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INDUSTRIAL PHARMACY - I

UNIT 4

TOPIC :

- **Ophthalmic Preparations :** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations



Ophthalmic Preparations

- Ophthalmic preparations are sterile dosage forms intended for instillation, application, or irrigation to the eye (conjunctiva, cornea, or surrounding tissues).
- They include eye drops, eye ointments, eye lotions, inserts, and gels.
- These preparations must be non-irritating, sterile, free from foreign particles, and isotonic with tear fluid.
- The average tear volume is about 7–10 μL , and the eye can hold only $\sim 30 \mu\text{L}$ at once, hence dosage volume is small.
- pH and osmolarity must be adjusted to avoid irritation and reflex tearing which can wash away the drug.

Formulation Considerations

To ensure safety, comfort, and effectiveness, ophthalmic formulations must satisfy the following criteria:

A. Sterility

- Most important requirement.
- Ophthalmic products must be free from microorganisms.
- Achieved by:
 - Filtration through $0.22 \mu\text{m}$ membrane filter
 - Autoclaving (if heat stable)
 - Aseptic processing for heat-sensitive drugs.

B. Isotonicity

- Lacrimal fluid has osmotic pressure equivalent to 0.9% NaCl solution.
- Hypotonic or hypertonic solutions cause tearing and irritation.
- Adjusted using NaCl, dextrose, or buffering agents.

C. pH and Buffering

- Normal tear pH = 7.4.
- pH must ensure drug stability and comfort.
- Buffer systems used:
 - Phosphate buffer (pH 6–8)
 - Borate buffer
 - Acetate buffer

D. Viscosity

- Viscosity enhancers increase contact time and bioavailability.
- Examples: Methylcellulose, Hydroxypropyl methylcellulose (HPMC), PVA, PVP, carbopol.
- Optimum viscosity: 15–25 cps for comfort.

E. Preservatives

- Prevent microbial contamination during storage and use (especially multi-dose containers).
- Must be non-irritant and effective at low concentration.
- Common preservatives:
 - Benzalkonium chloride (0.01%)
 - Phenylmercuric nitrate (0.002%)
 - Chlorobutanol (0.5%)
- *Note:* Avoid preservatives in post-surgical or single-use preparations.

F. Antioxidants

- Prevent oxidation of sensitive drugs (e.g., adrenaline, phenylephrine).
- Examples: Sodium metabisulfite, Thiourea, Ascorbic acid.

G. Stabilizers

- Maintain drug stability by preventing degradation.
- e.g., EDTA as chelating agent to stabilize oxidizable drugs.

H. Tonicity Adjusting Agents

- Used to make the solution isotonic with tears.
- e.g., Sodium chloride, dextrose, boric acid.

I. Vehicles

- Medium in which the drug is dissolved or suspended.
- Must be non-toxic, isotonic, and sterile.
- Common vehicles:
 - Purified water
 - Water for injection
 - Vegetable oils (for oily eye drops)

J. Clarity

- Must be clear and free from visible particles.
- Filtration through 0.45 μm filter is mandatory.

Formulation of Ophthalmic Preparations

Eye Drops (Ophthalmic Solutions)

- Eye drops are sterile aqueous or oily solutions meant for instillation into the conjunctival sac.
They deliver the drug directly to the eye for local therapeutic action.

Formulation of Eye Drops

1. Active Ingredient

- Selected based on the therapeutic purpose (antibiotic, antifungal, anti-inflammatory, mydriatic, etc.).
- Example: Chloramphenicol (antibiotic), Pilocarpine (glaucoma).

2. Vehicle

- Usually sterile water for injection (WFI).
- For oily preparations, light liquid paraffin or castor oil may be used for oil-soluble drugs.

3. Tonicity Adjusters

- Maintain isotonicity with lacrimal fluid ($\approx 0.9\%$ NaCl).
- Common agents: Sodium chloride, dextrose, mannitol, boric acid.

4. pH Adjusters and Buffers

- Maintain optimum pH (6.5–8.5) for comfort and stability.
- Common buffers: Borate buffer, phosphate buffer, acetate buffer.

5. Preservatives

- Prevent microbial growth in multi-dose containers.
- Example: Benzalkonium chloride (0.01%), Phenylmercuric nitrate, Chlorobutanol.

(Avoid in eye surgeries or for patients with hypersensitivity.)

6. Viscosity Enhancers

- Increase contact time with the eye surface.
- Example: Methylcellulose, Hydroxypropyl methylcellulose (HPMC), Polyvinyl alcohol.

7. Antioxidants

- Prevent oxidation of drugs (especially in adrenaline, vitamin C formulations).
- Example: Sodium metabisulfite, Thiourea, Ascorbic acid.

8. Stabilizers and Solubilizers

- Example: EDTA (chelating agent), Polysorbate 80 (solubilizer).

Method of Preparation

1. Dissolve the drug and required additives in sterile vehicle.
2. Adjust pH and make isotonic with suitable agents.
3. Filter through 0.22 μm membrane for sterilization.
4. Fill aseptically into sterile dropper bottles.
5. Seal immediately and label properly.

Labeling Requirements

- “For ophthalmic use only” or “Sterile Eye Drops”.
- Storage conditions (e.g., “Store in a cool, dry place”).
- Directions for use, concentration, and expiry date.
- If preservative-free, mention “Single use only”.

Containers

- Sterile glass or plastic dropper bottles, usually amber-colored.
- Fitted with a dropper cap to deliver uniform drops (approx. 50 μL per drop).

Evaluation Tests

1. Sterility test – For bacterial and fungal contamination (per IP/BP/USP).
2. Clarity test – No visible particles or turbidity.
3. pH determination – Should be within comfort range (6.5–8.5).
4. Tonicity test – Maintains isotonicity.
5. Viscosity measurement – Using viscometer.
6. Assay of active ingredient – Ensures correct drug concentration.
7. Volume and uniformity test – For accurate dosing.

Eye Ointments

- Eye ointments are sterile semisolid preparations meant for application to the conjunctival sac or eyelids.
- They provide longer contact time and sustained drug release.

Formulation of Eye Ointments

1. Active ingredient – Anti-infective, anti-inflammatory, etc.
2. Base – Non-irritant and compatible; should melt at body temperature.
 - Example: White soft paraffin, liquid paraffin, lanolin.
3. Preservatives – Same as eye drops (benzalkonium chloride, etc.).
4. Antioxidants – Ascorbic acid, sodium metabisulfite.

Method of Preparation

1. Melt the base gently and sterilize by dry heat (160°C for 1 hr).
2. Dissolve or disperse the drug in the sterile base.
3. Mix under aseptic conditions to ensure uniformity.
4. Fill into sterile collapsible tubes or ophthalmic ointment containers.

Labeling and Containers

- Labeled as “Sterile Ophthalmic Ointment – For external use only”.
- Packaged in small, sterile aluminum tubes fitted with narrow tips.

Evaluation Tests

1. Sterility test
2. Uniformity of drug content
3. Softness and spreadability
4. Particle size (should be $<25\ \mu\text{m}$)
5. Leakage and stability tests

Eye Lotions (Ophthalmic Irrigations)

- Eye lotions are sterile, aqueous solutions used for washing the eye to remove foreign particles, discharge, or chemicals.

Formulation

1. Vehicle – Sterile water for injection.
2. Tonicity adjusters – Sodium chloride or boric acid.
3. Buffer – To maintain physiological pH.
4. Preservatives – Optional (for multi-dose use).

Method of Preparation

1. Dissolve all ingredients in sterile water.
2. Adjust pH and isotonicity.
3. Filter through a 0.22 μm membrane.
4. Fill aseptically into sterile, large-volume bottles (100–200 mL).

Labeling and Containers

- Labeled as “Sterile Eye Lotion” or “Eye Wash”.
- Containers must allow easy irrigation of the eye (eye-cup bottles).
- Must not contain preservatives if intended for surgical use.

Evaluation Tests

1. Sterility test
2. Clarity and particulate matter test
3. pH and tonicity determination

