

OPHTHALMIC PREPARATION

A Concise Presentation

By

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Definition

- Ophthalmic preparations (eye preparations) are sterile, liquid, semi-solid preparations that may contain one or more active pharmaceutical ingredient(s) intended for application to the conjunctiva, the conjunctival sac or the eyelids.
- Unless the active ingredient itself has antimicrobial activity, ophthalmic preparations supplied as multi dose preparations may include a suitable antimicrobial agent. The antimicrobial activity should remain effective throughout the entire period of use.

TYPES OF OPHTHALMIC PRODUCTS

1. **Eye drops** - Ophthalmic drops (eye drops) are sterile aqueous or oily solutions, suspensions, or emulsions intended for instillation into the conjunctival sac.
 - Ophthalmic drops should be clear and practically free from particles when examined under suitable conditions of visibility.
 - "Water for injections" should be used in the manufacture of aqueous ophthalmic drops.
 - The preparation of aqueous ophthalmic drops requires careful consideration of the need for isotonicity, a certain buffering capacity, the desired pH, the addition of antimicrobial agents and antioxidants, the use of viscosity-increasing agents, and the choice of appropriate packaging.
 - Ophthalmic drops are considered isotonic when the tonicity is equal to that of a 0.9% solution of sodium chloride. The eye can usually tolerate solutions equivalent to 0.5-1.8% of sodium chloride.

2. Eye lotion – Eye lotions are the aqueous solutions used for washing the eyes. The eye lotions are supplied in concentrated form and are required to be diluted with warm water immediately before use.

3. Eye Ointments - Ophthalmic ointments are sterile, homogeneous, semi-solid preparations intended for application to the conjunctiva or the eyelids.

- They are usually prepared from non-aqueous bases e.g. soft paraffin (Vaseline), liquid paraffin, and wool fat.
- They may contain suitable additives, such as antimicrobial agents, antioxidants, and stabilizing agents.

- **4. Eye Suspensions** - Ophthalmic suspensions contain solid particles dispersed in a liquid vehicle; they must be homogeneous when shaken gently and remain sufficiently dispersed to enable the correct dose to be removed from the container.
 - A sediment may occur, but this should disperse readily when the container is shaken, and the size of the dispersed particles should be controlled.
 - The active ingredient and any other suspended material must be reduced to a particle size small enough to prevent irritation and damage to the cornea.
- 5 . Contact lens solution** - These are the sterile solutions used to clean and disinfect contact lenses.

REQUIREMENTS

Ophthalmic preparations should possess the following requirements:

- Foreign particles
- Viscosity
- Tonicity
- pH of preparations
- Sterility
- Surface activity

Foreign particles:

- ❖ All the ophthalmic products should be clear and free from foreign particles, fibres and filaments.
- ❖ Ophthalmic solutions should be clarified very carefully by passing through bacteria proof filters such as membrane filters, sintered glass filters.
- ❖ The particle size of the eye suspension should be in an ultrafine state of subdivision to minimize irritation.
- ❖ A separate filter should be used for different ophthalmic products in order to avoid the contamination.

Viscosity:

In order to prolong the contact time of the drug in the eye, various thickening agents are added in the ophthalmic preparations.

Polyvinyl alcohol (1-4%), polyethylene glycol, methyl cellulose, carboxy methyl cellulose are some of the commonly used thickening agents. These agents improve the viscosity of the preparation.

An ideal thickening agent should possess the following properties:

- it should be easy to filter.It should be easy to sterilize.
- It should be compatible with other ingredients.
- It should possess requisite refractive index and clarity level.

Thickening agents are not included in the formulation of eye drops and eye lotions which are required to be used during or after surgery due to some possible adverse effects on the interior of the eye.

Tonicity:

- Ophthalmic products should be isotonic with lachrymal secretions to avoid discomfort and irritation.
- It has been observed that eye can tolerate a range of tonicity from 0.5-2% .
- There are certain isotonic vehicles which are used to prepare ophthalmic products like 1.9% boric acid, sodium acid phosphate buffer.

pH of the preparations:

- pH plays an important role in therapeutic activity, solubility, stability and comfort to the patient.
- Tears have a pH of about 7.4. eye can tolerate solution having wide range of pH provided they are not strongly buffered, since the tear will rapidly restore the normal pH value of the eye.
- Alkaloid salt solutions are stable at pH 2-3 but this pH is irritant to eye.
- The alkaloids get precipitated at pH above 7 and creates a number of formulation problems

Sterility:

- Ophthalmic preparations must be sterile when prepared. *Pseudomonas aeruginosa* is very common gram -ve bacteria which is generally found to be present in ophthalmic products.
- It may cause serious infections of cornea. It can cause complete loss of eye sight in 24-48 hrs.
- To maintain sterility in multi dose container, containing ophthalmic products, a suitable preservative is added.
- The preservative should be non-toxic, non-irritant and should be compatible with medicaments.
- The ophthalmic products are generally sterilized by autoclaving, filtration through bacteria proof filters and addition of bactericides at low temperature.

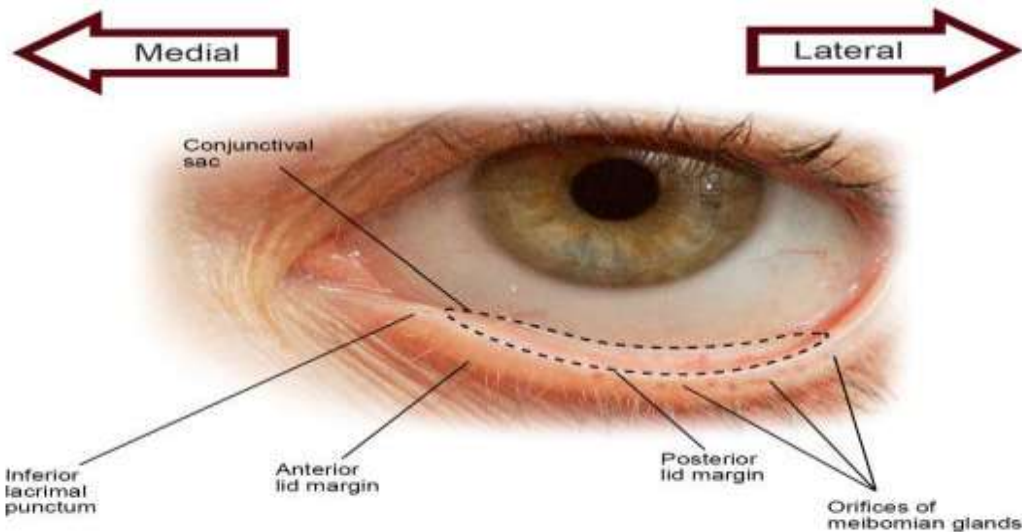
Surface activity:

- Vehicles used in ophthalmic preparations must have good wetting ability to penetrate cornea and other tissues.
- Certain surfactants or wetting agents added which are found suitable for ophthalmic products.
- It should not cause any damage to the tissue of eye. Benzalkonium chloride, polysorbate 20, polysorbate 80, dioctyl sodium sulpho succinate etc., are some of the surfactants which are commonly used.

Administration of Ophthalmic Products

- Ophthalmic medications include drops, ointments, and intraocular disks. Always considered sterile, they are often prescribed following cataract removal and to treat such eye conditions as glaucoma and infections. They are also used to soothe irritated tissue, to dilate or constrict the pupils, and to provide anesthesia. Because ophthalmic medications are available in a variety of concentrations, it is important to ensure that the patient is receiving the correct one so that the eye does not become irritated or damaged.
- The cornea of the eye contains many sensitive nerve fibers and is easily irritated. When instilling eye medications, do not instill the medication directly onto the cornea.
- Place drops, ointments, and suspension in the conjunctival sac. This area of the eye is much less sensitive and provides a more appropriate site for instilling ophthalmic medications.
- Before instilling an ophthalmic medication, gently wipe away any drainage or discharge along the eyelid margin.

Process of Instilling Ophthalmic Products



Packaging of Ophthalmic Products

Containers: The eye drops should be packed in neutral glass containers or in suitable plastic containers.

In olden days the eye drops are stored in vertically fluted amber colored glass bottles fitted with a Bakelite cap carrying a dropper.

The bottle must confirm to limit test for alkalinity of glass. Now a days neutral glass small bottles having capacity of 4ml to 8ml are used.

It has two poly propylene screw caps, one for attaching a silicone rubber teat to the container and the other for covering the teat.

The plastic squeeze bottles having ridged plastic cap and polythene friction plug containing baffle that produces uniform drops are also used these days.

These are very handy. These bottles are sterilized by gaseous sterilization method.



Figurs showing different types of Packing.

- (A) Many different container closure venders supply these bottle and cap configurations.
- (B) The container closure system design is not engineered to secure the plastic ring around the bottle neck. As a result, the plastic rings are likely to slip off the bottle neck on patients' eyes when the bottle is inverted to administer eye drops.
- (C) The sharp ridges on the rings formed when the seal is broken between the cap and ring can cause corneal abrasions.

A contact lens is a lightweight corrective, cosmetic or therapeutic device that is usually placed directly onto the cornea of the eye.

Contact lenses have many benefits for wearers, including appearance and practicality.

Many people choose to wear contact lenses as opposed to eyeglasses as they do not steam up, they provide a wider field of vision, and they are more suitable for a number of sporting activities.

Contact lens Solution

A sterile, isotonic solution that contains hyaluronan, sulfobetaine, poloxamine, boric acid, sodium borate, edetate disodium and sodium chloride and preserved with a dual disinfection system (polyaminopropyl biguanide 0.00013% and polyquaternium 0.0001%).

Types of Contact lenses

1. Hard Contact lenses – It is made from rigid plastic resin called polymethacrylate.
It is impermeable to oxygen and moisture.
2. Soft Contact lenses – It is made of hydrophilic transparent plastic called hydroxy ethyl methacrylate.
3. Rigid Gas Permeable – It is having the advantages of both soft and hard contact lenses.
4. Rigid hydrophobic – This lens has good gas permeability and poor wettability.

Care of Contact Lens

- Before handling contact lenses, wash your hands with soap and water, then rinse and dry them with a lint-free towel.
- Minimize contact with water, including removing lenses before going swimming or in a hot tub.
- Contact lenses should not be rinsed with or stored in water (tap or sterile water).
- Do not put your lenses in your mouth to wet them. Saliva is not a sterile solution.
- Do not use saline solution and rewetting drops to disinfect lenses. Neither is an effective or approved disinfectant.
- Wear and replace contact lenses according to the schedule prescribed by your eye care professional.
- Follow the specific contact lens cleaning and storage guidelines from your eye care professional and the solution manufacturer.
- During cleaning, rub your contact lenses with your fingers, then rinse the lenses with solution before soaking them. This "rub and rinse" method is considered by some experts to be a superior method of cleaning, even if the solution you are using is a "no-rub" variety.
- Rinse the contact lens case with fresh solution — not water. Then leave the empty case open to air dry.
- Keep the contact lens case clean and replace it regularly, at least every three months. Lens cases can be a source of contamination and infection. Do not use cracked or damaged lens cases.

Care of Contact lens Solution

- Do not re-use old solution or "top off" the solution in your lens case.
- Do not transfer contact lens solution into smaller travel-size containers. This can affect the sterility of the solution, which can lead to an eye infection.
- Do not allow the tip of the solution bottle to come in contact with any surface, and keep the bottle tightly closed when not in use.
- If you store your lenses in the case for an extended period of time, consult the instructions for the lenses or the contact lens solution to determine if re-disinfecting the lenses is appropriate before you wear them. In no case should you wear your lenses after storage for 30 or more days without re-disinfecting.

THANKS for viewing the ppt

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