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PHARMACEUTICS – I

UNIT 3

TOPIC :

- **Emulsions :** Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome

Emulsion

→ An emulsion is a biphasic liquid dosage form consisting of two immiscible liquids, where one liquid is dispersed as fine droplets within the other, and stabilized by an emulsifying agent.
→ The dispersed liquid is called the internal phase.
→ The liquid in which it is dispersed is the external or continuous phase.
→ An emulsifying agent is used to prevent separation and stabilize the droplets.

- Example:
  - **Oil in water (O/W)** emulsion – Milk
  - **Water in oil (W/O)** emulsion – Cold cream

Classification of Emulsions

1. Based on Nature of Phases

- **Oil in Water (O/W) Emulsion**
  – Oil is dispersed in water.
  – Example: Milk, oral emulsions.
- **Water in Oil (W/O) Emulsion**
  – Water is dispersed in oil.
  – Example: Cold creams, ointments.

2. Based on Route of Administration

- **Oral emulsions** – e.g., Castor oil emulsion
- **Topical emulsions** – e.g., Lotions, creams
- **Parenteral emulsions** – e.g., IV lipid emulsion
- **Ophthalmic emulsions** – e.g., Emulsified eye drops

3. Based on System Complexity

- **Simple emulsion** – Only one dispersed and one continuous phase (O/W or W/O)
- **Multiple emulsion** – e.g., W/O/W or O/W/O
- **Microemulsion** – Clear, thermodynamically stable system with nano-sized droplets

- **Microemulsion** – Droplet size 10–200 nm

Emulsifying Agents

➢ An **emulsifying agent** is a substance that helps in the **formation and stabilization of emulsions** by **reducing interfacial tension** between two immiscible liquids (typically oil and water) and by forming a **protective film** around dispersed droplets to prevent them from coalescing.

Types of Emulsifying Agents

1. Natural Emulsifying Agents

- Obtained from plant or animal sources
- Form a **viscous protective film**
- Used mostly in **oral and external emulsions**
- **Examples:**
  - Acacia (Gum Arabic)
  - Tragacanth
  - Gelatin
  - Lecithin (egg yolk or soy)

2. Synthetic Emulsifying Agents

- Chemically prepared surfactants

- Selected based on **Hydrophilic-Lipophilic Balance (HLB)** value
- **O/W emulsions** require emulsifiers with high HLB (e.g., Tween 80)
- **W/O emulsions** require emulsifiers with low HLB (e.g., Span 80)
- **Examples:**
  - Tween 20, Tween 80 (Polysorbates)
  - Span 20, Span 80 (Sorbitan esters)
  - Sodium lauryl sulfate (SLS)

3. Finely Divided Solids

- Act as **physical barriers** at the oil-water interface
- Adsorb onto droplets and prevent coalescence
- Commonly used in **topical emulsions**
- **Examples:**
  - Bentonite
  - Magnesium hydroxide
  - Aluminum hydroxide

4. Auxiliary Emulsifiers (Co-Emulsifiers)

- Not effective alone, but enhance the action of primary emulsifiers
- Help in **stabilizing the emulsion film**
- **Examples:**
  - Cholesterol
  - Cetyl alcohol
  - Stearyl alcohol
  - Glyceryl monostearate

Functions of Emulsifying Agents

1. Reduce **interfacial or surface tension** between oil and water.
2. Prevent **coalescence** (droplets merging).
3. Maintain the **physical stability** of emulsions.
4. Aid in the **uniform dispersion** of the internal phase.
5. Prolong the **shelf life** of the emulsion.

Tests for Identification of type of Emulsion

1. Dilution Test

Principle

- An emulsion can be diluted only with the external/continuous phase.

Procedure

- Take a small amount of emulsion.
- Add an equal volume of water or oil and mix gently.

Observation

- If it mixes easily with water → it's an O/W emulsion
- If it mixes easily with oil → it's a W/O emulsion

2. Dye Solubility Test

Principle

- Water-soluble dyes dissolve in the aqueous phase; oil-soluble dyes dissolve in the oil phase.

Procedure

- Add a water-soluble dye (e.g., methylene blue) or oil-soluble dye (e.g., Sudan III) to the emulsion.
- Mix gently and observe under a microscope or visually.

Observation

- Uniform blue color → water is continuous → O/W
- Dye appears in streaks or spots → oil is continuous → W/O

3. Conductivity Test

Principle

- Water conducts electricity, oil does not.

Procedure

- Dip two electrodes into the emulsion.
- Connect to a low-voltage bulb or conductivity meter.

➢ Observation

- If the bulb glows or meter reads → O/W emulsion
- If no conduction → W/O emulsion

4. Cobalt Chloride Paper Test

Principle

- Cobalt chloride paper is blue when dry and turns pink in the presence of water.

Procedure

- Place a drop of emulsion on a strip of cobalt chloride paper.
- Let it stand for a few minutes.

Observation

- Turns pink → external phase is water → O/W
- Remains blue → external phase is oil → W/O

Methods of Preparation of Emulsions

1. Dry Gum Method (Continental Method)

- In this method, the emulsifier (usually gum acacia) is first mixed with oil, and then water is added all at once.

Standard Ratio

- Oil : Water : Gum = 4 : 2 : 1 (for fixed oil emulsions)

Procedure

- Triturate gum acacia with oil in a dry mortar.
- Add water all at once and triturate vigorously.
- A creamy white emulsion will form ("clicking" sound indicates formation).
- Add remaining ingredients and dilute as required.

Use:

- ✓ Mainly for primary emulsions in pharmacy compounding.

2. Wet Gum Method (English Method)

- Here, the gum is mixed with water first, and then oil is added slowly with continuous trituration.

Standard Ratio

- Same as Dry Gum: 4 : 2 : 1

Procedur

- Triturate gum acacia with water to form a mucilage.
- Add oil slowly, in portions, with continuous mixing.
- After all oil is added, triturate until a uniform emulsion forms.
- Add remaining ingredients and adjust volume.

Use

- ✓ Preferred when more control over mixing is needed.

3. Bottle Method (For Volatile or Fixed Oils)

- ➢ A convenient method using a bottle or closed container, used for preparing small quantities.

Procedure

- Place gum acacia and oil in a dry bottle.
- Shake thoroughly to form a paste.
- Add required amount of water in small portions, shaking vigorously after each addition.
- Once primary emulsion forms, add rest of the water.

Use

- ✓ For light oils and volatile oils like clove oil.

4. Mechanical Method (Using Equipment)

- ➢ Mechanical devices are used to produce uniform and fine emulsions on a large scale.

Examples of Equipment

- High-speed blenders
- Homogenizers
- Colloid mills
- Ultrasonic emulsifiers

Use

- ✓ Used in industrial or large-scale production of emulsions.

Stability Problems in Emulsions

1. Creaming

- Upward or downward movement of dispersed droplets.
- Leads to non-uniform distribution but reversible.
- Cause: Difference in density between oil and water; large droplet size.
- Solution: Reduce droplet size, increase viscosity, use proper emulsifiers.

2. Cracking (Breaking)

- Complete and irreversible separation of oil and water phases.
- Cannot be redispersed by shaking.
- Cause: Inadequate emulsifier, temperature extremes, microbial growth.
- Solution: Use proper emulsifier (correct HLB), maintain storage conditions.

3. Coalescence

- Droplets merge to form larger droplets.
- Leads to eventual breaking of the emulsion.
- Cause: Weak or broken interfacial film.
- Solution: Use film-forming emulsifiers; stabilize interfacial tension.

4. Phase Inversion

- The dispersed phase becomes the continuous phase and vice versa (O/W ↔ W/O).
- Cause: Change in phase ratio, temperature, or emulsifier concentration.
- Solution: Maintain proper oil-to-water ratio; use phase-stable emulsifiers.

5. Flocculation

- Droplets cluster together but do not merge.

- May lead to coalescence or creaming.
- Cause: Inadequate zeta potential or weak repulsion.
- Solution: Use stabilizers or adjust ionic environment.

Methods to Overcome Stability Problems in Emulsions

1. Preventing Creaming

- Reduce globule size using homogenizers or colloid mills.
- Increase viscosity of continuous phase using thickeners (e.g., methylcellulose, xanthan gum).
- Use suitable emulsifying agents that form a strong interfacial film.
- Store in cool places to reduce temperature-induced density changes.

2. Preventing Cracking (Breaking)

- Use emulsifiers with proper HLB value (Hydrophilic-Lipophilic Balance).
- Maintain optimum oil-to-water ratio.
- Avoid temperature fluctuations and microbial growth.
- Use protective colloids (e.g., gelatin, acacia) for interfacial film stability.

3. Preventing Coalescence

- Reduce particle movement by increasing viscosity.
- Use emulsifiers that form a rigid, strong interfacial film (e.g., lecithin, span, tween).
- Avoid freezing and thawing which damages the emulsion film.

4. Preventing Phase Inversion

- Maintain correct phase volume ratio (dispersed phase should be $<50\%$).
- Choose temperature-stable emulsifiers.

- Avoid excessive stirring or temperature rise that can flip the emulsion type.

5. Preventing Flocculation

- Adjust zeta potential to provide repulsion between droplets.
- Use electrolytes or polymers to stabilize droplet repulsion.
- Add sufficient emulsifier to fully cover droplet surfaces.