



Netaji Subhas University, Jamshedpur

Shaista Sanuber
Assistant Professor
NSIP, NSU

Sterile Formulations

Sterile dosage forms are those which are free from any microorganisms, dust, fibres, and foreign particles, and should be isotonic.

Parenteral preparations are those which are administered other than enteral routes.

Examples of common parenteral routes are intramuscular (IM), subcutaneous (subcut), intradermal (ID), and intravenous (IV).

Injectables are (dermatological preparations) used to relax facial wrinkles and folds (such as “smile lines”), contour the body (such as reducing the appearance of a “double chin”) and improve the signs of facial fat loss by creating structure, framework and volume to the face and lips.

Ophthalmic preparations are sterile product free from foreign particles meant for instillation into the space between eye lid and eye balls.

Ophthalmic products include

- Eye drops
- Eye lotions
- Eye Suspension
- Eye Ointments

Eye drops are the aqueous or oily solution or suspension that is installed into the conjunctival sac of the eye.

These are used as anaesthetics, anti-inflammatory agents, antiseptics, diagnostic agent, mitotics, mydriatics and artificial tears.

Ideal characters of eye drops:

1. They should be free from foreign particles.
2. They should be free from pain and irritating effect
3. They must be sterile at all time
4. They must contain suitable preservatives

5. They should be chemically stable
6. All the eye drops must be isotonic with the lachrymal secretions

Examples:

- Atropine sulphate eye drops
- Physostigmine eye drops
- Hyoscine eye drops

Eye ointment is defined as soft, sterile semi solid preparations containing medicaments intended for applications to the conjunctival sac or to the eyelid margin.

Eye ointment base contains the following ingredients they are.

Wool fat	-10%
Liquid paraffin	-10%
Yellow soft paraffin	-80%

- Wool fat: It is used to produce emulsification of the aqueous solution and it promotes absorption of the medicament.
- Liquid paraffin: It produces smooth consistency to the preparation so that application to the eye lids is easier.
- Yellow soft paraffin: It acts as base white soft paraffin should not be used because it produces irritation.

Preparation of eye ointment:

1. Melt Wool fat, Yellow soft paraffin on a water bath.
2. Add Liquid paraffin.
3. Filter through coarse filter paper placed in heated funnel.
4. It is sterilised by dry heat method (160 °C for 2hrs).
5. Incorporate the medicament with the eye ointment base.
6. Pack in sterile containers.

White soft paraffin is not used in the preparation of ointment base because it is prepared by bleaching the yellow soft paraffin.

Wool fat is used in order to ensure satisfactory emulsification of the solution and helps in the absorption of active ingredients.

Liquid paraffin is incorporated to reduce the viscosity of the base, so that it can be easily expelled from the collapsible tube and apply to the eye.

Eg: Bacitracin, ophthalmic ointment.

Characteristics of Ophthalmic Preparations

There are the six main properties of ophthalmic preparations: Sterility, Preservation, Particle Limitations, pH, Stability, and Eye comfort. The main requirement is sterility, it is very important to make sure that medications applied to the eye should be sterile.

Clarity/Foreign Particulate matter.

- All the ophthalmic preparations must free be from foreign particles.
- Preparation must be clarified using Bacterial proof filter = 0.22 μ
- Particle size in ophthalmic suspension – Ultrafine state of subdivision to minimize irritation (not more than 10 μm (*micrometer*))

- Ophthalmic Suspension:- Large particle size – Favour retention in the cul-de-sac – Prolonged contact of drug, result into Larger duration of Action.
- Large particle disadvantage- Irritation
- Smaller particle size – more soluble – short duration of action
- So, the optimal particle size – should $<10\ \mu$

Thickening Agents

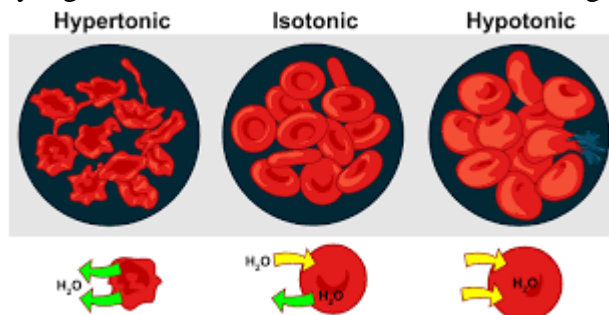
Thickening agents are added in the ophthalmic preparation to prolong the contact time of the drug in the eye.

- Should be 15-25 cps.
- To prolong the contact time of drug in the eye using thickening agent
- Polyvinyl agent (1-4%),
- Polyethylene glycol
- MC & CMC etc.
- Thickening agent are not used Eye lotion & drop has– Relatively brief contact time
- Thickening agent are used in the formation of eye suspension and ointments

Tonicity

Ophthalmic products should be isotonic with lachrymal secretion to avoid irritation and discomfort.

- Eye can tolerate 0.5 to 2% of NaCl [Acceptable range [0.7-1.5%]
- Preparation should be Isotonic with Lacrymal Secretion
- Tonicity Agent – NaCl, Boric Acid, KCl, dextrose, glycerine, Mannitol, PEG



pH Buffers:

Tears have the pH of 7.4. pH plays important role in therapeutic activity, solubility, stability and comfort to the patient. Eye can tolerate solution having wide range of pH provided they are not strongly buffered.

- pH =7.4, Boric Acid, Sodium citrate, Sodium Acid phosphates

Sterility

The most important properties of the ophthalmic preparation is that they must be sterile when prepared.

- All ophthalmic product must be sterile;
- Pyrogen free – not required

Very common gram negative bacteria named **Pseudomonas aeruginosa** which is generally present in the ophthalmic preparations. It may cause serious infection of cornea. It can cause total loss of eye sight within 24-48 hours.

Preservatives

To maintain the sterility in multi-dose container containing ophthalmic preparation a suitable preservative is added.

- Benzalkonium Chloride
- Phenyl mercuric nitrate &
- Phenyl mercuric acetate
- methyl paraben
- Propyl paraben

Containers:

Eye drops are dispensed in glass or suitable plastic containers with a screw cap fitted with a rubber teat and glass dropper for easy application of the drops or the containers may be fitted with a nozzle from which the drops can be directly instilled into the eye.

Storage: Eye drops are stored in a closed sterile container.

Labeling: “For external use only” if irritation occurs discontinues use.

Eye ointments are packed in small, sterilized collapsible tube of suitable metal or plastic containers (multi dose container). Eye ointments are also packed in soft gelatin capsules (single dose container) with applicator tips.

- **Glass container:**
- Sterilised previously with Autoclave
- Type –I / Borosilicate only
- **Plastic container**
- Polyethylene, Sterilised previously by Gamma Radiation or ethylene oxide
- **Metal container**
- Aluminium – For ointment (Sterilised previously with Autoclave)

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