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PHARMACEUTICS – I

UNIT 4

TOPIC :

- **Suppositories :** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

Suppositories

→ A suppository is a solid dosage form intended for insertion into body cavities like the rectum, vagina, or urethra, where it melts, softens, or dissolves to release the active drug for local or systemic action.

- Solid at room temperature.
- Melts/dissolves at body temperature (≈37°C).
- Useful when the oral route is unsuitable (e.g., vomiting, unconsciousness).

Types of suppositories

❖ **Rectal suppositories:** These are meant for insertion into the rectum for producing systemic effect. The rectal suppositories meant for adults usually weigh 2 gm and are torpedo shape, whereas the suppositories made for children are much smaller in size as compared to the adult suppositories. Children's suppositories weigh about 1 gm

❖ **Vaginal suppositories:** The vaginal suppositories are also known as Pessaries. They are meant for insertion into the vaginal cavities. They weigh about 3-5 gm and are molded in globular or oviform shape or compressed on a tablet press into conical shapes. The vaginal suppositories are larger than the rectal suppositories. They are used for their local action in vagina.

❖ **Urethral suppositories:** These are also called as bougies and are of pencil shape. The urethral suppositories are meant for insertion into the urethra. The urethral suppositories intended for males weigh 4 gm each and are 100-150 mm long and those for females are 2 gm each and 60-75 mm in length..

❖ **Nasal suppositories:** The nasal suppositories are also called as nasal bougies or buginaria. The nasal suppositories are meant for introduction in to nasal cavity. They are usually prepared with

glycerogelatin base. They have similar shape as that of the urethral bougies. They weigh about 1 gm and have length of 9-10 cm.

- **Ear cones:** Ear cones are used for insertion into the ear. They are also known as Aurinaria. They are used rarely. For preparation of ear cones generally theobroma oil is used as base. They are prepared in urethral bougies mould and cut according to size.

Advantages of Suppositories

- ✓ Suppositories can exert local effect on rectal mucosa.
- ✓ It is used to promote evacuation of bowel.
- ✓ It avoid any gastrointestinal irritation.
- ✓ Suppositories can be used in unconscious patients (e.g. during fitting).
- ✓ Suppositories can be used for systemic absorption of drugs and avoid first-pass metabolism.
- ✓ Babies or old people who cannot swallow oral medication.
- ✓ It is useful for post operative people who cannot be administered oral medication.
- ✓ A very suitable dosage form for people suffering from severe nausea or vomiting

Disadvantages of Suppositories

- Suppositories have a problem of patient acceptability.
- In some cases, the total amount of the drug must be given will be either too irritating or in greater amount than reasonably can be placed into suppository.
- Incomplete absorption may be obtained because suppository usually promotes evacuation of the bowel.
- Suppositories are not suitable for patients suffering from diarrhoea.

Types of Bases Used in Suppositories

1. Fatty or Oleaginous Bases

- **Examples:** Cocoa butter (theobroma oil), hydrogenated vegetable oils.
- **Properties:** Melt at body temperature; non-irritant.
- **Drawback:** Polymorphism in cocoa butter leads to variable melting points.

2. Water-Soluble and Water-Miscible Bases

- **Examples:** Glycerinated gelatin, Polyethylene Glycol (PEG).
- **Properties:** Dissolve (not melt) in body fluids.
- **Advantages:** More stable, no need for refrigeration.
- **Used for:** Vaginal and urethral suppositories.

3. Emulsifying Bases

- **Examples:** Witepsol, Massa Estarinum.
- **Properties:** Better emulsification and drug release.
- **Useful in:** Broad range of suppository formulations.

Methods of Preparation of Suppositories

1. Fusion (Molding) Method

- Most commonly used.
- Steps:
  - Melt the base gently.
  - Add the drug with constant stirring.
  - Pour into lubricated molds.
  - Cool and remove the suppositories.

2. Compression Method

- No heat used; ideal for heat-sensitive drugs.
- Steps:
  - Drug and base are mixed to form a plastic mass.
  - The mass is compressed into molds using a hand press or machine.

3. Hand Rolling Method

- Traditional method, rarely used now.
- Steps:
  - Drug and base are mixed, shaped by hand into cylinders.
  - Cut to the desired size and shape.
- Used only when equipment is unavailable.

Displacement Value (DV)

- The displacement value is the number of parts by weight of a drug that displaces one part by weight of the suppository base.
- It is used to calculate how much base is required after adding the drug, as drugs displace some amount of base.

Formula

Base Required =Total weight of suppositories–(Weight of Drug / Displacement Value)

Example Calculation

You are making 6 suppositories, each weighing 2 g = total 12 g
Drug weight = 3 g
Displacement value of the drug = 1.5

Base Required = 12 – (3/1.5)

= 12–2

= 10 g of base

Evaluation of Suppositories

1. Appearance

- Should be smooth, uniform, free from air bubbles or cracks.

2. Weight Variation

- Weigh each suppository and compare with average weight.

3. Melting Point / Softening Time

- Should melt close to body temperature (around 37°C).

4. Liquefaction Time

- Time required to melt under body-like conditions.

5. Disintegration Test

- Suppository should disintegrate within 30 minutes (for rectal).

6. Drug Content Uniformity

- Each suppository should contain consistent drug content (within limits).

7. In-vitro Release Test

- Carried out in a dissolution medium to determine drug release profile.

8. Irritancy Test

- Especially for vaginal and rectal use; checks for mucosal irritation.