Model question and answer

Subject- Pharmaceutics Subject Code- BP103T

B.Pharm First year Sem I

UNIT- I

Historical background and development of profession of pharmacy

1) Write in detail about the different career opportunities a pharmacy profession provides. (10 marks)

Ans: Historically, pharmacy has been a popular professional choice. There are several options for pharma professionals, depending on their credentials, abilities, and experience.

Hospital Pharmacist: Hospitals have a pharmacy department which is controlled and managed by a pharmacist. They undertake responsibility for stock control, storage, placing orders, labeling and financial budgeting, and account-keeping for the dispensary.

Retail Pharmacist: Pharma retailing is quickly gaining popularity in India's A and B-class cities. Given that these retail chains are organized under one roof, managing the entire operation requires an adequate number of chemists.

Drug Inspectors: They are employed by the state governments and they look after the day-to-day affairs of the pharma business. The job of a drug inspector includes the inspection of establishments where drugs, cosmetics, and medical devices are manufactured, handled, stored, or sold to enforce legal standardsof purity and grading**.**

Analytical Chemists: These are employed by labs thatprovide testing and validation about the pharma and related products.

Manufacturing Chemist: With a tremendous growth in the number of manufacturing units the demand for pharmacists is right on the top. Apart from the pharmaceutical units manufacturing chemists are also employed by allied industries such as nutraceuticals, food, cosmetics, etc. The job involves to preparation of a pilot sample and seeing that production of a particular formulation line is right from the raw material to the end of packaging.

Medical Representatives: These are salespeople who are brand ambassadors for their respective companies (both national and multinational companies).

Research and Development: The pharma industry is always searching for qualified individuals due to India's growth as an R&D center. More MNCs have also chosen India as a center for their research and development. The study's focus areas include standardizing

doses, process development, formulation and development, and new drug discovery research (NDDR).

Clinical Research: With many CRO operations in India, clinical research is an industry itself. India is becoming a hub for clinical research; the demand for professionals in this field is growing rapidly. Clinical research business in India will be worth $1 billion by 2010. Thus, there will soon be a massive demand for clinical research professionals, making it an interesting career option with massive growth potential.

Product Management: Managing a brand is the responsibility of the product management department. Pharma professionals enjoy an added advantage over scores others in terms of suitability for this job.

Medical Transcription: Medical transcription could be one of the speedy growing IT-enabled services in India also, with the rapid change in the outlook, of Indian healthcare and privatization of the insurance sector.

Pharma Publishing: This is becoming a new entrepreneurship business for pharma professionals. This involves publishing pharma magazines/Newsletters related to pharmacy topics.

Drug Regulatory: With Indian companies going globally the role of the drug regulatory department is increasing day by day. The job involves the preparation of a drug dossier and its registration in other countries. Further knowledge of exports and imports also becomes handy in such cases. The job also involves traveling abroad for licensing and alliances.

Academics: With many colleges mushrooming all over India, teaching is a good option for those interested in academics. As per the A.I.C.T.E. norms, the minimum entry-level qualification as a lecturer is M.Pharma. This is a profession associated with job satisfaction and social status as teaching is considered to be a noble profession. The higher posts in the hierarchy are Sr.Lecturer, Reader, Asst. Professor, Professor, Principal, etc. The emoluments are satisfactory. Besides teaching academic-related opportunities involve positions in research posts and training programs.

2. Define 'Pharmacopoeia' and write a brief note on IP.

- Pharmacopoeia derived from Greek word 'Pharmakon' means drug and 'Poiea' means to make.
- Pharmacopoeia is a book containing directions for the identification of samples and the preparation of compound medicines, and published by the authority of a government or a medical or pharmaceutical society.
- For this reason Pharmacopoeia is a legislation of a nation which sets standards and mandatory quality indices for drugs, raw materials used to prepare them and various pharmaceutical preparations.

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.
- In 1946 Government of India issued one list known as 'The Indian Pharmacopeial list' Committee under chairmanship of Sir R. N. Chopra alongwith 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.
- 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.
- Second edition of IP was published in 1966 under the chairmanship of Dr. B. Mukkerji.
- Third edition of IP was published in 1985 with two volumes & nine appendices.
- Fourth edition of IP was published in 1996 under the chairmanship of Dr. Nityanand.
- Fifth edition of IP was published in 2007 & addendum to this edition was published in 2008.
- 6th edition of IP is published in 2010.The 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.
- 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 Eighth edition of Indian Pharmacopoeia (IP- 2018) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and the Rules there under.

- **Union Minister for Health and Family Welfare and Chemicals and Fertilisers, Dr. Mansukh Mandaviya chaired IPC Conference 2022 and released 9th edition of Indian Pharmacopoeia on 1st July at Vigyan Bhawan, New Delhi.**

3. What is a Pharmacopeial Monograph?(2 marks)

- A pharmacopeialmonograph usually contains basic chemical information for the ingredient, as well as its description and function (for food ingredients).
- Furthermore, a monograph contains detailed instructions for identification, purity tests and other specific tests to limit theamount of undesirable impurities, all of which may be used to verify common requirements by manufacturers and formulators concerned with the quality of their ingredients and products.

4. What is a Pharmacopeia? (2 marks)

- Pharmacopoeia derived from Greek word 'Pharmakon' means drug and 'Poiea' means to make.
- Pharmacopoeia is a book containing directions for the identification of samples and the preparation of compound medicines, and published by the authority of a government or a medical or pharmaceutical society.

5. Define galenical pharmacy. ((2 marks)

- Medicines prepared according to the formulae of Galen is called galenical pharmacy.
- A medicinal preparation composed mainly of herbal or vegetable matter.
- It is prepared by extraction of crude vegetable drugs (active principles) with suitable solvent(s).
- The term is now used to denote standard preparations containing one more or active constituents of a plant and made by a process that leaves the inert and other undesirable constituents of the plant un-dissolved.

6. What is bowl of Hygeia?

- The meaning of the Bowl of Hygeia is rooted in Greek mythology; Hygeia was the daughter of the god of health,Asclepius.
- Hygeia is usually depicted with a serpent drinking from a cup held in her hand.
- This symbol has become the internationally recognized symbol of pharmacy, where the bowl represents medicine and the snake, potency or healing.

7. Write any two objectives of R.N. Chopra Committee.

- This Committee is also known as "Viceroy committee/R.N. Committee/Drug Enquiry Committee Committee". Objectives are-

01. Enquire the extent to which drugs of impure quality or defective strength were being imported, manufactured or sold in India.

02. Recommend steps for controlling import, manufacture and sale in public interest.

03. Enquire into the necessity of legislation to restrict the profession of pharmacy to qualified persons and to make recommendations.

8. Write a note on history of pharmacy in India. (10 marks)

We will discuss Pharmacy Professionals in India in two parts

1. Before independence

2. After independence

Before independence:

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. Initially all the drugs were imported from Europe. Later some drugs of this system began to be manufactured in this country.

1901: Establishment of the Bengal Chemical and Pharmaceutical Works Calcutta by Acharya PC Ray

1903: A small factory at Parel (Bombay) by Prof TK. Gujjar

1907: Alembic Chemical Works at Baroda by Prof. TK Gujjar

Drugs were mostly exported in crude form and imported in finished form. During World War-1 (1914 1920) the imports of drugs were cut-off. Imports of drugs were resumed after the War. In absence of any restrictions on quality of drugs imported, manufacturer abroad took advantage of the situation. The consequences were as follows:

(i) foreign manufacturers dumped inferior quality medicines and adulterated drugs.

(ii) Markets were full of all sorts of useless and deleterious drugs were sold by unqualified men.

Drug inquiry committee

✓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 and recommend the measures to be taken. 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.

✓Just after the publication of the report Prof. M.L.Schroff (Prof. Mahadeva Lal Schroff) initiated pharmaceutical education at the university level in the Banaras Hindu University. In

1935 United Province Pharmaceutical Association was established which later converted into Indian Pharmaceutical Association.

✓The Indian Journal of Pharmacy was started by Prof. M.L. Schroff in 1939. All India Pharmaceutical Congress Association was established in 1940. The Pharmaceutical Conference held its sessions at different places to publicize Pharmacy as a whole.

✓ 1937: Government of India brought 'Import of Drugs Bill; later it was withdrawn.

✓1940: Govt. brought Drugs Billto regulate the import, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as 'Drugs Act of 1940.

- ✓ 1941: The first Drugs Technical Advisory Board (D.T.A.B.) under this act was constituted. Central Drugs Laboratory (CDL) was established in Calcutta.

✓1945: 'Drugs Rule under the Drugs Act of 1940 was established.

✓ The Drugs Act has been modified from time to time and at present the provisions of the Act cover Cosmetics and Ayurvedic, Unani and Homeopathic medicines in some respects.

✓1945: Govt. brought the Pharmacy Bill to standardize the Pharmacy Education in India.

- ✓ 1946: The Indian Pharmacopoeia 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 were not included in British Pharmacopoeia.

✓Further read pharmacy profession after independence section...

In India, formal pharmacy education leading to a degree began with the introduction of a 3-year bachelor of pharmacy (BPharm) at Banaras Hindu University in 1937.

The pharmacy education pattern was based on the instructions provided by the pharmaceutical society of Great Britain.

Formal training of the compounders was started in 1881 in Bengal.Father of Pharmacy in India

- **The father of Pharmacy in India,** Mahadeva Lal Schroff, was born on 6th March 1902 at Darbhanga in Bihar. He was not a trained pharmacist, but he introduced and led pharmaceutical education and pharmaceutical industries towards success in India.
- During his time as a professor at Banaras Hindu University Schroff, he struck upon the idea to start a separate branch of pharmaceutical Sciences at BHU for the first time ever in India in 1932.
- First, heintroduced Pharmaceutical Chemistry as the principal subject in the B.Sc. course. Then, two years later, he proposed an integrated two-year B.Sc course with the subjects Pharma Chemistry, Pharmacy, and Pharmacognosy. It was later turned into a complete three-year B.Pharm course at BHU for the first time in India.
- B.pharm course was in 1944 at the Punjab University, Lahore now in Pakistan. The B.pharm course at BHU was industry oriented while that at Punjab University was oriented towards Pharmacy practice. Though the profession was oriented towards pharmacy practice at the introductory stage but as it grew it became more industry oriented. This bendlead to the development of the modern Indian pharmaceutical industry, which is now the 3rd in terms of volume.
- Prof Schroff started the M.Pharm education in 1940 at BHU. Slowly pharmacy education sprung up in different places in India. He left BHU in 1943 to join Birla Brothers as the Chief Chemist and Research Officer. Still, his efforts and interest earned him the position of principal at BITs, Pilani, where he successfully introduced Pharmacy education at a degree level for the next five years.
- Before India gained independence in 1947, there were 3 institutions offering pharmacy degree programs (Central University).

✓ 1937: Department of Pharmaceutical Engineering Institute of Technology, Banaras Hindu University, Varanasi.
✓ 1944: University institute of pharmaceutical science Panjab University, Chandigarh (State Govt).
✓ 1947: L. M. College of pharmacy. Ahemdabad (Private)

After Independence

- At independence in 1947, India inherited a system for the pharmacy profession from the British rulers that was unorganized and there was no legal restriction on the practice of pharmacy. The concept of pharmacy practice was not realized until after independence was gained. In 1948, the Pharmacy Act 1948 was enacted as the nation's first minimum standard of educational qualification for pharmacy practice to regulate the practice, education, and profession of pharmacy.

✓1948: Pharmacy Act 1948 published.

1948: Indian Pharmacopoeial Committee was constituted under the chairmanship of late Dr. B.N. Ghosh.

✓1949: Pharmacy Council of India (PCI) was established under Pharmacy Act 1948.

1954: Education Regulation have come in force in some states but other states lagged behind.

✓1954: Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 was passed to stop misleading advertisements (eg. Cure all pills)

✓ 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.

✓ DPCO: The DPCO (DRUGS (PRICES CONTROL) ORDER) was first passed in 1966 and then revised in 1970, 1979, 1987, 1995 & 2013 (Issued under the 'Essential Commodities Act, 1955")

✓1985: Narcotic and Psychotropic Substances Act has been enacted to protect society from the dangers of addictive drugs.

✓ DRUG POLICY: Drug policy 1978 & Drug policy 1986 & 1n September 1994, the new drug policy was announced.

✓ 2002: PHARMACEUTICAL POLICY 2002

• 2012: NATIONAL PHARMACEUTICAL PRICING POLICY (NPPA 2012) seeks to replace the Drug policy 1994

Note: National Pharmaceutical Pricing Policy (NPPP) is the policy governing price control and DPCO is the order by which price control is enforced.

Currently, one needs at least a diploma in pharmacy to practice as a pharmacist. Provisions of the Act are implemented through the Pharmacy Council of India. The Act requires individual states to establish state pharmacy councils that are responsible for controlling and registering pharmacists in their respective states.

Prescription

1. **Define Prescription. Describe all the parts of the Prescription as well as handling of prescription. (10 marks)**

Ans: A Prescription is a written order from registered Medical Practitioner or a Physician to a pharmacist to compound and dispense a specific medication for the patient.

- **What does prescription includes:**
  Patient details, Direction for the pharmacist to prepare and dispense medicament, Direction for the patient regarding administration of drugs.

Types of the prescription: NHS Prescription

Private Prescription

Prescription for hospital inpatients

Prescription for hospital outpatients

Prescription for patients discharged from the hospitals.

- **Parts of Prescription:** Date,

Name, age, sex and address of the patient

Superscription

Inscription

Subscription

Signatura

Renewal instruction

Signature, address & registration number of the prescriber.

- **Date:**

➢ Every prescription must bear the date on which the particular medicines are prescribed.

➢ This helps the pharmacist to keep day to day patient's record in chronologic order (listing, describing or discussing events happened as they relate to time) which helps the pharmacist or a physician to refer the old case in future.

➢ To avoid misuse of the narcotic or other habitat forming drug containing prescription by the patient a number of times for dispensing.

- **Name, age, sex and address of the patient:**

➢ It must be written on the prescription.

➢ Name helps the pharmacist to identify the correct patients avoiding any chance of giving the medicines to a person other than the one it is dispensed for.

➢ Patient's full name must be written instead of nicknames & surnames.

➢ Age of the patient becomes important in the case of pediatric and geriatric cases.

➢ Because the dose of drug in such cases varies due to their differences in ability to metabolize drugs.

➢ Hence dose of the drugs are calculated based on the age factor.

➢ In some cases, weight and height of the patients are also required.

➢ Address of the patient is generally recorded to contact the person at the later stage or to deliver the medication personally.

- **Superscription:**

➢ This part of the prescription is represented by the symbol Rx.

➢ In the ancient times it is considered as a prayer to Jupiter the god of healing for the fast recovery of the patient.

➢ Now a days it is used as a abbreviation for the Latin term "Take Thou" which means you take.

➢ (In ancient Egypt, this symbol was written on prescription as a prayer to the God of healing. "Rx" is also a symbol for the **Eye of Horus.** Horus was an Egyptian God who had his eye damaged and taken out of him. He had his eye healed by another God and Horus then gave his healed eye to his dead father to bring him back to life.

- In the days of mythology and superstition, the symbol was considered as a prayer to Jupiter, the God of healing, for the quick recovery of the patient.)

- **Inscription:**

- This is considered as the main part of the prescription order
- It contains the name and quantities of the prescribed ingredients.
- The name of each ingredients is written on a separate along with its quantity.
- In complex prescription is divided as three parts as base, adjuvants, vehicle.
- Nowadays, the majority of the drugs are prescribed which are already in a suitable formulation.
- The pharmacist is required to dispense the readymade form of drugs so, compounding is almost eliminated.

- **Subscription**:

- This part of the prescription contains directions of the prescriber to the pharmacist regarding the type and compounding of the dosage form along with number of doses to be dispensed.
- This is important because dose of drugs also depends on the type of dosage form.

- **Signature:**

- This part of the prescription contains directions to the patient regarding the administration of the drugs.
- It is generally represented as “sig” on the prescription.
- The instruction may include:

The quantity to be taken

The frequency of administration

The mode of administration

The special instruction such as dilation direction

- **Renewal Instruction:**

➢ The prescriberindicate on every prescription, whether it may be renewed & if so, how many times.

➢ It is very important for narcotics & other habit forming drugs to prevent its misuse.

- **Signature, address & registration number of the prescriber:**

➢ The signature and regd. no of the prescriber turns the prescription into legal and authentic order to the pharmacist.

➢ This helps in preventing the use of spurious drugs.

➢ Regd.no. is importance in prescription containing narcotic drugs.

Handling of Prescription:-

• The following steps are to be followed during handling of Prescription.

1. Receiving

2. Reading and Checking

3. Collecting and Weighing the material

4. Compounding, Labeling and Packing

1. Receiving :-• Pharmacist should himself receive the prescription and reading checking the prescription.

2. Reading the prescription:-• Prescription should be completely and carefully read from top to bottom. • Checking of Prescription:**-•** Prescription should be checking for any incompatibility.

3. Collecting and Weighing the material

• Before the compounding the prescription all the material required for it should be collected on the left hand side of the balance After weighting the material it should be shifter to RHS of the balance. • This give a check of ingredient which have been weight while compounding the label of every stock should be read at least 3 time in order to avoid any error. • When taken from the self or drawer. • When the content are remove from weighing and measuring. • When the content are return back to their proper place.

4. Compounding, Labeling and Packing• Compounding should be carried out in a neat place. All the equipment required are cleaned and dried thoroughly. • Only one prescription should be compounding at a time • The size of the label should be proportional to the size of the container. • Label should contain the required suggestions the patient.

Make a final check record the action taken issue medicines to the patient with clear instruction and advice.

2. What are prescription errors? (5 marks)

"Any preventable event that may cause inappropriate medication use or patient harm while the medication is in control of the health care professional, patient, or consumer"

Errors in Prescription:

1. Abbreviation:

In most of the prescriptions, abbreviated terms are used by the prescriber that leads to major errors during interpretation by the pharmacists. For example: 'SSKI' is the abbreviated term of 'Saturated Solution of Potassium Iodide'. It is preferable to avoid these types of misleading abbreviations.

2. Name of the drugs:

Names of some drugs (especially the brand names) either looks or sounds like. So any error in the name of a drug will lead to major danger to the patient. e.g. Althrocin – Eltroxin, Acidin – Apidin etc.

3. Strength of the preparation:

Drugs are available in the market in various strengths. So a drug must not be dispensed if the strength is not written in the prescription. For example, Paracetamol tablet 500 mg should not be dispensed when no strength is mentioned in the prescription.

4. Dosage form of the drug prescribed:

Many drugs are available in more than one dosage form e.g. liquid, tablets, injections, or suppositories. The dosage form intended for the patient must be mentioned in the prescription to reduce ambiguity.

5. Dose:

If an unusually high or low dose is mentioned in the prescription then it must be consulted with the prescriber. Sometimes a sustained-release (SR) dosage form is prescribed thrice or more times daily. Sustained Release dosage forms should be given once or twice a day.

6. Instructions to the patient:

Sometimes the instruction for a certain preparation is either omitted or mentioned partially. The quantity of the drug to be taken, the frequency and timing of administration, and theroute of administration should be mentioned clearly so that it is easy for patients to take medicine.

7. Incompatibilities:

It is essential to check that there are no pharmaceutical or therapeutic incompatibilities in the prescription. If more than two medicines are prescribed then the pharmacist must see whether their interactions will produce any harm to the patient or not. Certain drugs have interactions with food. The pharmacist has to advise the patient about it. For example, Tetracycline should not be taken with milk or antacid.

3. **Define 'Prescription' and mention its parts. (2 marks)**

- A Prescription is a written order from registered Medical Practitioner or a Physician to a pharmacist to compound and dispense a specific medication for the patient.
- Patient details, Direction for the pharmacist to prepare and dispense medicament, Direction for the patient regarding administration of drugs.
- **Parts of Prescription:** Date,

Name, age, sex and address of the patient

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Renewal instruction

Signature, address & registration number of the prescriber

Dosage form

1. **Define "Elixir". (2 marks)**

- Elixirs are clear, sweetened and flavoured hydroalcoholic liquids for oral use.
- The solvents are used to increase the solubility of drug. Elixir's main pharmaceutical ingredients are ethanol and water but they may also contain glycerine, sorbital propylene glycol, preservatives and flavouring agents.
- Elixirs are less viscous than syrups.

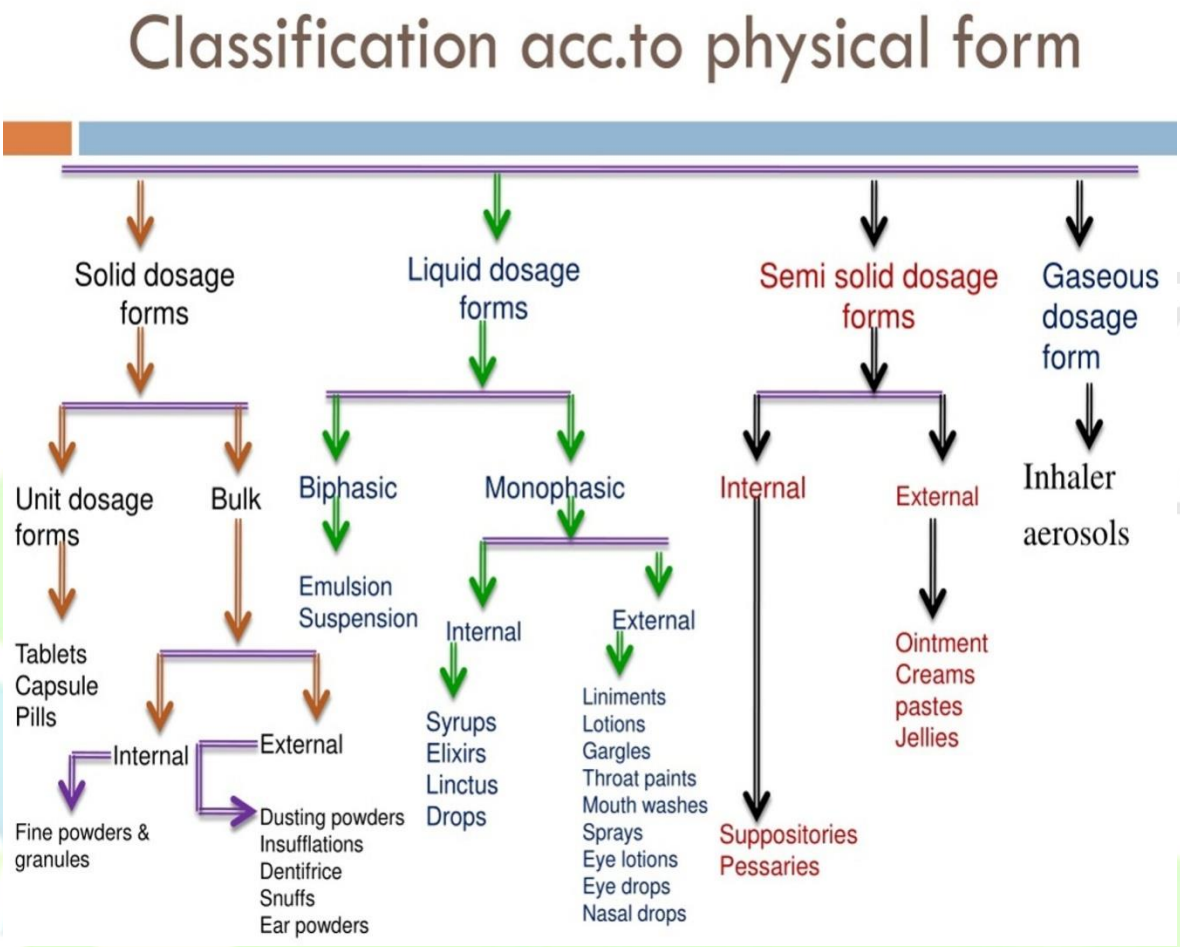
2. **Define"Emulsion". (2marks)**

- Emulsion is a heterogeneous system consisting two immiscible liquid, one of the liquid is dispersed in another in the form of droplets.
- These liquid droplets known as the emulsion globules form the dispense phase or the internal phase while the liquid in which they are dispersed is known as the continuous phase or external phase.
- There are two types of emulsions:
  • Oil in water emulsion in which the oil globules are dispersed in water
  • Water in oil emulsion in which water droplets are dispersed in oil.

3. **Define "Capsule'.**

- Capsules Capsules are solid dosage forms for oral medication in which drug is enclosed in a watersoluble shell.
- There are two types of capsules:
  - ✓ Hard gelatin capsules
  - ✓ Soft gelatin capsules
- Hard gelatin capsule is used for the administration of solids e.g. becosule/b-complex etc.
- Soft capsules are used for liquid or semi-solid e.g. pudinhara capsules.
- Hard gelatin capsules are cylindrical and made of body and cap where as Soft gelatin capsules are spherical, ovoid or cylindrical.

4. **Draw a flow chart of Dosage form classification according to physical form. (5 marks)**



5. **What is the difference between liniment and lotion?**

Difference between liniments and lotions

Liniments	Lotions
Alcoholic or oleaginous solutions	Aqueous or sometimes alcoholic preparation
Applied to the skin by rubbing	Application without friction
Higher viscosity than the lotion	Lower viscosity than liniment
Applied to relieve pain, and swelling of joints	Applied to cosmetic and medicinal purpose
Suitable for unbroken skin	Suitable for mild to slightly dry skin

6. **What is the difference between Emulsion and Suspension. (2 marks)**

Emulsion	Suspension
It is a heterogeneous mixture of two immiscible liquids.	It is a heterogeneous mixture
Dispersed particle do not settle on standing	Dispersed particle settle on standing
Dispersed particle size 1 to part 1000 nm.	Dispersed particle size more than 1000 nm
Particles are not visible through the naked eye.	Particles are visible through the naked eye
It cannot be separated by filtration	It can be separated by filtration
Dispersed in solid liquid or gas	Dispersed in liquid
Emulsifying agents are required	Suspending agents are required
Freezing should be avoided during as it leads to cracking	Freezing should be avoided as it will leads to aggregation

7. **Define syrup. Write down its strength according to USP AND IP?**

- Syrups are concentrated aqueous preparations of a sugar or sugar substitute with or without flavoring agents and medicinal substances.
- **According to IP – 66.7 % W/W**
- **According to USP – 85 % W/V Or 64.3 % W/W**

8. **Define dosage form. Give a detailed classification of dosage forms.**

Definition of Dosage Form:

Dosage forms are the mechanism by which drug molecules / APIs are administered to areas of action inside the body to generate maximum intended benefits and the lowest unwanted effects. OR

The Dosage form is the combination of Active Pharmaceutical Ingredients (API) and Excipients in the formulation.

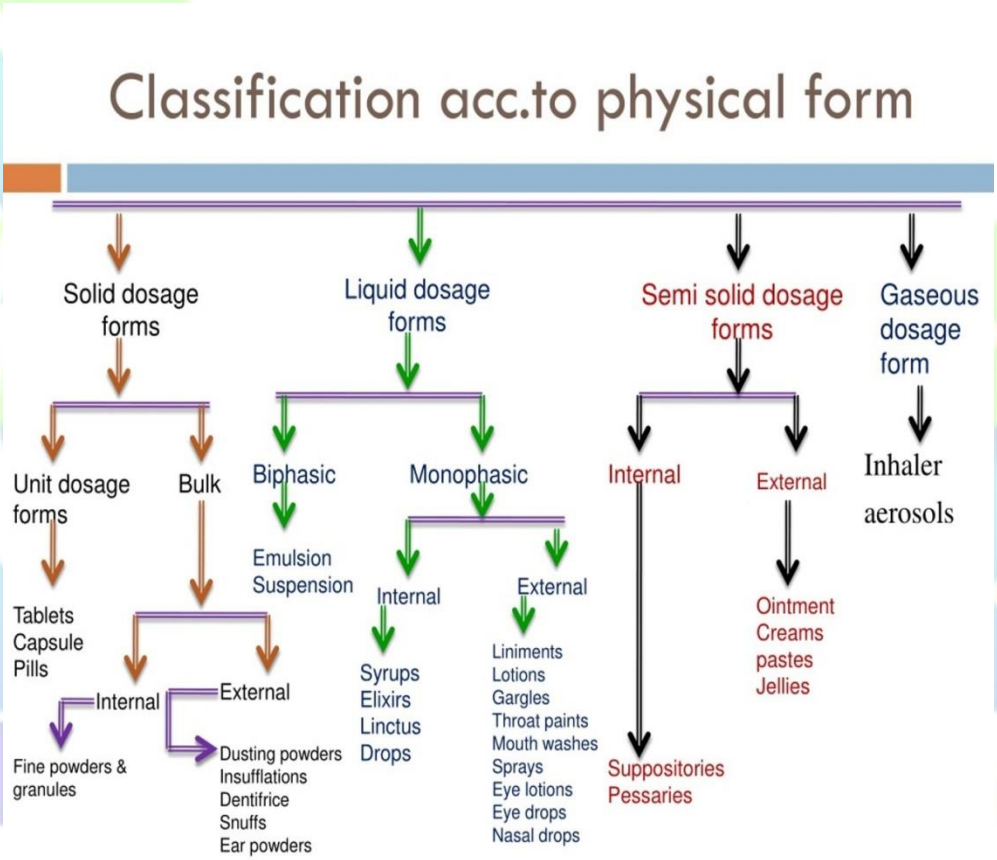
Need of Dosage Forms

Mainly depend on Patient Safety and Drug Safety/ Benefits.

1. Deliver precise dosages in a safe and easy manner. Example – Tablets, capsules, syrups
2. Cover bitter taste or odor of drug substances. Example – Capsules, coated tablets, flavored syrups
3. Insoluble or unstable in the selected vehicle, provide a liquid formulation of the insoluble or unstable medication. Example – Suspension

4. Controlled-release methods prolong the duration of medication effect. Example – Controlled release tablets, capsules, suspensions
5. After oral delivery, a drug substance is protected from stomach acid. Example – Enteric-coated tablets

6. Provide optional drug action from topical administration sites. Example – Ointment, cream, ear and nasal preparations
7. Drugs can be injected into the body's tissues. Example – Implants
8. Inhalation treatment is the most effective way to get optimum medication activity. Example – Inhalants
9. Liquid dosage forms of chemicals soluble in the vehicle of your choice. Example – Solution
10. Provide for the introduction of medication into the body's orifice. Example – Rectal and vaginal suppositories
11. Protection of a drug substance from atmospheric oxygen or moisture. Example – Coated capsules, sealed ampules.



Site of application

1. Skin- Ointments, creams, lotions, liniments
2. Eye- Solutions, ointments, creams
3. Tooth- Tooth powder, tooth paste
4. Hand- Hand creams, lotions, hand washings
5. Foot- Creams, ointments, dusting powders
6. Hair- Hair cream, hair lotions, shampoos, hair fixing
7. Nasal- Solutions, sprays, inhalations

Uses

1. Internal – all preparations except external
2. External – Ointments, lotions, creams, powders, solutions, liniments, paste, hair dyes, hair colorants

Solid dosage forms –

Powders: Solid dosage forms containing finely divided particles in micron size

Tablets: Solid dosage form containing medicaments with or without excipients

Granules: Aggregate of particles

Capsules: Drug enclosed with gelatin capsule

Cachets: Drugs enclosed with wafer sheet of rice

Pills: Small tablet containing excipients

Lozenges: Solid preparations containing sugar and gum used to medicate mouth and throat
Suppositories: Solid dosage containing medicaments with suitable suppository base that inserted in to the body cavities other than mouth, like rectum, nose, ear

Poultices: Solid dosage form converted to paste like preparation used externally in the skin to reduce inflammation

Liquid dosage forms

1. Collodions: Liquid preparations for external use having nitro cellulose used to protect the skin
2. Droughts: Liquid preparations for oral containing medicaments available in single dose or multiple dose

3. Elixirs: Liquid preparation for oral containing medicaments with suitable excipients

4. Emulsions: Biphasic liquid dosage form for oral containing medicaments in which fine oil globules dispersed in continuous phase

5. Suspensions: Biphasic liquid dosage form for oral containing medicaments in which fine solid particles suspended in continuous phase

6. Enemas: Liquid preparation for rectal containing medicaments

7. Gargles: Concentrated aqueous solutions for external use used to treat throat infections

8. Gels: Aqueous colloidal suspensions containing medicaments used as antacids

9. Linctus: Viscous, liquid oral preparations used to relief cough

10. Lotions: Liquid preparations for external application usually applied without friction

11. Liniments: Liquid preparations for external application usually applied with friction

12. Mixtures: Liquid oral preparations containing one or more medicaments

13. Mouth washes: Concentrated aqueous solutions for external use used to treat mouth infections and oral hygiene.

14. Nasal drops: Liquid preparations containing medicaments that are instilled in to the nose with a dropper used to treat nose infections and blockage of nose

15. Paints: Liquid preparations for external application to the skin or mucous membrane with soft brush

16. Solutions: Clear liquid preparation containing with or without medicaments used to internal or external preparations

17. Syrups: Sweet, viscous, concentrated liquid preparations containing with or without sugar and medicaments

Semisolid dosage forms

1. Ointments: Semisolid dosage forms for external use containing with or without medicaments with suitable ointment base

2. Creams: Semisolid dosage forms for external use containing with or without medicaments with suitable fatty base

3. Paste: Semisolid dosage forms for external use containing high proportion of finely powdered medicaments with suitable fatty base

4. Gels: Transparent semisolid dosage forms for external use containing hydrophilic or hydrophobic base with gelling agents

5. Poultices: Semisolid dosage forms for external use containing medicaments applied to the skin to hold the dressing and protective

Gaseous dosage forms

1. Aerosols: Suspension of fine solid or liquid particles with gas used to apply drug to respiratory tract having atomizer with in device

2. Inhalations: Internal liquid preparations containing medicaments dissolved in suitable solvent or if insoluble suspended in the propellent

3. Sprays: Gaseous preparations of drugs containing alcohol applied to mucous membrane of nose or throat with atomizer or nebulizer.

Posology

1. **Define posology. Explain factors affecting the dose of the drug (posology). (10marks)**
   Posology is derived from the Greek word posos meaning how much and logos meaning science. So posology is the branch of medicine dealing with doses.

   a) Age: Human beings can be categorized into the following age groups:

   1. Neonate: From birth up to 30days.
   2. Infant: Up to 1 year age
   3. Child in between 1 to 4 years
   4. Child in between 5 to 12 years.
   5. Adult
   6. Geriatric (elderly) patients

   In children the enzyme systems in the liver and renal excretion remain less developed. So all the dose should be less than that of an adult. In elderly patients the renal functions decline. Metabolism rate in the liver also decreases. Drug absorption from the intestine becomes slower in elderly patients. So in geriatric patients the dose is less and should be judiciously administered.

b) Sex: Special care should be taken while administering any drug to a woman during menstruation, pregnancy and lactation. Strong purgatives should not be given in menstruation and pregnancy. Antimalarials, ergot alkaloids should not be taken during pregnancy to avoid deformation of foetus. Antihistaminic and sedative drugs are not taken during breast feeding because these drugs are secreted in the milk and the child may consume them.

c) Body Weight:

It is always given in milligrams per kilogram of body weight (mg/kg) in any situation. This technique is also used for individuals weighing 50-100kg. It is possible that obese adults, small children, and malnourished individuals will not receive this dosage. It should be dependent on the individual's body weight. Children's medication dose should be determined based on body weight rather than age.

d) Route of administration

In case of intravenous injection the total drugs reaches immediately to the systemic circulationhence the dose is less in i.v. injection than through oral route or any other route.

e) Time of administration: The drugs are most quickly absorbed from empty stomach. The presence of food in the stomach delays the absorption of drugs. Hence a potent drug is given before meal. An irritant drug is given after meal so that the drug is diluted with food and thus produce less irritation.

f) Emotional Factor: Females are more emotional than males, therefore certain medicines require less dosage in order to get the desired effect. Angina pectoris and bronchial asthma have been successfully treated with placebos, which are inert dose forms that physically mimic the genuine medication.

g) Accumulation: After repeated administration, medications that are slowly eliminated can build up to hazardous levels in the body, resulting in toxic symptoms. E.g., digitalis, emetine and heavy metals.

h) Environmental Factors: Stimulating medicines are more effective when taken in the daylight, whereas hypnotic drugs are less effective when used in the daytime. This is due to the fact that darkness is a sedative. At night, hypnotics are more effective than during the daytime. During the day, the amount of barbiturate necessary to induce sleep is significantly higher than that needed at night.

i) Presence of Disease: Patients with liver cirrhosis may experience exceptionally long-lasting effects from drugs such as barbiturates and chlorpromazine. Because streptomycin is mostly eliminated via the kidney, people with renal failure may be at risk of toxicity.

j) Additive Effect: Additive impact occurs when the combined pharmacological activity of two or more medicines is equal to the total of their separate actions. The treatment of asthma can involve the use of substances such as ephedrine and aminophylline.

k) Idiosyncrasy: Allergy is another name for idiosyncrasy. It is termed idiosyncrasy when a patient's response to a medication is distinct from its typical pharmacological effect. Aspirin, for example, may induce gastrointestinal hemorrhage at modest doses. Penicillin with sulphonamide, for example, can induce severe toxic effects in certain people.

l) Synergism: When two or more medicines are used together, their effects are enhanced as a result. As a result, a phenomenon known as synergism has developed. Examples include a mixture of procaine and adrenaline that extends procaine's effect.

m) Tachyphylaxis: If a medication is delivered repeatedly, the cell receptors get blocked and the drug's pharmacological effect is reduced. Tachyphylaxis or acute tolerance is the term used to describe the occurrence of a reduced reaction that cannot be reversed by increasing the dose. Due to tachyphylaxis, repeated doses of Ephedrine in the treatment of bronchial asthma, for example, may generate very little response.

n) Antagonism: Drug antagonism occurs when one drug's activity is countered by another drug's action on the same pharmacological system.

When acid poisoning is treated with milk of magnesia, the alkaline action of milk of magnesia neutralizes the effects of acid poisoning.

- Competitive/Reversible antagonism: Both agonists and antagonists attach to the same location on the cell membranes. Acetylcholine and atropine are two examples.
- Non-competitive/Irreversibleantagonism: Antagonists inactivate receptors, preventing the formation of an effector complex with an agonist. A combination of phenoxybenzamine and adrenaline acts on the -receptor in the brain.
- Physiological antagonism: Two receptors are occupied by an agonist and an antagonist, but their actions are opposing. Hepatotoxic substances include adrenaline (bronchodilation) and histamine (bronchoconstriction).

o) Tolerance: The capacity to withstand the effects of a drug, especially if it is developed via repeated usage. It is typical for medicines, such as antihistaminic and narcotic analgesics, to cause tolerance. Normal sensitivity can be restored by temporarily stopping the drug's administration. When starting therapy, use the lowest effective dosage and avoid extended administration to limit the development of tolerability.

p) Metabolic Disturbances: It is possible that changes in water-electrolyte balance, acid-base equilibrium and body temperature may alter the effects of medicines. Salicylates only lower the body temperature if the individual's body temperature has increased. They do not have antipyretic properties at all.

q) Drug Dependence/ Addiction:

- **Euphoria; Tolerance; Dependence/Habituation**

  i) Physical Dependence: Tea, Nicotine
- Rely on drugs in order to function.
- Withdrawal syndrome can occur.
- When a drug is abruptly stopped.

  a) Drug classes differ from one another.

  b) Unbalance is created by compensating processes**.**

  ii) Psychological Dependence: LSD, Marijuana, Opiates
- In addition, there is a behavioural dependency.

- High incidence of drug use, drug desire, and tendency to relapse after ceasing usage.
- Properties of drugs that enhance their effectiveness

2. **What is the dose for an 8 months old infant if the average adult dose of a drug is 250 mg? 2 marks**

Ans: By using Fried's formula Dose for the child = 8 / 150 x 250 = 13.3 mg

3. **Calculate the dose for a (i) 9 months old infant; (ii) a child of 5 years age; and (iii) a boy of 16 years age when the adult dose of a drug is 100 mg.**

Ans: (i) Dose for an infant of nine months according to Fried's formula:

9 /150 = × 100 = 6 mg

(ii) Dose for a child of 5 years age according to Young's formula:

5/ 5+12 = × 100 = 30 mg

(iii) Dose for a boy for 16 years age according to Dilling's formula:

16/ 20 = x 100 = 80 mg

4. **Calculate the dose for a child that has a body surface area of 0.57 m^2, when the adult dose of a drug is 100 mg.**

Ans: Child dose (approx.) = 0.57 / 1.73 × 100 = 33 mg

5. **How you can calculate child dose according to bastedo's formula?**

Ans: Dose for the child = Age in year + 3/ 30 × Adult dose

6. **What will be the dose for a 7 years old and the adult dose is 450 mg. (Bastedo's formula).**

Ans: Dose for the child = Age in year + 3/ 30 × Adult dose

= 7+ 3/ 30× 450

= 10/30× 450 = 1/3× 450 = 150 mg

7. **150 mg of adult dose then what will be the child dose for 13 years old (Cowling's formula).**

Ans: Dose for the child = Age in year + 1/ 24 × Adult dose

= 13+ 1/ 24 × 150

= 14/24 × 150 = 1/3× 450 = 87.5 mg

8. **How you can calculate child dose according to Catzel's formula?**

Ans**:** Dose for the child =

Body surface area of child (m^2) / body surface area of adult (1.73 m^2) × Adult dose

9. **Calculate a dose for a child of 5 years old whose weight is 22 pounds and adult dose is 600 mg (Clark's formula).**

Ans: Dose for the child = Childs weight in pound /150 × Adult dose

= 22/150 × 600 = 88 mg

10. **The adult dose of the drug is 5 mg/kg body weight, how much the drug is required for the boy of 12 years who weigh 21 kg.**

Ans: Dose for the child = Childs weight in kg /70 × Adult dose

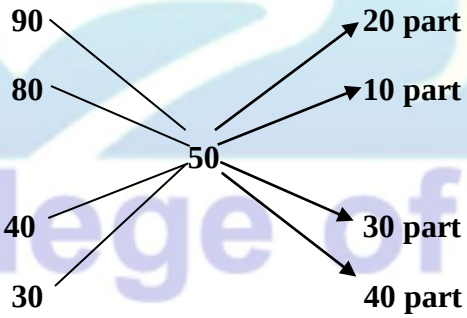
= 21/70 × 5 = 1.5 mg

Unit - II

Pharmaceutical calculations

1) **How much vol of each 90%, 80%, 40% and 30% alcohol is required to prepare 500ml of 50% alcohol? (Alligationmethod) (10/5 marks)**

Ans:



For 90%, 500 × 20/100= 100 ml is required

For 80%, 500 × 10/100= 50 ml is required

For 40%, 500 × 30/100= 150 ml is required

For 30%, 500 × 40/100= 200 ml is required

2) **Calculate the volume of 95% alcohol required to prepare 600 ml of 70% alcohol from 40% alcohol. (5/2 marks)**

Ans: 90 → **30part**

70

40 → **25part**

Total part = 55 part

Volume = Volume required × part / total part

= 600 × 30 / 55 = 327.2 ml

3) **Calculate the volume of 95% alcohol required to prepare 400ml of 45% of alcohol?(alcohol dilution method)**

Ans: formula – **vol. of strong alcohol used/ vol. required = % required / % used**

x/400 = 45/95

x = 189.4 ml

4) **What percentage of conc. Alcohol is used to prepare 300 ml of 20% alcohol from 100 ml of conc. alcohol.**

Ans: more conc. of volume / less conc. of volume = % less / %high

- ⇨ 100/300 = 20/x
- ⇨ X = 6000/100 = 60 %

5) **Find the strength of 95% v/v alcohol in terms of proof spirit.**

Ans: proof spirit/strength =% strength of alcohol × 1.753 – 100

= 95 × 1.753 – 100

= 66.53˚OP

6) Calculate the real strength of 30˚OP and 40˚UP.

Ans: proof spirit/strength =% strength of alcohol × 1.753 – 100

% strength of alcohol = proof strength + 100 / 1.753

For 30˚OP, % strength of alcohol = 30+100 / 1.753 = 74.15% v/v

For 40˚UP, % strength of alcohol = (- 40)+100 / 1.753 = 34.23% v/v

7) Find the conc. of Nacl required to make 1% solution of boric acid isotonic with blood plasma. Given that F.P. of 1% w/v of boric acid = 0.288˚C andF.P. of 1% w/v of Nacl= 0.576˚C.

Ans: % w/v of Nacl required is = 0.52 – 0.288 / 0.576 = 0.402%

8) Find the conc. of Nacl required to produce a solution isotonic with blood plasma.

Ans: Mol. Wt. of Nacl = 58.5

Nacl ionizing into 2 ions. so (N = 2)

W = 0.03W/N = 0.03 × 58.5 / 2 = 0.88% w/v

Powder

1. Define powder with their advantages and disadvantages. (5 marks)

Powder is defined as a uniform and dry mixture of one or more finely divided particulate material. OR

Pharmaceutical Powders are intimate mixtures of dry, finely divided drugs and/ or chemicals that may be intended for internal (oral powders) or external (topical or dusting powder) use.

CLASSIFICATION OF POWDERS

- Bulk powder for external use.
- Bulk powders for internal use.
- Simple and compound powders for internal use.
- Powders enclosed in catches and capsules
- Compressed powders (tablets)

Advantages: Powdered dosage forms exhibit the following advantages:

- Powders being the solid preparation are more stable than liquid and semi-solid preparations.
- Convenient forms, to dispense large dose of drugs.They can be best administered in powder form by mixing them with food or drinks.
- Since powders are in the form of small particles they offer a large surface area and are rapidly dissolved in the gastrointestinal tract minimizing the problems of local irritation.
- More convenient to swallow, faster dissolution and absorption than tablets or capsules. Powders.
- Powders offer a lot of flexibility in compounding or incompatible solids and possess good chemical stability.
- They are easy to apply.
- They absorb skin moisture, which leads to reduced friction between skin surfaces, discourages bacterial growth and has a cooling effect.
- Can be applied to many body cavities such as ears, nose, tooth socket and throat.
- Can be made into many different dosage formulations eg capsules, tablets, powders for reconstitution, dusting powders, bulk powders, powders for inhalation etc. Powders
- Highly compatible compared to liquid dosage forms.
- Manufacturing of powder is economic, hence product cost is quite low as compared to other dosage forms.

Disadvantages:

- Less convenient to carry
- Bulk powders are not suitable for administering potent drugs with a low dose.

- Difficult to mask the unpleasant taste of the drugs.
- Light fluffy powders may be inhaled by infants leading to breathing difficulties.
- Variable dose accuracy.
- Not suitable form for drug inactivated in the stomach or cause damage to stomach these should be presented as enteric-coated tablets.
- Not suitable for bitter, nauseating and corrosive drugs, if are meant for oral administration.
- Difficulty of protecting hygroscopic, deliquescent or aromatic materials and not suitable for drugs which are unstable in normal atmospheric conditions.
- They are susceptible to physical instability.

2. **Explain the simple and compound powders with examples.**

Simple powders:

There are generally only one or two ingredients in a powder, either crystallized or amorphous. The powder may be present in crystalline form, in which case it is crushed to a fine powder, measured, divided into portions, and packaged individually.

Example - Dispatched six aspirin powders, each containing 300 mg of aspirin

Rx, aspirin 300mg

Procedure - Prepare the aspirin by powdering it & weighing the required amount. Individually wrapped powder paper is used to weigh and package aspirin powder. There is 300 mg of aspirin in each packet.

Direction - You need to take one powder after every eight hours.

Compound powders:

Powders mixed from two or more substances constitute compound powders. Afterward, divide it into the desired number of doses. Each powder paper is then dispensed with the solution.

Example - Dispense 8 powders of A.P.C, each powder containing 500mg of A.P.C

Rx, Aspirin 300mg

Paracetamol 150mg

Caffeine 50mg

Procedure - Make sure that each powder is accurately weighed and mixed in ascending order by weight. Each dose should be wrapped in powder paper after weighing 500 mg of the mixed powder.

3. **Define the term dusting powder, effervescent and eutectic mixture. (5 marks)**

Dusting powders:

• Dusting powders usually contain substances such as zinc oxide, starch and boric acid or natural mineral substances such as kaolin or talc.

• Talc may be contaminated with pathogenic microorganisms such as - Clostridium tetani etc., and hence it should be sterilized by dry heat.

• Dusting powders should not be applied to broken skin.

• If desired, powders should be micronized or passed through a sieve # 80 or 100.

• Dusting powders should preferably be dispensed in sifter-top containers. Such containers provide the protection from air, moisture and contamination as well as convenience of application

• They are widely used as lubricants, protective, absorbents, antiseptics, astringents & antiperspirants.

Effervescent granules

• This class of preparations can be supplied either by compounding the ingredients as granules or dispensed in the form of salts.

• The ingredients whether in granular form or present as salts, react in presence of water evolving carbon dioxide gas.

• For evolution of the gas two constituents are essential, a soluble carbonate such as sodium bicarbonate and an organic acid such as citric or tartaric acid.

• The preparation can be supplied either as a bulk powder or distributed in individual powders.

Eutectic mixtures

• Defined as mixture of low melting point ingredients which on mixing together turn to liquid form due to depression in melting point of the mixture below room temperature

• They are mixtures of substances that liquefy when mixed, rubbed or triturated together.

• The melting points of many eutectic mixtures are below room temperature.

• Examples of the substances which tend to liquefy on mixing are camphor, thymol, menthol, salol. Any two of these drugs turn to liquid when mixed.

• This problem can be solved during formulation of powders of such material by using inert adsorbent such as starch, talc, lactose to prevent dampness of the powder and dispensing the components of the eutectic mixture separately.

4. Classify of powder. 10 marks

Powders are classified on the basis of following three Categories

- Based on particle size.
- Based on uses
- Based on physical form

(a) clarification based on particle size

On the basis of particle size powder classified in to 5 Categories.

- Very coarse powder -All particle pass through sieve no. 8.
- Coarse powder- All particle pass through sieve no.20
- Moderately Coarse – All particle pass through sieve no 40
- Fine powder- All particle pass through sieve no 60
- Very fine- All particle pass through sieve no 80

(b) on the basis of use, powder are classified into 2 categories :-

- Powders for internal use
- powders for external use

Powder for internal use

It consists of drugs in the form of powder intended to be Swallowed directly or with water / another suitable Liquid.

powders for internal we can be taken Orally, administered through nose as snuffs or can be taken into body cavity as insufflation.

Basically two types-

- ✓ simple powder
- ✓ compound powder

Simple powder:

These are the powders that contain only one active ingredients either in Crystalline or amorphous form.

Compound powder:

These are the powders that contain two or more than 2 API;

Powder for external use

Powder for external use are pharmaceutical prep. Consisting of Solid, loose, dry particles of varyingdegree of fineness.

They are generally meant to apply on the Body areas.

They basicallyincludes-

(i) Dusting Powder
(ii) Surgical powder.

(iii) Dentifrices, etc.

Dusting powder:

- ✓ Dusting powder are very fine, free flowing powders meant for application to unbroken skin.
- ✓ These powder works as protectives and having antiseptics, antifungal properties.

A good dusting powder includes:

- Ease of flow
- Non irritability
- Good absorption and adsorption
- Good stability

Surgical powder:

✓ These are also a type of dusting powder consist of sterile product intended to be used on open large wounds or on damaged skin.

Dentifrices:

✓ Dentifrices are tooth cleaning powder used with a tooth brush for the purpose of cleaning teeth.

(c) Classification based on physical form:
Two types.

✓ Bulk powder: mixture of material and packed into properly designed bulk container such as tight, wide mouthed glass/plastic bottle.
✓ Divided powder: divided powders are single doses of powder drug mixtures. In divided powders each dose of medicament is separately packed and dispensed to the patient.
✓ It provides advantages of accurate dose.

5. Write a note on general method of preparation of powder. 5 marks

Ans: Mixing of powder -

- Spatulation
- Trituration
- Geometric dilution
- Shifting
- Tumbling

Spatulation:

Mixingis done by movement of spatula throughout the powders.

This method is useful in mixing

- small amount of powder & for
- solid, substance that liquify or eutectic mixture

Trituration:

It is used for both size reduction & mixing of powder.

The apparatus used isMortar & Pestle.

Porcelain mortar & pestle, with a roughinner Surface is preferred...if size reduction is desired with mixing.

Glass mortar & pestle used for chemical- that may stain porcelain surface.

Geometric dilution:

- When a small amount of a potent substance is to be mixed with a large amount of diluent, the geometric dilution method is used to ensure the uniform distribution of the potent drug
- By this method, the potent drug is placed with an approximately equal volume of the diluent in a mortar and is mixed thoroughly by trituration.
- Then, a second portion of diluent equal in volume to the mixture is added and the trituration repeated.
- This process is continued by adding an equal volume of diluent to the powder mixture and repeating this until all of the diluent is incorporated.

Sifting:

The powders are mixed by passing through sifters results in a light fluffy products.

Tumbling:

It is the process of mixing powders in a large container rotated by electrical motor (industrial use)

6. Define effervescent powder. 2 marks

- Effervescent salts are granules, or coarse to very coarse powders, containing the medicinal agent in a dry mixture usually composed of sodium bicarbonate, citric acid, and tartaric acid
- When added to water, the acids and the base react to liberate carbon dioxide, resulting in effervescence.

Liquid dosage form

1. **Write down the advantages and disadvantages of liquid dosage form. (5 marks)**
   Ans:

Advantages:

- Children and the elderly may struggle to swallow tablets or capsules, so liquid dosage forms may be a better choice than tablets and capsules.
- Their appearance is attractive and they provide psychological benefits.
- Sweetened, colored, and flavored vehicles can be used to deliver bitter and unpleasant medicines.
- Dosage is more flexible with liquid dosage forms compared with solid dosage forms like tablets and capsules.
- Measurement of a different volume can easily and conveniently adjust the dose of the drug substance.
- It is more difficult for tablets and capsules to be absorbed than liquid dosage forms if they are taken orally.
- Liquid dosage forms are absorbed at a much faster rate than solid dosage forms.
- Liquid dosage forms are suitable for the administration of hydrophobic and deliquescent medicines that are not suitable for solid dosage forms.
- Adsorbents and antacids deliver more intense effects in liquid dosage form than they do in tablet form.
- Solid dosage forms are more difficult to take correctly than liquid dosage forms. In certain types of medicines, such as cough preparations, liquid dosage forms are expected

Disadvantages:

- The chemical degradation of liquid dosage forms is typically more pronounced than solid dosage forms.
- Bulky and not convenient to transport or store, they take up a lot of space.
- If the container is accidentally broken, the entire dosage form is lost.
- Because liquid dosage forms are inherently unstable, their shelf-life is very often shorter than that of their corresponding solid dosage forms.
- It is not uncommon for a solution to provide an ideal environment for microbial growth. For this reason, preservatives are often required.
- Vaccines, for instance, need to be stored in special conditions due to their liquid form
- A solid form of a drug has an unpleasant taste that is always more apparent when the drug is dissolved.

- The patient's measurement of the correct volume determines whether the dose is given correctly, which increases the chance for variability. For patients with vision impairments, arthritis, or struggles with reading numbers on their oral dosing syringe and medicine cup, this can be a significant issue.
- Breakage of containers is an issue.
- Instable compared to other forms.

2. **Write down the excipients used in liquid dosage form.**
   Compared to solid dosage form, liquids are processed and formulated as solutions, suspensions, and emulsions according to the dosage form required or API solubility andstability. Powder may also be delivered as syrups, solutions, suspensions, and emulsionsby reconstitution in which powder and vehicle are combined prior to delivery.Liquid formulation (LDF) requires various additives which are elaborated asfollow:

- **Vehicles:** That carry drug APIs and other additives in dissolved or dispersed state.

• Aqueous Vehicles: water (SWFI, WFI, USP purified water), propylene glycol, ethyl alcohol,glycerine.
• Oily Vehicle: Vegetable oils, mineral oils, organic oily bases or emulsified bases.

- **Co-solvent:** these are basically liquid components often used to increase the solubility of drugs in the desired solvent. Examples: ethanol, glycerol etc.
- **Solubilizers:** Breaking the hydrogen bond between the particles so they get soluble in water. Solubility can be modified by use of cosolvent, pH change, complex formation, or the use of surfactants. Example of solubilizers in LDF are ethanol, PEGs such as PEG-400, etc.
- **Sweeteners:** Generally, sweeteners are used in between 30% and 50% of the total formulationconcentration except for cold syrups that contain 80% of sweetener.

• Natural Sweeteners: Sucrose, lactose, mannitol, etc.
• Artificial Sweetener: Aspartame, saccharin, etc.

- **Antimicrobial Preservatives:** Preservative used in preparation to preventthe growth of microbes so it should be of wide spectrum. It should benontoxic, non-sensitizing, compatible with other additives, and have no taste andodor, e.g., parabens (0.015%0.2% w/v.), Phenol, benzyl alcohol (2%), chlorocresol, etc.
- **Surfactant:** Anionic Sodium lauryl sulfate (SLS), 2-naphthalene sulfonate sodium, docusatesodium.

• Cationic: cetylpyridinium chloride.
• Nonionic: poloxamer, polysorbate.

- **Suspending Agent and Viscosity Modifying Agent:** Cellulose derivatives: MCC (and derivativessuch as carboxymethylcellulose (CMC)); Clays: magnesium aluminum silicate;sodium alginate, xanthan gum, carbomer povidone, tragacanth, guar gum; colloidal silicondioxide.
- **Color:** Different colorants are frequently used in the liquid dosage forms and most of the time the purpose is to enhance the elegance of the formulation and thereby the acceptability of the dosage forms, e.g., food, drug, and cosmetic colors. Examples- tartrazine, brilliant blue etc.

- **pH Modifiers and Buffering Agents:** Buffers used to control or prevent changes in the
1. formulation pH which could prevent and increase the stability.
   Example- phosphate buffer, acetate buffer, citric acid phosphate buffer

3. Write a note on solubility enhancement technique. (10 marks)

When in aqueous media solubility of drug is limited, there are various techniques to improve the solubility of poorly soluble drug (Figure 1). There are some traditional and novel techniques to increase the solubility are:

- **PARTICLE SIZE REDUCTION**

Solubility of drug is also related to particle size of drug. By reducing particle size, surface area increases which improves the dissolution property of drug. Drug particle size is often related to bioavailability of poorly soluble drugs. Particle size reduction is done by milling techniques using colloid mill, jet mill etc. The saturation solubility of drug does not change, this is not suitable for drugs having a high dose number. Particle size reduction can be achieved by nanosuspension &Micronization.

- **MODIFICATION OF CRYSTAL HABIT**

a) Polymorphs

b) Pseudo polymorphs

Polymorphism is the ability of solid material to exist in 2 or more different crystalline forms with different arrangements in crystal lattice. Polymorphs are different crystalline forms. Crystalline forms of drugs are chemically same but they have different physiochemical properties like melting point, texture, density, solubility, stability. Similarly, amorphous form of drug is more suitable than crystalline form. Due to more surface area and high associated energy. Order of different solid form of drugs.

Amorphous > Metastable polymorphs > Stable polymorphs.

- **SOLUBILISATION BY SURFACTANTS**

Microemulsion: A microemulsion is an optically clear, transparent, thermodynamically stable, isotropic translucent system, contain a mixture of oil, surfactant and hydrophilic solvent which dissolve a poorly aqueous soluble drug. HLB and non-toxicity are the parameters for selecting a surfactant. When the formulations come into contact with water, they self-emulsify, forming a highly clear emulsion of small, homogeneous oil droplets carrying the solubilized weakly soluble medication. Microemulsions have been used to improve the solubility of numerous medications that are nearly insoluble in water, as well as to incorporate proteins for oral, parenteral, and intravenous

administration. The most suited formulation is an oil-in-water (o/w) microemulsion, which is intended to enhance solubility by dissolving molecules with low water solubility into an oil phase solubility.

- **COMPLEXATION**

  Drugs have been complexed with cyclodextrins to improve water solubility and drug stability. In pharmaceutical formulations, the most often used β-cyclodextrin derivatives with improved water solubility are utilized. Because cyclodextrins are big molecules with

  molecular weights larger than 1000 Da, they are unlikely to penetrate the skin easily. Skin penetration has been reported to increase and decrease as a result of cyclodextrin complexation. CDs can also be utilized as membrane permeability enhancers and stabilizing agents in addition to their solubility enhancement application. The presence of cyclodextrins improves permeability through biological membranes. In pulmonary drug delivery systems, CDs can also be used as a permeability enhancer.

- **CO-SOLVENCY**

  Co-solvency is a mixture of one or more miscible liquids used to improve the solubility of drugs. The addition of a co-solvent solution can improve the solution's solubility and miscibility, as well as its dissolution. In comparison to the simple drugs, the co-solvent enhanced the low solubility drug by almost a thousand times.A co-solvent technique may be appropriate for poorly soluble lipophilic or highly crystalline molecules with a high solubility in the solvent mixture. Because of the low toxicity of many co-solvents and their relative ability to solubilize nonpolar pharmaceuticals, it has primarily been used in parenteral dosage forms.
  Propylene glycol, ethanol, glycerin, and polyethylene glycol are the most common low-toxicity cosolvents used in parenteral administration. Because of their considerable solubilization capacity for poorly soluble drugs and their comparatively low toxicity, dimethyl sulfoxide (DMSO) and dimethyl acetoamide (DMA) have been widely employed as cosolvents.

- **NANOTECHNOLOGY**

  The study and use of materials and structures at the nanoscale level of around 100 nanometres (nm) or less is referred to as nanotechnology. Oral bioavailability increase via Micronization is insufficient for many new chemical entities with limited solubility because micronized products have a relatively small effective surface area for dissolving, hence the next stage was nanonization.

- **SALT FORMATION**

Improvements in drug solubility and dissolution are achieved via salt generation techniques. This method is used to observe the effects of various drugs or chemical reactions. When a medication is ionized, salt is produced. It works effectively in parenteral and other liquid dose forms, as well as solid dosage forms. It uses several methods, such as

physiochemical properties, to alter the drug's stability, bioavailability, purity, and manufacturability. For many years, salt production of low soluble medication candidates has been used to improve solubility.Examples- Aspirin, Barbiturates, Theophylline etc. Progesterone, a water-insoluble steroid that is soluble in peanut oil, is a commercially accessible example of this method.

- **pH adjustment**

A drug that is poorly water soluble may be able to dissolve in water if the pH is changed. The buffer capacity and tolerability of the chosen pH must be considered when obtaining solubility using this method.Excipients that increase the pH of the environment within the dosage form to a level higher than the pKa of weekly acidic pharmaceuticals increase the drug's solubility; excipients that function as alkalizing agents may increase the solubility of weekly basic drugs. It can be used on crystalline and lipophilic poorly soluble substances as well.

Unit -3

Monophasic liquids

1. Write down the advantages and disadvantages of Mono phasic liquid dosage form. (5 marks)

Monophasic dosage form refers to liquid preparation containing two or more components in one phase system, it is represent by true solution. A true solution is a clear homogenous mixture that is prepared by dissolving solute in a suitable solvent.

The component of the solution which is present in a large quantity is known as “SOLVENT" where as the component present in small quantity is termed as "SOLUTE".

Advantages

It is easier to swallow, therefore easier for children and old age people.

Facilitate absorption of drug faster than solid dosage form as drug is already in solution form.

It is homogenous therefore give uniform dose than suspension or emulsion which need shaking.

Simple and fast to formulate

It can be administered by various routes :Oral, Parenteral (injection), enema for rectal use, otic(ear)

Disadvantages

They are bulky, so difficult to transport and store.

Water is commonly use vehicle, which is prone to microbial growth. So addition of preservative is needed.

When expose to direct sunlight it may undergo hydrolysis, so need to store in cool and dark place.

Drug stability reduce by hydrolysis or oxidation. So, they have shorter expire date than solid dosage form.

Other major sign of drug instability are color change, Precipitation, microbial growth etc.

2. Write the formula for Mandl's Paint?

MANDL'S Paint

Rx

Potassium Iodide	25g
iodine	12.5g
Alcohol	40ml
water	25ml
peppermint oil	4ml
glycerin	1000ml

Dissolve the Potassium iodide in water. Add the iodine & stir until completely dissolved. Dissolve peppermint oil in alcohol 90% in a small container & then transfer it into the iodine solution. Mix well. Add glycerin & mix thoroughly. Add more of glycerin to make the required volume. The preparation is to be stored in a cool place since iodine is volatile in nature.

3. Define Throat paint and give the direction for application of throat paint?

Throat paints are viscous liquid preparation used for mouth and throat infections. Glycerin is commonly used as a base because, being viscous, it adheres to mucous membrane for a long period and it possesses a sweet taste.

It is used for the treatment of laryngitis, pharyngitis, sore throat and tonsils. Dilute 1 ml to 20 ml or as per directions by the physician with water, gargle for 30 seconds, repeat 3 to 4 times a day. Dispensed in concentrated form with warm water. Make contact with the mucous membrane of the throat and let it sit there for few moments.

4. Define syrup and explain their method of preparation (5marks)

Syrups: Aqueous preparation of 60% to 80% sucrose with/without flavoring agents & medicinal substance.
The syrups may be divided into two groups

Syrups prepared by simple solution

Syrup I.P; Rx

sucrose	667g
purified water	1000g

Add sucrose to purified water & heat it to dissolve sucrose with occasional stirring. Cool it & makeup the volume with water.

Syrups made by a process of extraction

Tolu syrup I.P; Rx

Tolu balsam	12.5g
sucrose	660.0g
p.w	1000g

Add boiling p.w to the Tolu balsam contained in a tared vessel. Cover the vessel lightly & boil the contents gently for half an hour. Stirring frequently. Add p.w to adjust the specified weight. Cool ,filter the solution and add sucrose. Heat on a water bath to dissolve the sucrose. Finally add sufficient pw to produce the required volume.

5. What is gargle? Mention their ingredients. (2marks)

Gargles are aqueous solutions used to prevent or treat throat infections. They are usually available in concentrated form with direction for dilution with warm water before use. They are brought into intimate contact with the mucous membrane of the throat and are allowed to remain in contact with it for a few seconds, before they are thrown out of the mouth. They are used to relieve soreness in mild throat infection.

Phenol gargle:

Rx

Potassium chlorate	30.0 g
Patent blue V	0.009 g
Liquefied phenol	15.0 ml
Water sufficient	1000 ml

6. Define liniments and their ingredients with uses? (2marks)

Liniments: Liniments are liquid and semi liquid preparation meant for application to the skin. Liniments are usually applied to the skin with friction and rubbing of the skin. The liniments may be alcoholic or oily solution/ emulsion.

A liniments should not be applied to broken skin because it may cause excessive irritation.

Ammoniated camphor liniment; Rx

camphor	125g
eucalyptus oil	5ml
ammonia solution	250ml
alcohol	1000ml

Dissolve the camphor & eucalyptus oil in 600ml of alcohol 90%. Add the ammonia solution strong gradually with frequent shaking into it. Add sufficient alcohol 90% to produce the required volume.

7. What is mouthwash? Mention their ingredients. (2marks)

Mouth washes:

These are aqueous solution with a pleasant taste and odour used to make clean and deodorize the buccal cavity.

Generally they contain antibacterial agents, alchohols, glycerin, sweetening agent, flavoring agents and coloring agents.

Chlorohexidine Mouth wash

Rx

Chlorohexidine gluconate	0.12g
Brilliant blue	q.s
Sorbitol	3g
Ethanol	5ml
Pippermint water	1000ml

Biphasic liquids

1.What is an emulsion?

An emulsion is a mixture of more than one liquid that is generally immiscible due to liquid-liquid phase separation. It consists of two phases, i.e. dispersed phase and the dispersion medium.

2. What is an emulsifier?

An emulsifier is a substance that increases the emulsion's kinetic energy, thereby stabilizing it.

3. What are the types of emulsions?

An emulsion is an immiscible mixture of two or more liquids. We can classify it into two types.

1. Oil in Water emulsion

2. Water in Oil emulsion

4. How do emulsifier agents stabilize the emulsion?

An emulsifier increases the kinetic energy and decreases the interfacial tension between the liquids, forming an emulsion, thereby stabilizing it.

5. Give some examples of emulsions

Paint, egg yolk, butter, mayonnaise, and cream are some examples of emulsions.

6. What is water in oil emulsion?

Emulsion having water as a dispersed phase and oil as the dispersion medium is known as water in oil emulsion. Water acts as an internal phase, whereas oil acts as an external phase in this emulsion.

Example: Butter, cold cream.

7. What is oil in water emulsion?

Emulsion having oil as a dispersed phase and water as the dispersion medium is known as oil in water emulsion. The oil acts as an internal phase, whereas water acts as an external phase in this emulsion.

Example: Milk, egg yolk.

8. Explain the tests for identification of type of emulsions/ Define emulsions? Explain the various identification tests for emulsions?

Definition of Emulsions

An emulsion is a type of colloid formed by combining two liquids that normally do not mix. In an emulsion, one liquid (the dispersed phase) is dispersed in the form of tiny droplets within another liquid (the continuous phase). The two types of emulsions are:

Oil-in-water (O/W) emulsion: where oil droplets are dispersed in water (e.g., milk, mayonnaise).

Water-in-oil (W/O) emulsion: where water droplets are dispersed in oil (e.g., butter, cream).

Emulsions are typically stabilized by substances known as emulsifiers or surfactants, which help to reduce the surface tension between the two immiscible liquids, allowing for a more stable mixture.

Identification Tests for Emulsions

Several tests can be used to identify and characterize emulsions, particularly distinguishing between oil-in-water (O/W) and water-in-oil (W/O) emulsions:

Dilution Test:

Purpose: To determine the type of emulsion by observing its behavior upon dilution.

Procedure: Add water to a small amount of the emulsion. If the emulsion mixes smoothly with water, it is likely an oil-in-water (O/W) emulsion, indicating water is the continuous phase. If the emulsion does not mix well and appears to separate, it is likely a water-in-oil (W/O) emulsion, indicating oil is the continuous phase.

Dye Test:

Purpose: To visualize the continuous phase of the emulsion.

Procedure: Use a water-soluble dye (such as methylene blue) and add it to the emulsion. If the dye disperses evenly, the continuous phase is water, suggesting an oil-in-water (O/W) emulsion. If the dye forms beads or does not disperse well, the continuous phase is oil, indicating a water-in-oil (W/O) emulsion.

Conductivity Test:

Purpose: To determine the type of emulsion based on electrical conductivity.

Procedure: Apply a small voltage across the emulsion. If the emulsion conducts electricity, it is likely an oil-in-water (O/W) emulsion since water is a better conductor of electricity. If it does not conduct, it suggests a water-in-oil (W/O) emulsion.

9. Describe different types of emulsifying agent with example/ Write a brief note on Emulsifying agents.

Emulsifying Agents

Emulsifying agents, also known as emulsifiers, are substances used to stabilize emulsions by reducing the surface tension between two immiscible liquids such as oil and water. Emulsifiers are crucial in preventing the separation of these two phases and improving the stability and shelf-life of the emulsion. They work

forming a protective barrier around the dispersed droplets, which prevents them from coalescing or joining together.

Types of Emulsifying Agents

Emulsifying agents can be classified based on their molecular structure and source. Here are some of the main types:

1. **Natural Emulsifiers:**
   - **Plant Source:**
     - *Example:* Gum Acacia, Agar, Tragacanth, Starch
   - **Animal Source:**
     - *Example:* egg yolks and Gelatin.
2. **Synthetic Emulsifiers:**
   - **Anionic:** Sodium lauryl sulfate (SLS), used in shampoos and toothpastes.
   - **Cationic:**Cetrimonium chloride.
   - **Non Ionic***:* Polyoxyethylene (20) sorbitan monooleate (Tween 80), commonly used in food and cosmetics.
3. **Semi Synthetic Emulsifiers:** Methyl cellulose, Sodium Carboxy
4. **Inorganic Emulsifiers:** Milk of Magnesia
5. **Alcohols:** Cholesterol, Lecithin

Functions of Emulsifying Agents

Emulsifying agents serve multiple functions in a variety of products:

- **Stabilization:** They stabilize emulsions by preventing the coalescence of droplets.
- **Texture and Consistency:** Emulsifiers can influence the texture and viscosity of products, making creams smoother and dressings thicker.
- **Interfacial Tension Reduction:** They reduce the interfacial tension between the oil and water phases, facilitating the formation of finer emulsions.
- **Improvement of Shelf Life:** By maintaining the stability of an emulsion, emulsifiers extend the shelf life of products.

10. Explain different methods of preparation of emulsions/ explain the methods of preparation of emulsion. Add a note on stability of emulsions/ Write a note on different methods of preparation of emulsions and stability problems in emulsions.

Emulsions are mixtures of two immiscible liquids, such as oil and water, where one of the liquids is dispersed in the other in the form of tiny droplets.

Method of preparations are basically three types

1. Dry Gum Method:
   - The ratio of oil: water: Gum is 4:2:1
   - It requires Mortar and Pestle. First oil is mixed with Gum and triturated it.
   - Little amount of water is added and trituration continued till a clicking sound is heard and thick cream is formed.
   - Once primary emulsion is formed remaining water added to form the final emulsion.

2. Wet Gum Method:

   - The ratio of oil: water: Gum is 4:2:1
   - It requires Mortar and Pestle. First water is mixed with Gum and triturated it.
   - Little amount of oil is added and trituration continued till a clicking sound is heard and thick cream is formed.
   - Once primary emulsion is formed remaining water added to form the final emulsion.

3. Bottle Method:

   - The ratio of oil: water: Gum is 2:2:1
   - The method is basically used for volatile & viscous oils.
   - First oil is mixed with Gum and shaken thoroughly

- Required quantity of water is added and shaking continued to form a primary emulsion.
- Once primary emulsion is formed remaining water added to form the final emulsion.

Stability Problems in Emulsions

Emulsions can suffer from various stability issues, which can compromise the quality and functionality of the product. The major stability problems include:

1. **Creaming:** Separation of two layers/ phases of the emulsion. May occurs due to
   - Addition of wrong emulsifying agent.
   - Growth of micro organism
   - Change in Temperature
2. **Flocculation:** Creaming can be defined as upward or downward movement of disperse phase to form a thick layer at surface/ bottom of the emulsion
3. **Coalescence:**
   - This is the process where droplets merge to form larger droplets, which can eventually lead to the separation of the emulsion into its constituent liquids.
   - Coalescence is generally irreversible and detrimental to emulsion quality.

Phase Inversion:

4. This technique involves changing the phase volumes and/or temperature to invert the continuous phase and the dispersed phase. For instance, a water-in-oil emulsion (where water is the dispersed phase) might be inverted to an oil-in-water emulsion (where oil is the dispersed phase) by increasing the water phase's proportion or changing temperature.
5. Phase inversion is useful in processes where the final emulsion type is critical for product effectiveness.

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11. Write the ratio's for primary Emulsion for different oils.

General Ratio Guidelines for Primary Emulsions

In cosmetic and pharmaceutical formulations, the ratios can vary widely based on the desired viscosity, spread ability, and absorption characteristics. Here are some general starting points:

1. **For Light Oils (like sunflower, sweet almond, or grapeseed oil):**
   - **Oil-in-Water (O/W) Emulsion**: 20-40% oil, 60-80% water, 3-5% emulsifier
   - **Water-in-Oil (W/O) Emulsion**: 25-50% oil, 50-75% water, 4-10% emulsifier
2. **For Medium Viscosity Oils (like olive oil, sesame oil):**
   - **Oil-in-Water (O/W) Emulsion**: 30-50% oil, 50-70% water, 3-6% emulsifier
   - **Water-in-Oil (W/O) Emulsion**: 30-60% oil, 40-70% water, 5-10% emulsifier
3. **For Heavy Oils (like castor oil, mineral oil):**
   - **Oil-in-Water (O/W) Emulsion**: 10-30% oil, 70-90% water, 2-5% emulsifier
   - **Water-in-Oil (W/O) Emulsion**: 20-50% oil, 50-80% water, 5-10% emulsifier

Unit – IV

Suppositories

1. **Define Suppository, Discuss different method of Preparation.**

Suppositories are a form of medication designed for insertion into the rectum, vagina, or urethra, where they dissolve or melt.

They are used for various purposes, including the administration of drugs for local or systemic effects.

Method of preparation: The method of preparation for suppositories depends on the type and intended use, but the most common methods are the hand molding method, the compression method, and the fusion method.

- Hand rolling method
- Compression molding/ cold compression method
- Hot process/ fusion method

Hand rolling method: it is the oldest and simplest method of suppository preparation and may be used when only a few suppositories are to be prepared in a cocoa butter base.

- This method is less common and is typically used for small batches or compounding pharmacies. It involves manually shaping the suppository mixture (after mixing the drug with the melted base) in a special handheld mold.
- A plastic-like mass is prepared by triturating grated cocoa butter and active ingredients in a mortar.
- The mass is formed into a ball in the palm of the hands, then rolled into a uniform cylinder with a large spatula or small flat board on a pill tile.
- The cylinder is then cut into the appropriate number of pieces which are rolled on one end to produce a conical shape.

This method is simple and economical but it is very time consuming and rarely uses now-a-days.

Compression molding/ cold compression method: (Heating is not required)

- Onsmall scale it is prepared in mortar pestle but in large scale.
- It is prepared in compression machine.

- It's essential to maintain aseptic conditions throughout the process to prevent contamination.

- It is a method of preparing suppositories from a mixed mass of grated suppository base and medicaments which is forced into a special compression mold.

Hot process/ Fusion process:

- Involves first melting the suppository base, and then dispersing or dissolving the drug in the melted base.
- The mixture is removed from the heat and poured into a suppository mold.
- When the mixture has congealed, the suppositories are removed from the mold.
- The fusion method can be used with all types of suppositories and must be used with most of them.
- Suppositories are generally made from solid ingredients and drugs which are measured by weight. When they are mixed, melted, and poured into suppository mold cavities, they occupy a volume – the volume of the mold cavity. Since the components are measured by weight but compounded by volume, density calculations and mold calibrations are required to provide accurate doses.

2. Explain evaluation parameters of suppository

Aim to accesses their physical chemical and microbiological properties to ensure they meet quality standard and safe for patient use.

Uniformity of weight
Melting range
Test of appearance
Test of dissolution rate
Liquefaction/ softening test

Uniformity of weight:

- The suppository may vary in weight if the molds are non-uniformly filled. (Under filled/ over filled)
- Weight 20 suppository individually.
- Determine their average weight.

- Not more than two of individual weight should deviate from the average weight more than 5% and non-deviates by more than 10%

Melting range test:

- The physical properties and absorbing capacity of the suppository are examined by this test. There are three technique to determine the melting behavior
    - Open capillary tube method
    - U – Tube method
    - Drop point method
- All three have same principle, setting up the equipment then placing suppository unit to be tested in the apparatus and applying heat. Observing the changes a system undergoes.

Test of Appearance:

- The suppository when cut longitudinally and examined with naked eye, the internal & external surfaces of the suppository should uniform in appearance. The visually examined parameters of suppository are shape, surface, color, texture etc.

Disintegration/ Dissolution rate:

- The rate at which suppository dissolve is evaluated to ensure that the drug is released at a consistent rate.
- It takes the suppository to breakdown and disintegrate after insertion.
- It is important for patient comfort.

- Disintegration occurs is not more than 30 min for lipophilic and not more than 60 min for hydrophilic.

Liquefaction/ Softening:

- It consists of a U-Tube partially immersed in a constant temperature water bath.
- The suppository to be tested is placed in a constriction on one side of the tube.
- On the top of the suppository a glass rod is placed and the time it takes to cross the constriction is noted.
- This time is the softening time of the suppository.
- This test can be carried out as a quality control check temperature range 35.5ºC-37 ºC.

3. Define suppository, classify their types. What are the ideal suppository base?

Suppositories are a form of medication designed for insertion into the rectum, vagina, or urethra, where they dissolve or melt.
They are used for various purposes, including the administration of drugs for local or systemic effects.

Types of suppositories:

1. Rectal suppositories
2. Vaginal suppositories
3. Urethral suppositories
4. Nasal suppositories
5. Ear cone

Rectal suppositories are intended for placement into the rectum.

- They are often prepared from Theobroma oil (cocoa butter, a light yellow vegetable fat derived from cocoa beans).
- Suppositories for adults weigh 2 gm, whereas those for children weigh around 1 gm.
- They are usually cone or torpedo shaped.

Vaginal suppositories are intended for insertion into the vagina.

- They are sometimes referred to as pessaries.
- They are bigger than the rectal suppositories.

- They weigh between 3 and 5 grams and are molded into globular or oviform forms, or crushed into conical shapes using a tablet press.

- They are commonly used to treat vaginal infections

Urethral suppositories are supposed to be inserted into the urethra

- They're also known as bougies and pencil shapes.
- Male versions weigh 4 gm and are 100-150 mm long, while female versions weigh 2 gm and are 60-75 mm long.

Nasal suppositories are intended for placement into the nasal cavities.

- They are sometimes called nasal bougies.
- They are produced with a glycerogelatin base. They weigh around 1 gram and have a length of 9-10 cm.
- Nasal suppositories are thin, cylindrical in form.

Ear cones are meant for insertion into ears

- They are also known as aurinaries
- They are weigh about 1 gm
- They are cylindrical in shape

Suppository bases: Suppository bases are the foundational ingredients in suppository formulations that carry the active pharmaceutical ingredients.

- It should possess a less irritating property.
- They should be able to produce an inflamed sensation in body cavities like the vagina, urethra, etc.
- It should be stable during storage conditions. Changes in color, shape.
- They should be soft so that they can be handled easily
- It must be nonreactive with drugs and additives so that harmful reactions can be avoided

1.oily/fatty base

2. Water soluble base
3. Emulsifying base

4. **If a prescription required 500mg of tetracycline per suppository weigh 3g. Define Displacement value if 6 suppository with required tetracycline weigh 20.06g.**
    - Theoretical weight of total base = 6×3=18gm.
    - Practical weight of 6 medicated suppository = 20.06gm
    - Theoretical weight of total drug in medicated suppository = 6×500=2400mg=2.4gm
    - Theoretical weight of total medicated suppository = theoretical weight of total base + theoretical weight of total drug = 18+ 2.4 =20.04gm
    - Difference between practical weight of suppository and theoretical weight of suppository = 20.06-20.04 = 0.02gm
    - DV = Theoretical weight of total drug in medicated suppository/ difference between practical weight of suppository and theoretical weight of suppository
      = 2.4/0.02 = 120
5. **10 ciprofloxacin hydrochloride suppository contain 600mg of drug weigh 35g. The mold of suppository used was 1gm.**
    - Theoretical weight of total base = 10×1=10gm.
    - Practical weight of 10 medicated suppository = 35gm
    - Theoretical weight of total drug in medicated suppository = 10×600=6000mg=6gm
    - Theoretical weight of total medicated suppository = theoretical weight of total base + theoretical weight of total drug = 10+ 6 =16gm
        - Difference between practical weight of suppository and theoretical weight of suppository = 35-16 = 19gm
    - DV = Theoretical weight of total drug in medicated suppository/ difference between practical weight of suppository and theoretical weight of suppository = 6/19=0.315gm
6. **If 6 theobroma oil suppository contain 40% ZnO weigh 20g. (Suppose suppository made in 1g mold)**
    - Theoretical weight of total base = 6×1=6gm.
    - Practical weight of 6 medicated suppository = 20gm

- Theoretical weight of total drug in medicated suppository

- = 40/100×20 = 8gm
- Theoretical weight of total medicated suppository = theoretical weight of total base + theoretical weight of total drug = 6+ 8 =14gm
- Difference between practical weight of suppository and theoretical weight of suppository = 20-14 = 6gm
- DV = Theoretical weight of total drug in medicated suppository/ difference between practical weight of suppository and theoretical weight of suppository = 8/6 = 1.33

7. **What would be the displacement value of hydrocortisone acetate if it is known that six suppository containing 200mg each of the drug weigh 16.18g.**
   - Theoretical weight of total base = 6×1=6gm.
   - Practical weight of 6 medicated suppository = 16.18gm
   - Theoretical weight of total drug in medicated suppository
     - = 200 ×6 = 1.2gm
     - Theoretical weight of total medicated suppository = theoretical weight of total base + theoretical weight of total drug = 6+ 1.2 =7.2gm
     - Difference between practical weight of suppository and theoretical weight of suppository = 16.18-7.2 = 8.98gm
     - DV = Theoretical weight of total drug in medicated suppository/ difference between practical weight of suppository and theoretical weight of suppository = 1.2/8.98 = 0.133
8. **Pessaries is another term for ear cone (True/False)**
   False
9. **What are the merits and demerits of suppository**
   Advantages:
   - It can be utilized with unconscious patients.
   - It's a compact dose form.

- They have lower risks of side effects.
- It can be used to treat people who have severe nausea and vomiting.
- Suppositories are appropriate for youngsters and elderly individuals who are unable to swallow pills.
- They can be used to prevent rectal and vaginal infections.

Disadvantages:

- Patient acceptance issues include suppositories not being appropriate for people with diarrhea.
- In rare situations, administering a large dose of a medicine may cause irritation or exceed the capacity of a suppository.
- They must be stored at low temperature otherwise they will get melt

10. How softening time of a suppository can be calculated?

- It consists of a U-Tube partially immersed in a constant temperature water bath.
- The suppository to be tested is placed in a constriction on one side of the tube.
- On the top of the suppository a glass rod is placed and the time it takes to cross the constriction is noted.
- This time is the softening time of the suppository.
- This test can be carried out as a quality control check temperature range 35.5ºC-37 ºC.

11. What is displacement value?

Displacement value can be defined as the volume of drug that displace 1gm of suppository base.

12. What are the types of suppository base, discuss it with example

1. oily/fatty base
2. water soluble base
3. emulsifying base

Cocoa Butter (Theobroma Oil): The most common traditional base, it melts at body temperature. It is derived from the roasted seeds of Theobroma cacao. It is yellowish white in appearance, with a chocolatey smell and a butter-like consistency. It is a combination of fatty acids.

M.P. = 30-35ºC

More suitable for rectal suppositories.

Emulsified theobroma oil: less sticky in nature.large quantity of aqueous solution are used basically. composed of 5% glyceryl monostearate, 10%lanette wax, 2-3% cetyl alcohol,4% bees wax, 12% spermaceti.
Emulsifying base:mainly contain witepsol (consists of triglyceride fatty acids, non irritant), massaeastarinum(mix of mono,di,tri glycerides of fatty acids)
Combination Bases: Combination bases are composed of a combination of fatty and water-soluble components.

13. **Ear cone is also known as ……..?**
    Aurinaries

14. **Cocoa butter is derived from ……..?**
    Cocoa Beans

Pharmaceutical incompatibilities

1. **Describe physical Incompatibility and how to overcome them/ Define and classify incompatibility. Explain physical incompatibility and methods to overcome physical incompatibility with examples.**

It is the result of prescribing/mixing two/more substance which are antagonist in nature and an undesirable product is formed which may affect the safety, purpose or appearance of the preparation.

It can occur between different drugs, drug components, excipients or drug delivery systems.

These incompatibilities can lead to adverse effect on the patients such as reduced therapeutic efficacy increased toxicity or physical instability of the dosage form.

Types of incompatibility: Physical Incompatibility, chemical incompatibility, therapeutic incompatibility.

Incompatibility may occur during compounding, formulation, manufacturing, packaging, dispensing, storage, administration.

Incompatibility can affect safety of medicament, efficacy of product, appearance of medicine, purpose of medicament.

Physical Incompatibility: when two /more than two substances are combined together and a physical changes takes place which result in the formation of an unacceptable product then this phenomenon is known as physical incompatibility.

Correction of physical incompatibility:

- Changing the order of mixing
- Emulsification
- Addition of suspending agent
- Addition/substitution of a therapeutically inactive substances.

- **Precipitation**: Insoluble complexes are formed when drugs are mixed, visible as particles or sediments.
- **Turbidity**: Cloudiness or a reduction in clarity upon mixing.
- **Color Change**: An interaction may cause a visible color change due to chemical structure modifications.
- **Phase Separation**: Unmixable layers forming in a solution, often observed with emulsions or suspensions.

Overcoming Physical Incompatibility
Physical incompatibility can be overcome or prevented through various methods:

1. **Compatibility Studies**: Before mixing drugs, it is important to consult compatibility charts, literature, or databases that provide information on the compatibility of various drugs when mixed together. This is often based on rigorous scientific testing.
2. **Physical Modification**: Adjusting the physical properties of the solution such as pH, ionic strength, or using solvents that can enhance the solubility of the drugs might prevent precipitations or phase separations.

3. **Use of Stabilizers or Surfactants**: Adding substances that stabilize the formulation can help maintain homogeneity and prevent interactions. For example, surfactants can help stabilize emulsions, preventing phase separation.

4. **Sequential Administration**: Instead of mixing drugs together, administering them separately or flushing the system (e.g., intravenous line) between administrations can prevent physical interactions.
5. **Alternative Formulations**: If incompatibility arises from a specific form of a drug, using a different formulation (e.g., switching from a solution to a tablet or a different salt or ester of the drug) may resolve the issue.

Examples

- **Calcium and Phosphate**: When solutions containing calcium ions are mixed with those containing phosphate ions, a white precipitate of calcium phosphate may form. This can be prevented by careful manipulation of the concentrations or by administering the drugs at different times.
- **Heparin and Hydrocortisone**: These two drugs can form a precipitate when mixed directly in the same syringe or IV line. The administration should be separated temporally or flushed with a neutral solution such as saline between administrations.

2. Define chemical incompatibility. Give two examples.

Chemical incompatibility refers to a situation where two or more chemical substances react with each other in a formulation, leading to undesirable outcomes such as degradation of the active ingredients, reduction in drug potency, formation of toxic by-products, or physical changes like precipitation or color change. These reactions can occur due to the interaction between active pharmaceutical ingredients (APIs) themselves or between APIs and excipients.

Examples of Chemical Incompatibility

1. **Ascorbic Acid and Riboflavin**:
   - **Situation**: When ascorbic acid (vitamin C) and riboflavin (vitamin B2) are combined in a solution, they can interact, especially in the presence of light.
   - **Reaction**: The reaction leads to the degradation of riboflavin, catalyzed by light and the reducing power of ascorbic acid.

- **Outcome**: This results in a decrease in the effectiveness of riboflavin within the formulation, which can be observed as a loss of the characteristic yellow color of riboflavin, turning the solution colorless.

2. **Aminophylline and Ciprofloxacin**:

- **Situation**: When aminophylline (a bronchodilator) and ciprofloxacin (an antibiotic) are mixed in an intravenous solution.
- **Reaction**: Ciprofloxacin can cause the precipitation of aminophylline due to the complexation and pH-dependent solubility changes.
- **Outcome**: The precipitation reduces the bioavailability of aminophylline, potentially leading to therapeutic failure or the risk of local irritation and phlebitis where the IV is administered.

3. Describe methods to overcome physical and chemical incompatibility with examples.

Overcoming physical and chemical incompatibilities in pharmaceutical formulations is crucial to ensure the stability, efficacy, and safety of medications. Here are some strategies to address these incompatibilities, along with practical examples:

Methods to Overcome Physical Incompatibility

Physical incompatibility typically involves issues like precipitation, phase separation, or changes in color or texture that occur without chemical changes in the substance.

6. **Compatibility Studies**: Before mixing drugs, it is important to consult compatibility charts, literature, or databases that provide information on the compatibility of various drugs when mixed together. This is often based on rigorous scientific testing.
7. **Physical Modification**: Adjusting the physical properties of the solution such as pH, ionic strength, or using solvents that can enhance the solubility of the drugs might prevent precipitations or phase separations.
8. **Use of Stabilizers or Surfactants**: Adding substances that stabilize the formulation can help maintain homogeneity and prevent interactions. For example, surfactants can help stabilize emulsions, preventing phase separation.

9. **Sequential Administration**: Instead of mixing drugs together, administering them separately or flushing the system (e.g., intravenous line) between administrations can prevent physical interactions.
10. **Alternative Formulations**: If incompatibility arises from a specific form of a drug, using a different formulation (e.g., switching from a solution to a tablet or a different salt or ester of the drug) may resolve the issue.

Examples

Calcium and Phosphate: When solutions containing calcium ions are mixed with those containing phosphate ions, a white precipitate of calcium phosphate may form. This can be prevented by careful manipulation of the concentrations or by administering the drugs at different times.

Methods to Overcome Chemical Incompatibility

Chemical incompatibility occurs when substances react chemically, leading to degradation or the formation of new, potentially harmful compounds.

Use of Antioxidants:

- **Strategy**: Add antioxidants to prevent oxidation reactions, which can degrade active substances.
- **Example**: Incorporating ascorbic acid or tocopherols in formulations containing easily oxidizable drugs like epinephrine to prevent its degradation
    - **Buffering Agents**:
        - **Strategy**: Utilize buffers to maintain a consistent pH, minimizing the risk of hydrolysis or other pH-sensitive reactions.
        - **Example**: Incorporating a buffer system in a lidocaine injection solution to maintain a stable pH and prevent the degradation of lidocaine through hydrolysis.
    - **Physical Separation**:
        - **Strategy**: Formulate products in a way that physically separates incompatible substances until the point of administration.
        - **Example**: Multilayer tablets where one layer contains an acid-sensitive drug and another contains an acid, separated by an inert layer to prevent interaction until after ingestion.

Tolerated: Thee reaction may minimized by applying some sutable order of mixing the solution in diluted form but no alteration is made in API of preparation.

Adjusted: The reaction is prevented by addition one of the reacting substance with another of equal therapeutic value but dosenot affect the medicinal of the preparation.

4. Define and classify in compatibility. Explain chemical incompatibility with examples.

If two/more ingredient are mixed then chemical reaction will be occurs due to their chemical properties. It will formation of a toxic/ inactive dosage form.

Immediate chemical incompatibility and Delayed chemical incompatibility

Chemical incompatibility often occur due to oxidation reduction, Acid base hydrolysis, PH change of solution.

These reaction can be noticed by precipitation, decomposition, colour change, explosion.

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5. Explain the term tolerated and adjusted incompatibilities.

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6. Define therapeutic incompatibility. Explain the terms potentiation and synergism/ Explain therapeutic incompatibility

Therapeutic incompatibility refers to a situation where the combined effects of two or more drugs are less favorable than their effects when administered separately. This could manifest as reduced effectiveness of one or both drugs or increased risk of side effects and adverse reactions. Such incompatibilities are crucial to consider in drug therapy, as they can significantly impact patient safety and treatment outcomes.

Potentiation

Potentiation occurs when one drug enhances the effect of another drug, but this effect is beyond a mere additive effect. In potentiation, the presence of the potentiating drug increases the efficacy or toxicity of another drug without showing much (if any) effect when given alone. This interaction can be beneficial or harmful depending on the context and the drugs involved.

Example:

- **Alcohol and Benzodiazepines**: Alcohol can potentiate the sedative effects of benzodiazepines, leading to enhanced central nervous system depression. Although alcohol has its own CNS depressant effects, when combined with benzodiazepines, the resultant sedation and respiratory depression can be more severe than the sum of the effects when each is used alone.

Synergism

Synergism refers to a situation where two or more drugs interact in a way that their combined effects are greater than the sum of their individual effects. This can be particularly useful in treatment strategies where a synergistic combination allows for lower dosages of each drug, potentially reducing side effects while maximizing therapeutic benefits.

Example:

- **Antibiotics like Amoxicillin and Clavulanic Acid**: Clavulanic acid inhibits beta-lactamase, an enzyme produced by bacteria that can degrade and inactivate amoxicillin. By inhibiting this enzyme, clavulanic acid effectively increases the efficacy of amoxicillin against beta-lactamase producing bacteria, leading to a synergistic antibacterial effect.

Both potentiation and synergism are forms of drug interactions that can have significant therapeutic implications. Understanding these interactions helps in designing optimal drug regimens, particularly in complex therapies involving multiple medications, such as in treating chronic diseases, infections, or cancer. These concepts are fundamental in clinical pharmacology and are critical for ensuring safe and effective drug therapy.

7. Give an example for insolubility in a formula and how to overcome it.

A suspending agent is required to uniform distribution of the solids in the liquid phase for sufficiently long time so as to facillate accurate measurement of dose.

Insolubility takes place when a drug is insoluble in a particular solvent

Eg: Ephedrine sulphate 0.25g

Methanol 0.2ml.

Liquid paraffin 30ml

Now in the above prescription ephedrine sulphate is not soluble in liquid paraffin. But anhydrous ephedrine is soluble in it. Hence ephedrine sulphate is substituted with anhydrous ephedrine in the above prescription to make a clear solution.

8. Identify the type of incompatibility in the given prescription. Rx Menthol – 5 gm, Camphor – 5 gm, Thymol – 5 gm, Make an insufflations powder

The prescription you provided involves Menthol, Camphor, and Thymol to be compounded into an insufflation powder. Each of these ingredients has unique properties that must be considered when compounding them together

To identify the type of incompatibility in this prescription, we consider the physical and chemical properties of the components:

1. **Menthol**: Solid at room temperature, menthol melts at around 31-36°C and sublimes at room temperature. It has a cooling effect and is used in pharmaceutical formulations for its sensory properties.
2. **Camphor**: Also solid at room temperature, camphor has a melting point around 175°C and sublimes at room temperatures. It is used for its aromatic and cooling effects.

3. **Thymol**: Another crystalline substance that is solid at room temperature with a melting point around 49-51°C. It is used for its antiseptic properties and strong aroma.

Type of Incompatibility: The primary concern in this prescription is a physical incompatibility related to the different physical states and properties of the ingredients, particularly concerning their tendency to sublime. Sublimation can affect the stability and consistency of the powder mixture. When a substance sublimes, it transitions directly from a solid to a gas at temperatures below its melting point. Both menthol and camphor are prone to sublimation at room temperature, which can lead to a decrease in their concentration in the powder over time, affecting the potency and consistency of the dose.

Moreover, there can be difficulties in ensuring a uniform and stable mixture due to the different particle sizes and the crystalline nature of the components. This could result in segregation of particles, with some components possibly clumping together.

Solutions:

- To address these issues, consider encapsulating the volatile substances (menthol and camphor) to prevent sublimation.
- Utilizing a suitable excipient that can adsorb or somehow bind the volatile components might also be helpful.
- Ensuring very fine and uniform particle size through meticulous milling and mixing during the compounding process can help achieve a more stable and homogeneous product.

In conclusion, the prescription you have involves a **physical incompatibility** due to the tendency of ingredients to sublime, which could lead to a reduction in efficacy and dose inconsistency. Addressing this through careful formulation and processing techniques is crucial for ensuring the quality and effectiveness of the final product.

9. Identify the type of incompatibility in the following prescription and add a note on how to overcome the incompatibility. Rx Ferric chloride solution-2ml, Sodium salicylate-4g, Water up to 90ml.

The prescription you've described involves combining Ferric Chloride solution and Sodium Salicylate in water. To determine the type of incompatibility present in this formulation, we need to consider the chemical properties and interactions of the components involved.

Ferric Chloride (FeCl3) is an ionic compound, typically used in pharmaceutical formulations as an astringent or for its hemostatic properties. When dissolved in water, Ferric Chloride dissociates into Ferric ions (Fe^{3+}) and Chloride ions (Cl^-).

Sodium Salicylate is a sodium salt of salicylic acid, which is often used for its anti-inflammatory, analgesic, and antipyretic properties. When dissolved in water, Sodium Salicylate dissociates into Sodium ions (Na^+) and Salicylate ions.

Type of Incompatibility: The incompatibility in this prescription is primarily **chemical incompatibility**. When Ferric Chloride solution is mixed with Sodium Salicylate, a chemical reaction occurs between the Ferric ions (Fe^{3+}) and the Salicylate ions. This reaction results in the formation of an insoluble complex or precipitate, Ferric Salicylate. This precipitate can decrease the effectiveness of the drug, alter the intended dosage, and lead to stability issues in the solution.

Solution to Overcome Incompatibility: To overcome this incompatibility, consider the following approaches:

1. **Separate Administration**: Avoid combining these two substances in the same solution. If both medications are required for treatment, administer them separately to avoid direct interaction and ensure that each retains its therapeutic efficacy.
2. **Formulation Adjustment**: If it is necessary to use both in the same therapeutic regimen, consider stabilizing the formulation by adjusting the pH, using a different salt of iron, or modifying the salicylate used. These adjustments might prevent or reduce the formation of the precipitate.

1. **Use of Chelating Agents**: Consider incorporating a chelating agent that can bind to Ferric ions more strongly than salicylate, preventing the reaction with the Sodium Salicylate. However, this approach should be carefully evaluated as it might affect the bioavailability of the iron.
2. **Physical Barriers**: In some formulations, encapsulating one of the components (e.g., microencapsulation) could prevent direct interaction, although this is more common in solid dosage forms than in solutions.

In summary, the prescription you provided exhibits a chemical incompatibility leading to the formation of an insoluble precipitate when Ferric Chloride and Sodium Salicylate are combined. It is advisable to administer these compounds separately or to reformulate the preparation to prevent this interaction and ensure the effectiveness and safety of the treatment.

Semi Solid Dosage form

Write Notes on pastes.[5]

Definition: Pastes are semi-solid preparations consisting of finely powdered solids dispersed in a fatty or aqueous base.

Composition: They are composed of a large proportion of finely powdered solids (usually >20%) dispersed in a base such as petrolatum, water, or glycerin**.**

Uses:

Protective: Used to protect the skin from irritants or moisture.

Absorbent: Used to absorb exudates from wounds or skin lesions.

Astringent: Used to promote healing by causing contraction of tissues.

Antiseptic: Used to prevent infection in minor cuts and wounds.

Preparation: Pastes are usually prepared by triturating the powdered solids with the base until a smooth, homogenous mixture is obtained. Sometimes, heat may be applied to facilitate mixing.

Examples:

Zinc oxide paste: Used for diaper rash, minor skin irritations, and as a sunblock.

Glycerin paste: Used as a protective and emollient agent for chapped skin.

Calamine paste: Used to relieve itching and discomfort from minor skin conditions.

Advantages:

Provide a protective barrier.

Can be used to deliver medications topically.

Can be formulated to provide specific properties such as absorbency or astringency.

Disadvantages:

Can be messy to apply.

May be greasy or sticky.

Some formulations may stain clothing or be difficult to remove.

Overall, pastes are versatile semi-solid dosage forms that can be used for a variety of skin conditions due to their protective and therapeutic properties.

Differentiate between Cold cream& vanishing cream. [5]

Cold cream	Vanishing cream
It is w/o type of emulsion	It is o/w type of emulsion
Emollient and moisturizing cream	Used as foundation cream
Typically used to cleanse the face off makeup	Used as adhesive for makeup powders
Heavily moisturizes dry skin	Reduces loss of moisture from dry skin
It can also be used as a balm for dry cracked lips	Smoothens the skin and keeps its soft
It can also be used as a shaving cream alternative for men.	Prevents skin from roughening and chapping.

Describe each ointment base in detail.

Ans: Hydrocarbon Bases:

Composition: These bases are composed of hydrocarbons, such as petrolatum (petroleum jelly), which is a purified mixture of semisolid hydrocarbons obtained from petroleum.

Properties: Hydrocarbon bases are inert, stable, and non-reactive. They are greasy, providing a good barrier against moisture loss and external irritants.

Examples: White petrolatum, Yellow petrolatum.

Advantages: Simple, stable, and non-irritating. They have good emollient properties.

Disadvantages: Lack of absorption, can be greasy and occlusive.

Absorption Bases:

Composition: These bases contain anhydrous lanolin, which is a purified form of wool wax obtained from sheep's wool, along with other ingredients such as mineral oil and water.

Properties: Absorption bases can absorb water and aqueous solutions, allowing for the incorporation of medications that are not soluble in oils.

Examples: Anhydrous lanolin, Aquaphor.

Advantages: Emollient, absorb water, and allow incorporation of aqueous solutions.

Disadvantages: Can cause sensitization, not suitable for water-in-oil emulsions.

Water-Removable Bases (O/W Emulsions):

Composition: These bases are oil-in-water emulsions, meaning they contain water as the continuous phase and oil as the dispersed phase, along with emulsifying agents.

Properties: Water-removable bases are non-greasy and easily washable. They are compatible with aqueous solutions.

Examples: Hydrophilic ointment, Cold cream.

Advantages: Non-greasy, easily washable, compatible with aqueous solutions.

Disadvantages: Less occlusive, can cause irritation in some individuals.

Water-Soluble Bases:

Composition: These bases are made of water-soluble substances such as polyethylene glycols (PEGs) and glycerin.

Properties: Water-soluble bases are water-washable and non-greasy. They can incorporate large amounts of aqueous solutions.

Examples: Polyethylene glycol ointment, GlycoLax.

Advantages: Water-washable, non-greasy, can incorporate large amounts of aqueous solutions.

Disadvantages: Can be drying, not suitable for lipophilic drugs.

Oleaginous Bases:

Composition: These bases are primarily composed of hydrocarbons or triglycerides, such as mineral oil, vegetable oils, or waxes.

Properties: Oleaginous bases are greasy and occlusive, providing a good barrier against moisture loss.

Examples: White ointment, Yellow ointment.

Advantages: Good emollient properties, occlusive.

Disadvantages: Can be greasy, may stain clothing, can block pores.

4.What are paste? Discuss in brief different bases used in the Preparation of paste.

Ans:

Paste is a type of semisolid dosage form that is thicker and more viscous than ointments.

It is made by incorporating a large proportion of finely powdered solids into a suitable base, such as petrolatum, water, glycerin, or a combination of these.

Pastes are used for their protective, absorbent, and astringent properties and can be used to deliver medications topically.

They are often used to protect the skin, absorb exudates from wounds, or provide a barrier against moisture loss.

Pastes are typically applied in a thick layer to the affected area and are especially useful for conditions where a longer contact time is desired.

Three types of bases are used for the preparation of pastes.

1. **Hydrocarbon base**

A mixture of Soft paraffin and liquid paraffin are used. (e.g., zinc oxide paste, Aluminium paste compound)

2. **Water miscible base**

Emulsifying ointment bases are used.e.g. Resorcinol & sulfur paste

3. **Water-soluble base/macrogels**

Water-soluble bases are prepared from mixtures of high and low-molecular-weight polyethylene glycols (or macrogels).

PEG (mixture of high & low Mw Polyethylene glycols to get desired consistency) find more…

e.g. dental paste containing neomycin sulfate, Triamcinolone Dental paste B.P.C

5.Differentiate between the following (Any three)[5×3]

(i)Ointment and paste

Difference between paste and ointment	
Paste	**Ointment**
It is water-based	It is oil-based
Contain a large amount of finely powdered solids	Contain less amount of finely powdered solids
Less greasy than ointment	Greasy than paste
Stiff and thick	Soft
More viscous than ointments	Less viscous than pastes
Less penetrating than ointments	More penetrating than pastes
Slowly absorbed	Rapidly absorbed
Does not spread more easily	More easily spread on the skin

(ii) Ointment and cream

Difference between cream and ointment	
Cream	**Ointment**
Water-based semisolid preparation	Oil-based semisolid preparation
Contains 50% oil and 50% water	Contains 80% oil and 20% water
Non-greasy, rich, and heavy	Greasy, smooth and soften
Thick liquid preparation	Soft semisolid preparations
White to off-white in color	Usually translucent
Thicker consistency	Thinner consistency
Easily spreadable	Less spreadable
Rapidly absorbed	Slower absorbed
Rapid onset of action	Slow onset of action
Easily washed off	Not easily washed off

B. Very short Answer type Question (3marks)

(i)Name the various bases used for paste.

Three types of bases are used for the preparation of pastes.

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Water-soluble bases are prepared from mixtures of high and low-molecular-weight polyethylene glycols (or macrogels).

PEG (mixture of high & low Mw Polyethylene glycols to get desired consistency) find more…

e.g. dental paste containing neomycin sulfate, Triamcinolone Dental paste B.P.C

(ii)Define keratolytic ointment.

- **Ans;** Keratolytic ointment is a type of topical medication used to soften and exfoliate the outer layer of the skin (epidermis).
- It contains ingredients that help break down and remove dead skin cells, keratin, and other debris from the surface of the skin. This process is known as keratolysis.
- Keratolytic ointments are commonly used to treat various skin conditions, such as dry, rough, or scaly skin, calluses, corns, and warts.
- They can also be used to improve the penetration of other medications into the skin. Examples of keratolytic agents include salicylic acid, urea, and alpha hydroxy acids.

(iv)Ointment Classification based on penetration.

Ans: Epidermic ointments

- These ointments are intended to produce their action on the surface of the skin and produce local effect.
- They are not absorbed.
- They act as protective, antiseptic and parasiticide.

(b) Endodermic ointments

- These ointments are meant for action on deeper layers of cutaneous layer. They are partially absorbed and acts as emollients, stimulants and local irritants.

(c) Diadermic ointments

- These ointments are intended to release the medicaments that pass through the skin and produce systemic effects.

6. **Define Ointment. briefly the various methods involved in The Preparation of ointment. (5 marks).** 10 marks

Ans :An ointment is a semisolid preparation that is applied to the skin or mucous membranes for medicinal or protective purposes. It consists of a base, which can be an oil, water, or a combination of both, and may contain one or more active pharmaceutical ingredients (APIs).

Ointments prepared by Fusion method:

When an ointment base contain a number of solid ingredients such as white beeswax, cetyl alcohol, stearyl alcohol, stearic acid, hard paraffin, etc. as components of the base, it is required to melted them. The melting can be done in two methods:

Method-I

The components are melted in the decreasing order of their melting point i.e. the higher m.p. substance should be melted first, the substances with next melting point and so on. The medicament is added slowly in the melted ingredients and stirred thoroughly until the mass cools down and homogeneous product is formed.

Advantages:

This will avoid over-heating of substances having low melting point.

Method-II

All the components are taken in subdivided state and melted together.

Advantages:

The maximum temperature reached is lower than Method-I, and less time was taken possibly due to the solvent action of the lower melting point substances on the rest of the ingredients.

Example:

(i) Simple ointment B.P. contains

Wool fat	50g
Hard paraffin	50g
Cetostearyl alcohol	50g
White soft paraffin	850g

Type of preparation: Absorption ointment base

OINTMENT PREPARED BY TRITURATION

This method is applicable in the base or a liquid present in small amount.

(i) Solids are finely powdered are passed through a sieve (# 250, # 180, #125).

(ii) The powder is taken on an ointment-slab and triturated with a small amount of the base. A steel spatula with long, broad blade is used. To this additional quantities of the base are incorporated and triturated until the medicament is mixed with the base.

(iii) Finally liquid ingredients are incorporated. To avoid loss from splashing, a small volume of liquid is poured into a depression in the ointment an thoroughly incorporated before more is added in the same way. Splashing is more easily controlled in a mortar than on a tile.

Example:

(i) Whitfield ointment (Compound benzoic acid ointment B.P.C.)

Formula: Benzoic acid, in fine powder	6gm
Salicylic acid, in fine powder	3gm
Emulsifying ointment	91gm

Method: Benzoic acid and salicylic acid are sieved through No. 180 sieves. They are mixed on the tile with small amount of base and levigated until smooth and dilute gradually.

(ii) Salicylic acid sulphur ointment B.P.C.

OINTMENT PREPARATION BY CHEMICAL REACTION

Chemical reactions were involved in the preparation of several famous ointments of the past, e.g. Strong Mercuric Nitrate Ointment, Example: Non-staining Iodine Ointment B.P.C.

formula :
Iodine
Arachis Oil
Yellow Soft Paraffin
Method:
(a) Iodine is finely powdered in a glass mortar and required amount is added to the oil in a glass-stoppered conical flask and stirred well.
(b) The oil is heated at 500C in a water-bath and stirred continually. Heating is continued until the brown color is changed to greenish-black; this may take several hours.
(c) From 0.1g of the preparation the amount of iodine is determined by B.P.C. method and the amount of soft paraffin base is calculated to give the product the required strength.
(d) Soft paraffin is warmed to 400C. The iodized oil is added and mixed well. No more heat is applied because this causes deposition of a resinous substance.
(e) The preparation is packed in a warm, wide-mouthed, amber color, glass bottle. It is allowed to cool without further stirring.

PREPARATION OF OINTMENTS BY EMULSIFICATION

An emulsion system contain an oil phase, an aqueous phase and an emulsifying agent.
For o/w emulsion systems the following emulsifying agents are used:
(i) water soluble soap
(ii) cetyl alcohol
(iii)glyceryl monostearate
(iv) combination of emulsifiers: triethanolamine stearate + cetyl alcohol
(v) non-ionic emulsifiers: glyceryl monostearate, glyceryl monooelate, propylene glycol stearate
For w/o emulsion creams the following emulsifiers are used:
(i) polyvalent ions e.g magnesium, calcium and aluminium are used.
(ii) combination of emulsifiers: beeswax + divalent calcium ion
The viscosity of this type of creams prevent coalescence of the emulsified phases and helps in stabilizing the emulsion.
Example:
Cold cream:
Procedure:
(i) Water immiscible components e.g. oils, fats, waxes are melted together over water bath (700C).
(ii) Aqueous solution of all heat stable, water soluble components are heated (700C).

(iii) Aqueous solution is slowly added to the melted bases with continuous stirring until the product cools down and a semi-solid mass is obtained.
N.B. The aqueous phase is heated otherwise high melting point fats and waxes will immediately solidify on addition of cold aqueous solution.

2. Write a note on factors affecting dermal penetration of drug. (10 marks)

The dermal penetration of drugs refer to the absorption of medications through the skin and into the systemic circulation**.**

These factors are mainly categorised into two major headings:

a) **Biological factor**
b) **Physiochemical factor**

A) Biological factor:

1. Skin condition

- The intact, healthy skin is a tough barrier but acids and alkali injure barrier cells and thereby promote penetration.
- Mixtures of non-polar and polar solvents, such as chloroform and methanol, remove the lipid fraction and molecules pass more easily.
- Disease alters skin condition, skin inflamed, with loss of stratum corneum thus permeability increases.
- If organ thickened, with corns, calluses and warts, drug permeation decreases.

2. Skin age

- Skin of the young and the elderly is more permeable than adult tissue.
- Children are more susceptible to the toxic effects of drugs and chemicals, because of their greater surface area per unit body weight; thus potent topical steroids, Causes severe side-effects and death.

3.Blood flow:

- An increased blood flow could reduce the amount of time a penetrant remains in the dermis, and also raise the concentration gradient across the skin.
- In clinically hyperaemic disease damages the skin barrier and increase absorption.

4. Regional skin sites:

- Variations in permeability depend on the thickness and nature ofthe stratum corneum and the density of skin appendages.
- Facial skin in general is more permeable than other body sites

5. Skin metabolism:

- The skin metabolizes steroid hormones, chemical carcinogens and some drugs.
- This is advantage to prodrugs.
- Skin can metabolize 5% of topical drugs.

7. Species differences:

- Mice, rats and rabbits are used to assess percutaneous absorption, but their skins have more hair follicles than human skin and they lack sweat glands.
- Hairless mouse, monkey and pig skins are most like that of humans.

Physicochemical factors

1. Skin hydration:

- When water saturates the skin the tissue swells, softens and wrinkles and hydration of the stratum corneum increases permeability.
- Dusting powders or lotions, provide a large surface area for evaporation and therefore dry the skin

3. Temperature and pH:

- The penetration rate of material through human skin can change tenfold for a large temperature variation.
- Occlusive vehicles increase skin temperature and increase permeability.
- According to pH-partition hypothesis, only unionized molecules pass readily across lipid membranes.
- Weak acids and bases dissociate to different degrees, depending on the pH and their PKa or Pkb values.
- Stratum corneum is resistant to alterations in pH, range of 3-9.

3. Diffusion coefficient:

- The diffusional speed of a molecule depends mainly on the state of matter of the medium.
- In gases, diffusion coefficients are large than liquids
- In skin, the diffusivities reach their lowest values within the compacted stratum corneum matrix.
- The diffusion coefficient of a drug in a topical vehicle depends on the properties of the drug and the diffusion medium and on the interaction between them.

6. Drug concentration:

- The drug penetration depends upon the concentration gradient.

- Concentration gradient will be higher if concentration of drug will be more across the barrier.

7. Molecular size and shape:

- Absorption is apparently inversely related to molecular weight.
- Small molecules penetrate faster than large ones.
- It is more difficult to determine the effect of molecular shape, as it is related to partition coefficient.