 is published by the Indian Pharmacopoeia Commission (IPC) Ghaziabad in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.

It supersedes the 2007 edition but any monograph of the earlier edition that does not figure in this edition.

This edition would be effective from 1st September, 2010.

The Indian Pharmacopoeia 2010 is presented in three volumes.

- Volume I contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters.
- Volume II contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids (A to M).
- Volume III contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z).
- Followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood- related products, Biotechnology products and Veterinary products.
- The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a day are omitted from this edition.
- The number of monographs of Excipients, Anticancer drugs, Herbal products and antiretroviral drugs has been increased in this edition.
- Monographs of Vaccines and Immunosera are also upgraded in view of development of latest technology in the field.

- A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.
- A chapter on NMR is incorporated in Appendices.
- The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

7. **Seventh Edition of Indian** Pharmacopoeia
   - The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
   - The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
   - The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.

8. Seventh Edition of Indian Pharmacopoeia

A list of 577 New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing 313 New Monographs on drug substances, Dosage forms & Pharmaceutical aids (A to Z), 43 New Drugs Substances Monographs, 10 Antibiotic Monographs, 31 Herbal Monographs, 05 Vaccines &immunosera for human use, 06 Insulin Products, 07 Biotechnology Products etc. along with the 19 new General Chapters.

- New Radiopharmaceutical Monographs & 1 General chapter is first time being included in this edition.
- This edition of Indian Pharmacopoeia-2014 is now under printing and will be available to stakeholders probably in Sept.2013, before three months of its effective date, i.e. 1st Jan. 2014.

BRITISH Pharmacopoeia

1. First edition of BP was published in 1864.
   - ✓ It consist of two sections
   - ✓ Part I: -MateriaMedica& Part II: - Preparation & compounds.
2. Second edition of BP was published in 1867.

3. Fourth edition of BP was published in 1898.
4. Fifth edition of BP was published in 1914.
5. Eighth edition of BP was published in 1953.
    - In this edition titles of drugs & preparations were in English instead of Latin and metric system.
    - It has been published annually.
    - In BP 2007 monographs has been introduced for material specifically used in preparation of Traditional Chinese medicines.
    - Term Prolonged release" has been replaced the term „Slow" and the term „Gastro-resistant" has been replaced with „Enteric coated" in number of monographs.
    - BP 2008 contains approximately 3100 monographs for substances, preparations and articles used in practice.
    - It has been made effective from 1st January 2008.

- BP 2007 -2009 were given in Six Volumes i.e. Volume I to Volume VI.
- Volume I & II contains medicinal substances.
- Volume III contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homoeopathic preparations.
- Volume IV contains supplementary chapters, IR spectra etc. Volume V contains veterinary.
- Volume VI contains CD ROM version.
- Current edition of BP 2010 is in process.

UNITED STATE Pharmacopoeia

- First edition of United state Pharmacopeia was published on 15th December 1820 in both Latin & English.
- From 1820 to 1942 it was published at Ten years intervals.
- From 1942 to 2000 it was published at Five years intervals.
- From 2002 it was published annually.
- First National Formulary of the united state appeared in 1888.
- USP21-NF16 have eight supplements.
- First appeared in January 1985 & last in November 1988.
- USP22-NF17, 1990 is the third revision that consolidates USP & NF into a single volume.

- Electronic version of USP-NF on floppy disks was introduced in 1992. USP23-NF18, was published in Mumbai as an Asian edition at the end of 1994.
- USP23 has ten supplements.
- First supplement was published in January 1995 & Last in May 1999. USP24-NF19, appeared from first January 2000.
- USP30-NF25, appeared from May 2007.
- It contains Scientific standards for drugs, dietary substances, biological products & Excipients used in dosage forms.
- It contains 4,100 monographs and 200 general chapters.
- It has been printed in three volume set.
- Volume I contains general chapters & Volume II & III contains monographs.
- First supplement to USP30-NF25, appeared from August 2007 & second supplement from November 2007 which will be considered official from May 2008.
- From 2006, Spanish edition of USP is also being published.
- Current edition of USP 2014 is in process.

UNITED STATES PHARMACOPOEIA 30 – NATIONAL FORMULARY 25 Highlights include:

- New heavier paper stock
- Complete table of contents and index in each volume
- Special 'Using the New USP-NF Print' tutorial CD
- Convenient slipcase for easy access and storage (English edition only).

NATIONAL FORMULARY 26

The USP-NF is a single-volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP. Excipient monographs are included in the NF.

The USP 32-NF 27 Contains:

- More than 4,200 monographs
- Includes over 200 general chapters, covering general tests and assays
- Displays helpful guides and charts that make it easy to find focus-specific information Includes information on emerging areas of science and medicine

- Helps ensure compliance with official standards
- Enables validation of test results against proven benchmarks
- Creates in-house standards for operating procedures and specifications
- Expedites new product development and approvals.

The USP 33-NF 28 Contains:

- More than 4,400 monographs
- Over 200 general chapters covering general tests and assays
- A new, easy-to-read format and monograph layout
- Helpful guides and charts that make it easy to find focus-specific information
- Ensures compliance with official standards
- Establishes in-house standard operating procedures and specifications
- Facilitates new product development and approval.

29 features more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics. USP 34-NF 29 also offers harmonized material and more than 230 General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.

European pharmacopeia commission started working since 1964 to prepare EP Editions

- 1st edition: published 1967
- 2nd edition: published 1980
- 3rd edition: published 1997
- 4th edition: published 2001, valid from 1 January 2002
- 5th edition: published 15 June 2004, valid from 1 January 2005
- 6th edition: published 16 July 2007, valid from 1 January 2008
- 7th edition: published June 2010, valid from 1 January 2011
- 8th edition: published June 2013, valid from 1 January 2014

Since its **5th edition**, the pharmacopoeia is published in 2 volumes.

- ✓ Volume 1 contains general chapters and monographs (e.g. on dosage forms, methods of analysis, reagents),
- ✓ volume 2 contains all substance monographs. During runtime of current edition several supplements are published. Electronic versions are also available (CD-ROM, USB stick and online version).

The European Pharmacopoeia (Ph. Eur.) defines requirements for the qualitative and quantitative composition of medicines, the tests to be carried out on medicines and on substances and materials used in their production.

It covers active substances, excipients and preparations of chemical, animal, human or herbal origin, homoeopathic preparations and homoeopathic stocks, antibiotics, as well as dosage forms and containers. It also includes texts on biologicals, blood and plasma derivatives, vaccines and radiopharmaceutical preparations. The European Pharmacopoeia and its requirements are legally binding in the member states of the European Pharmacopoeia Convention and the European Union.

PHARMACY PROFESSION IN INDIA

INTRODUCTION

Pharmacy is the health profession that links the health sciences with the chemical sciences and it is charged with ensuring the safe and effective use of pharmaceutical al drugs .

Nowadays in India Pharmacy profession is becoming very popular among individuals because of its vast scope Worldwide. In countries like India, people are now focusing to this profession apart from Doctors and Engineers. Parents are also interested to send their Son and Daughters to this profession. As a result numerous colleges and branches have been opened in this profession.

MYTHOLOGY

Lord brahma was the first teacher of universe who wrote “Ayurveda” (Science of life) in 5000 BC.

VEDIC PERIOD

Lord dhanwantriseas worshipped as “God of Health” holding the amrut (nectar) in his hand. Rig-Veda described the various herbs used in treating numerous diseases. Charka and substrata spread the massage of Ayurveda in ancient India.

PRE-HISTORIC PERIOD

BC 226-Hospital concept in the period of Great Asoka was well developed and practiced in India AD Period 900 AD- Tamilnadu (Tirumakkudal village) d is covered organized hospital activity in India treating diseases like piles, jaundice, dropsy, TB, hemorrhage, etc. 1000 AD- All the medical works were madelled on the Charaka pattern of treatment of diseases Europe was influenced by Indian drugs and herbs in 1500 century. Portuguese physician cum teacher

Garcia d aorta published a treatise: "Co loguious dos stroples adrogus da indica" describing various Indian herbs in 1563. First general hospital was set up in Chennai in 1664. Chennai medical college started atChennai in 1835 and Calcutta Medical College, Calcutta in 1936.

PRE-INDEPENDENCE ERA

The western or the so-called Allopathic system came into India with the British traders who later become the rulers. Under British rule this system got state patronage. At that time it was meant for the ruling race only. Later it descended to the people and become popular by the close of 19th Century.

The history of pharmacy profession or practice in India starts with opening of chemist shop in 1811 by Scotch M Bathgate opened in Kolkata. This was probably the beginning of pharmacy practice in India. Hindustani version of London Pharmacopoeia availablein India in the year 1824 is described to control pharmaceutical activities in India. This forced the Indian community to import drugs from overseas and pushed Indian pharmacy to rudimentary stage.

Goa medical college, started at **Panjim, Goa in 1840.**

Bengal dispensary and pharmacopoeia-Vol 11 published from Calcutta, Editor Prof, W BO Shaugh Neesy, 1841. The devnagri transcription in **Hindi**and **Bengali** of London pharmacopoeia made available in India in 1843.

H.W.Honey, the "**first qualified person"** to get recognition as chemist and druggist in India in 1866.

"**First Pharmacopoeia of India**" under British Monarchy in India was published in 1868. ModerSheriff, "Pharmacist" in Chennai College and Hospital, compiled "Venacular names of Indian Medicinal Plants and Herbs" in 1869 which formed the nucleus for "Indian Pharmacopoeia". Starting of regular two years course for "**Chemists and Druggists Diplo ma"** at MMC, Chennai in 1874.

Opium act implanted in 1878. Pharmacy education pattern was based on the instructions provided by the pharmaceutical society of Great Britain. "Chemists and Druggists Diploma" course of MMC, Chennai made equivalent to that diploma issued by **Royal Pharmaceutical Society of Great Britain, London,** in 1893 (2 Years study + 3 months practical training + 1 year internship). January 1894- The Indian Journal of Pharmacy started publishing from Calcutta but soon became defunct. 1914 Punjab Excise Act **Poison Act** was passed in 1919. 1919 **Bengal Food Adulteration Act.** In 1919 **Bihar and Orissa Prevention of Adulteration Act** was come.

1919 **Madras Prevention of Adulteration Act** Chiefly concerned with food adulteration. November 1920- The first organized move to form a pharmaceutical society, the Calcutta Chemists & Druggists Association released this, which changed its name to Bengal Chemists &Druggists Association in 1926.

Government of India on 11th August 1930, appointed a committee under the chairmanship of Late Col.R.N.Chopra to see into the problems of Pharmacy in India. This committee published its report in 1931. It was reported that there was no recognized specialized profession of Pharmacy. A set of people known as **compounders** were filling the gap. In 1930, Dangerous drugact and Drugenquiry committee under the Chairmanship of Col. R.N. Chopra (Chopra Committee) was came.

Inclusion of pharmaceutical chemistry as a subject course at degree at **Banaras Hindu University (BHU)**, Varanasi- great vision of **Late Pt. Madan Mohan Malviya, 1932** – the then Vice Chancellor of BHU. The first pharmaceutical society with education platform and view emerged in November 1935 under the banner of BHU Pharmaceutical Society. First All India Pharmaceutical Conference was held at Banaras in January 1941.

Regular degree course (B.Pharm) started at BHU under the leadership of Prof. M.L. Shroff- **"The Father of Indian Pharmacy**" education in India- 1937-38 session. The course provided for studies in pharmaceutical chemistry, pharmacy, pharmacognosy, pharmaceutical economics and German Human physiology andpharmacology we are not included. The graduates generally preferred to go for jobs in pharmaceutical manufacturing and analysis. It was later that human physiology and pharmacology got to form part of the syllabus at the BHU. First issue of Indian journal of Pharmacy was released in 1939- Official publication of IPA.

In 1940 Prof. Schroff introduced M.Pharm at BHU, Varanasi. Subhadra Kumar Patni became the first Pharmacy Graduate in India in 1940 – Formation of Pharmacy and Allied Manufacturers & Distributor's Association Ltd. (PAMDA L) – head quartered at Mumbai.

1940: Govt. Brought Drugs Bill"to regulates the import, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as „Drugs Act of 1940". The Drug Act partly implanting Chopra Committee 1941 – First ever holding of All India Conferences of IPA at BHU, Banaras. Post of Hospital Pharmacist created at KEM Hospital, Mumbai, 1941 (Modern pharmacy services started at CMCH,Vellore; Jaslok; JJ Hospital and other hospitals in India). Gorakh Prasad Srivastava became the first Post Graduate in Pharmacy from BHU in 1943. The

University of the Panjab, Lahore, which came next to institute the degree course in pharmacy in 1944, aimed at producing man power particularly for professional pharmacy. Dr Khem Singh Grewal was the founder of pharmaceutical education at the Panjab University, the nucleus he created now stands as the famous University Institute of Pharmaceutical Sciences of the Panjab University at Chandigarh. Grewal became an accomplished pharmacologist. As Professor of Pharmacology he headed the Department of Pharmacology at the K. E. Medical College (1940-47). PhD degree in Pharmaceutical l Sciences is started in 1945 at BHU. Drug and Cosmetic Act and Rules have effective in 1945. Association of Pharmaceutical Teachers of India (APTI) was formed in 1946. 1945: Govt. brought the Pharmacy Bill to standardize the Pharmacy Education in India 1946: The Indian Pharmacopoeial List was published under the chairmanship of late Col. R.N. Chopra. It contains lists of drugs in use in India at that time which was not included in British Pharmacopoeia. Health survey Development Committee (BhoreCommittee) report tabled in 1946 recommending 3-tier system of pharmacy education in India, viz, dip lo ma-degree and technologists in pharmacy

POST INDEPENDENCE ERA

Indian Pharmaceutical Congress Association (IPCA) was floated in 1948 at Calcutta and the first annual conference was held in Calcutta itself in December 1948 with Prof. M.L. Shroff as a president.

1948: Indian Pharmacopoeia Committee was constituted under the chairmanship of late **Dr. B.N. Ghosh**. The statutory regulation of pharmacy institutions in India was established with the enactment of the **Pharmacy Act 1948,** and **The Pharmacy Council of India** was established in the year 1949 and the first education regulations (ER) framed in 1953, which were subsequently amended in 1972, 1981 and 1991. The Pharmacy Act passed in 1948- Constitution of **Pharmacy Council of India (PCI)** and framing **of Education Regulations (ER)** under section 19 0f the Act. First Diploma in Pharmacy education institute started at Jalpaiguri, 1949 at West Bengal. **SheovihariLal** became the first **PhD holder in Pharmacy field**, obtaining his Doctorate degree from **University of Patna (Patna Medical College)** under the guidance of **Dr Achari, Department of Pharmacology,** 1953. Pharmacy Enquiry Committee Report 1954 (Major Genera l S.L.Bhatia) recommended pay scales for pharmacists. Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 was passed to stop misleading

advertisements in 1954. 1955: Medicinal and Toilet Preparations (Excise Duties) Act 1955 was introduced to enforce uniform duty for all states for alcohol products.

1955: First Edition of Indian Pharmacopoeia was published. Master of Pharmacy syllabus was drafted by AICTE in 1960. Indian Drug Manufacturers Association (IDMA) was founded in 1961. Formation of Indian hospital Pharmacists Association (IHPA) in 1963, head quartered at New Delhi. First issue of Indian journal of Hospital pharmacy was published in 1964. Organization of Pharmaceutical Producers of India (OPPI) established in 1965 which has head quarter in Mumbai.

Second Edition of Indian Pharmacopoeia released in 1966. India joined the Common wealth Pharmaceutical Association (CPA) as constituent member in 1970. Nayudamma Committee directed holding of GATE examination for M.Pharm courses with scholarship in 1978.

All India Organization of Chemists & Druggists (AIOCD) formed, merging all the other bodies in 1979. Establishment of Pharmacy graduates Association (IPGA) on 1980. Amendment in Pharmacy Act 1948 to restrict the practice of pharmacy to "Qualified Registered Pharmacists" only was done in 1984. Third Edition of Indian Pharmacopoeia released in 1985. In 1985, Narcotic and Psychotropic Substances Act has been enacted to protect society from the dangers of addictive drugs. Establishment of National Institute of Pharmaceutical Education & Research (NIPER) at Mohali 1991 and Dr C.L. Kaul appointed as the First Director. All India Board of Pharmaceutical Education and National board of Accreditation was formed in 1994. Drug price Control Order formed in 1995. Fourth Edit ion of Indian Pharmacopoeia released in 1996. The Pharmacy Council of India (PCI), The Indian Pharmaceutical Association (IPA) and leaders of pharmacy profession have undertaken several initiatives including the rolling out of the Charter of Pharma Vision 2020, released by His Excellency Dr. A.P.J. Abdul Kala m, during 55th IPC 2003 at Chennai and roadmap document during 58th IPC 2006 at Mumbai proposing various activities to shape the future of pharmacy profession and pharmaceutical services in India by 2020. Fifth Edition of Indian Pharmacopoeia was published in 2007. The Pharm.D regulations u/s 10 of the Pharmacy Act 1948, have been notified in the Gazette of India on10thMay, 2008. The 6-year PharmD and 3-year post-baccalaureate PharmD began to be offered as professional The Pharm.D program is comprised of 6 academic years, with 5 years of study and 1 year of internship and residency at a practice site.

CURRENT STATUS OF PHARMACY PROFESSION IN INDIA:

The Pharmacy education in our country has witnessed tremendous expansion in last one decade. However, the standards in education have been eroded by rising tides of mediocrity. There is an urgent need to initiate an academic exercise aimed at attaining revamping of curriculum keeping in pace with current and emerging trends in the field of pharmacy. We have today 6 lacs pharmacists in the country, of which lacs are in community pharmacy. Diploma holders largely handle the pharmacy profession and the providing of quality pharmaceutical care is still a dream. The admissions to undergraduate courses (B. Pharm) have fallen down drastically during 2008-09 session, (nearly 40 % seats are lying vacant across the country and the situation is worst for D. Pharm course where admissions are in single digits in many colleges). The slowing down of economy is expected to affect the job opportunities for the post-graduates (M. Pharm) in the coming years.

IMPORTANT QUESTION

Very Short answer (2 Marks)

1. What is Pharmacopoeia? Mention all the editions of Indian Pharmacopoeia.
2. Give the significance of Pharmacopoeias.
3. Enlist various Pharmacopoeias.
4. List the editions of Indian Pharmacopoeia chronologically
5. Mention the contents of the National Formulary of India
6. Differentiate between Indian Pharmacopoeia and National Formulary ofIndia.
7. What is the latest edition and year of publication of the IndianPharmacopoeia?
8. Write the difference between Pharmacopoeia and Formulary.
9. Write any four salient features of the first edition of Indian Pharmacopoeia.
10. Write any four salient features of the second edition of Indian Pharmacopoeia.
11. Write any four salient features of the third edition of Indian Pharmacopoeia.
12. Define monophasic liquid dosage forms with examples.
13. Names any four monophasic dosage forms used externally for example.
14. Names any four monophasic dosage forms used internally with example

Short questions (5 Marks)

1. Discuss the brief historical background of the profession of pharmacy in India.
2. Significance of the profession of pharmacy in relation to education and industry.
3. Write a note on pharmacy as a career.
4. Classify monophasic liquid dosage forms with examples.
5. Define dosage form and classify with examples.
6. Discuss Pediatric dose calculations based on age, body weight, and body surface area.
7. Define isotonicity. Write any two formulas to adjust the isotonicity.
8. What will be the dose for a child of 5 years if the adult dose of a drug is 400mg?
9. Calculate the dose for a child that has a body surface area of 0.57m, when the adult dose of a drug is 100mg.

Long questions (10marks)

1. Discuss in detail the historical background and development of pharmacy in India.
2. Define prescription with the help of an ideal example describe the importance of all the parts of a prescription.

3. Define prescription. Explain the handling of prescriptions. Write about the sources of errors in prescription.
4. Explain the factors affecting dose selection. Give any two formulae to calculate children's dose.
5. Define posology. enumerate different factors affecting the selection of the dose of a drug