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A Review on Preparation and Evaluation of Liquid Dosage Form-Eye Drop

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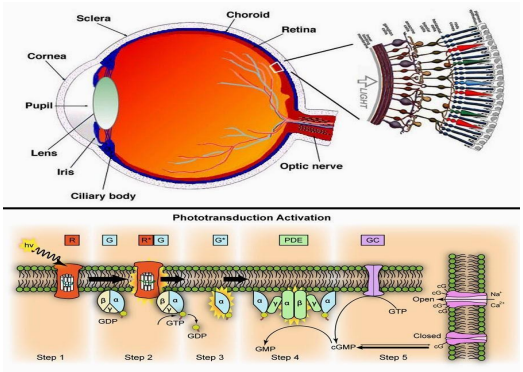
Abstract: *Ophthalmic products are sterile preparations that encompass specialized dosage forms which can be administered onto the external surface of the eye. The slightest inflammation in the eyes can cause intense soreness and cause eye infections, swelling, allergies, challenge vision, and can cause permanent harm and cause lack of vision as well. Therefore, all ophthalmic preparations are required to stringently follow analytical testings and evaluations. Procedures and recognized standards for testing ophthalmic preparations are labeled into quality tests and overall performance checks to evaluate the integrity, drug release, and different attributes that relate to in vivo drug overall performance of the ophthalmic preparations. Quality control of ophthalmic preparations consists of conventional checks which include identification, potency, purity, sterility particulate matter, and dissolution testing, etc.*

Keywords: Ophthalmic products

I. INTRODUCTION

Opthalmic preparation are specialized dosage forms deSigned to be instilled onto the external sureyee of the eye (topical) or administered inside the eys (intraocular)
The purpose may be therapeutic, prophylactic or palliative.
The most commonly employed opthalmic dosage forms are solutions, suspension,and ointments.
The newest dosage forms for opthalmic drug delivery are: geli, gel-forming solution, ocular insert, intravitreal injections and implants



II. LITERATURE REVIEW

Goal: understand eye Drops formulation and test
Key focus: ingredients, innovation, evolution test, methods, packing, formulation,

Plane of work
Eye drops are sterile solutions, suspensions or emulsions inten instillation in theeye. Solutions are Manufactured by dissolution of the active ingredients and theexcipients into all portion of water and sterilization of this solution done.

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If the drug is not sufficiently soluble, it can be formulated as a suspension.
Topical ophthalmic emulsions generally are prepared by dissolving or dispersing the active ingredient(s) into an oil phase, adding suitable emulsifying agent and mixing with water vigorously to form a uniform oil-in-water emulsion.

Material and method

Drugs- Ophthalmic products contains drugs of various categories including –Miotics e.g. Pilocarpine HCl
Mydriatics e.g. Atropine
Anti-inflammatories e.g. Corticosteroids
Anti-infectives (antibiotics, antivirals and antibacterials)
Anti-glucoma drugs e.g. Pilocarpine Hel
Diagnostic drugs e.g. Sodium fluorescein
Anesthetics e.g. Tetracaine

Preservation
Eye drop should be sterile and should contain preservatives to avoid microbialcontamination when container is open.
The preservative for ophthalmic use includes-
benzalkonium chloride
chlorbutanol
phenylmercuric acetate
phenylmercuric nitrate etc.

Sterilization
Eye drops are sterilized by autoclaving at 121°C for 15 minutes.Bacterial filters are used to avoid thermal degradation.
E.g.- preservative chlorbutanol hydrolyzes at hightemperature
Slide 10

Surfactants
The order of surfactant toxicity is:
anionic > cationic >> nonionic.
Several nonionic surfactants are used in relatively low Concentration to aid in dispersing steroids in suspensions and to achieve or to improve solution clarity.
Those principally used are the sorbitan ether esters of oleic acid (polysorbate ortween 20 and 80).

Buffers and PH adjuster
pH adjustment is very important as pH affects-1- To render the formulation more stable
The comfort, safety and activity of the product.
Eye irritation
increase in tear fluid secretion
Rapid loss of medication.
To enhance aqueous solubility of the drug.4- To enhance the drug bioavailability
5- To maximize preservative efficacy
Note: If buffers are required there capacity is controlled to be as low as possible (low buffer capacity) thus enabling the tear to bring the pH of the eye back to thephysiological range.

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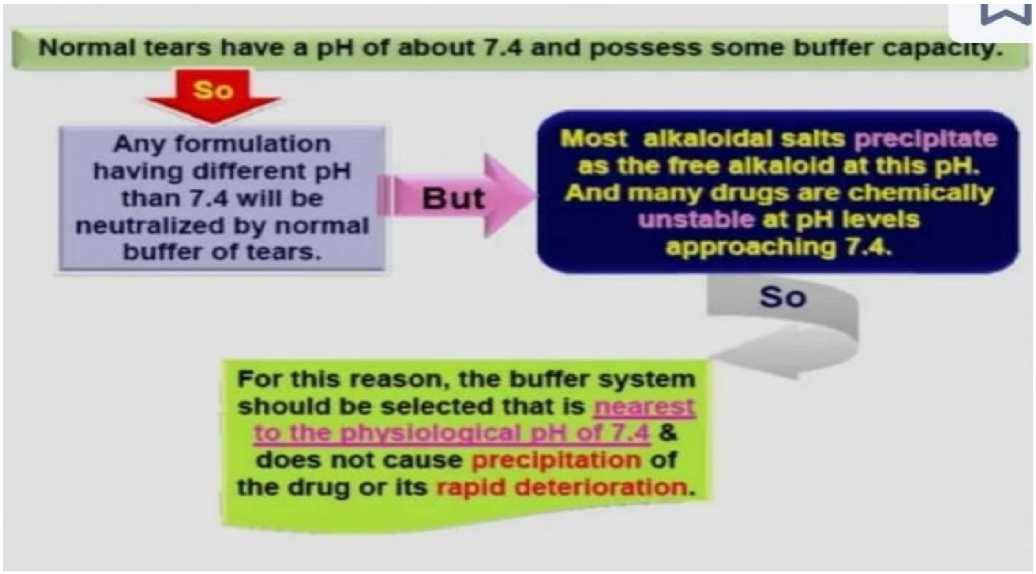
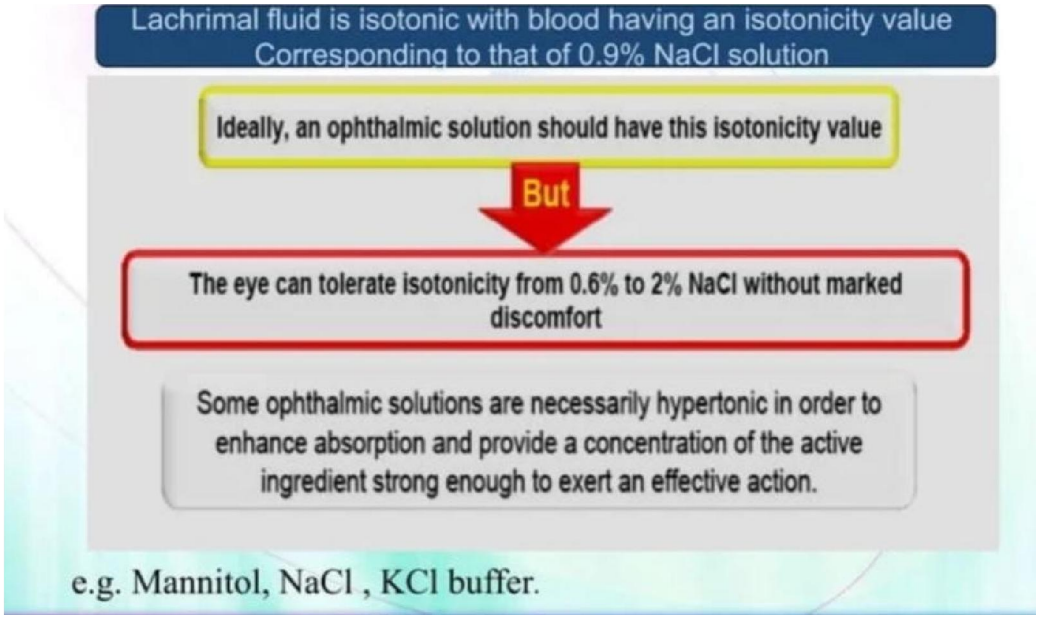


Tonicity and tonicity Adjusting Agent



Viscosity Impacting agent 55

Polyvinyl alcohol, methylcellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, and carbomers,are commonly used to increase the viscosity of solution and suspensions (to retard the rate of setting of particles) They increase the ocular contact time, there by decreasing the drainage rate, increase the mucoadhesiveness and Increasing the bioavailability.

Disadvantage: produce blurring vision as when dry, form a dry film on the eye lids. Make filteration more difficult. Commercial viscous vehicles are:

1. polyvinyl alcohol (liquifilm)
2. hydroxypropyl methylcellulose (isopto)

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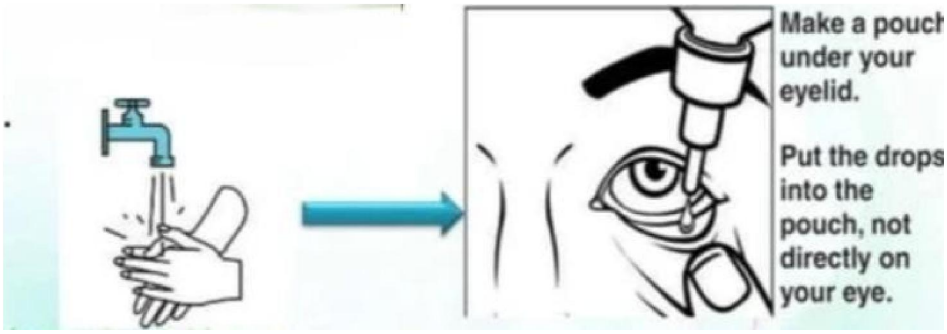
Vehicle
Ophthalmic drop (using purifies water USP) as the solvent.
Purified water meeting USP standards may be obtained by: Distillation, deionization,or reverse osmosis.
Oils have been used as vehicles for several topical eye drops products that areextremely sensitive to moisture.
When oils are used as vehicles in ophthalmic fluids, they must be of the highestpurity.

ADMINISTRATION
Pull down the eyelid.
Tilting the head backwards.
Look at the ceiling after the tip is pointed close to the lower cul-de- sac.
Apply a slight pressure to the rubber bulb or plastic bottle to allow a drop to fallinto the eye.
Do not squeeze lids.
To prevent contamination:
Clean hands
Do not touch the dropper tip to the eye and surrounding tissue



Packing
Eye drops have been packaged almost entirely in plastic dropper bottlesThe main advantage of the Drop-Trainer are:
Convenience of use by the patient Decreased contamination potentialLower weight
Lower cost
The plastic bottle and dispensing tip is made of low-density polyethylene (LDPE) resin,which provides the necessary flexibility and inertness. Room
The cap is made of harder resin than the bottle.
A special plastic ophthalmic package made of polypropyle introduced. The bottle isfilled then sterilized by steam under pressure at 121°C.

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Powder for reconstitution use glass containers, owing to their heat-transfercharacteristics, which are necessary during the freeze- drying processes.
The glass bottle is made sterile by dry-heat or steam autoclave sterilization.
Amber glass is used for light-resistance

Evaluation test
Evaluation of the ophthalmic product is done by following tests:
Sterility Test
Clarity Test
Leakage Test

Metal particles in ophthalmic ointment
Sterility Tests:
Ophthalmic products should be free from anaerobic and aerobic bacteria andfungi.
Sterility tests are therefore performed by the:
Membrane filtration method.
Directinoculation method.
In the Membrane filtration method:
A solution of test product (1%) is prepared in isopropyl myristate and allowed topenetrate through cellulose nitrate filter with pore size 0.45 µ m.
If necessary, gradual sunction or pressure is applied to aid filtration.
The membrane is then washed three times with 100 ml qu: of sterile diluting and rinsing fluid and transferred aseptically into fluid thioglycolate medium (FTM) andsoybean – casein digest medium (SBCD).
The membrane is finally incubated for 14 days.
Growth on FTM indicates the presence of anaerobic and aerobic bacteria.
Growth on Soybean casein digest medium indicates the presence of fungi and aerobicbacteria.
Absence of any growth in both these media establishes the sterility of the product.

In the Direct – inoculation technique:
1 part of the product is diluted with 10 parts of sterile diluting and rinsing fluid with thehelp of an emulsifying agent
Incubate in Fluid thioglycolate medium (FTM) and soybean – casein digest (SCDM)media for 14 days.
In both techniques, the number of test articles is based on the batch size of the product.If the batch size is less than 200 the containers, either 5% of the containers or 2 containers (whichever is greater) are used.
If the batch size is more than 200, 10 containers are used for sterility testing.
Clarity tests
Clarity is tested by visual inspection of containers under light and against a blackand white background.
Instrumental methods of evaluation is based on the principles of light scattering, light absorption and electrical resistance which are used to count particle and particlesize distribution.

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Unwanted mobile insoluble matter other than gas bubbles are present in the givenproduct are detected.
It may be dangerous when the particle size is larger than R.B.C. And may block theblood vessel.
Leakage test
This test is mandatory for ophthalmic products, which evalua the intactness of theointment tube and its seal.
Ten sealed containers are selected, and their exterior surfaces are cleaned.
They are horizontally placed over absorbent blotting paper. Maintained at 60±3°C for 8h.
The test passes if leakage is not observed from any container.
If leakage is observed, the test is repeated with an additional 20 tubes.
The test passes if not more than 1 container shows leakage out of 30 tubes.

Test of metal particles
This test is required only for ophthalmic ointments.
The presence of metal particles will irritate the corneal or conjunctival surfaces ofthe eye.
It is performed using 10 ointment tubes.
The content from each tube is completely removed onto a clean 60mm diameter Petri dish which possesses a flat bottom.
The lid is closed and the product is heated at 85 °C for 2 hours.
Once the product is melted and distributed uniformly, it is cooled to room temperature. The lid is removed after solidification.
The bottom surface is then viewed through an optical microscope at 30xmagnification
The viewing surface is illuminated using an external light sc positioned at 45° on thetop.
The entire bottom surface of the ointment is examined, and the number of particles 50µm or above are counted using a calibrated eyepiece micrometer.
The USP recommends that the number of such particles in 10 tubes should not exceed50, with not more than 8 particles in any individual tube.
Limits are not met, the test is repeated with an additional 20 tubes.
In this case, the total number of particles in 30 tubes should not exceed 150, and notmore than 3 tubes are allowed to contain more than 8 particles, the test passes.

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