



Ophthalmic Products

By
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Ophthalmic Preparations:

- “They are specialized dosage forms designed to be instilled onto the external surface of the eye (topical), administered inside (intraocular) or adjacent (periocular) to the eye or used in conjunction with an ophthalmic device.”
- The most commonly employed ophthalmic dosage forms are solutions, suspensions and ointments.
- The newest dosage forms for ophthalmic drug delivery are: gels, gel-forming solutions, ocular inserts, intravitreal injections and implants.

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Drugs Used in The Eye:

- **Miotics** e.g. pilocarpine Hcl
- **Mydriatics** e.g. Atropine
- **Cycloplegics** e.g. Atropine
- **Anti-inflammatories** e.g. corticosteroids
- **Anti-infectives** (antibiotics, antivirals and antibacterials)
- **Anti-glaucoma drugs** e.g. pilocarpine Hcl
- **Adjuncts** e.g. Irrigating solutions
- **Diagnostic drugs** e.g. sodiumfluorescein
- **Anesthetics** e.g. Tetracaine

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Ideal Requirements:

Following characteristics are required to optimize ocular drug delivery system:

1. Good corneal penetration.
2. Prolong contact time with corneal tissue.
3. Simplicity of instillation for the patient.
4. Non irritative and comfortable form
5. Appropriate rheological properties

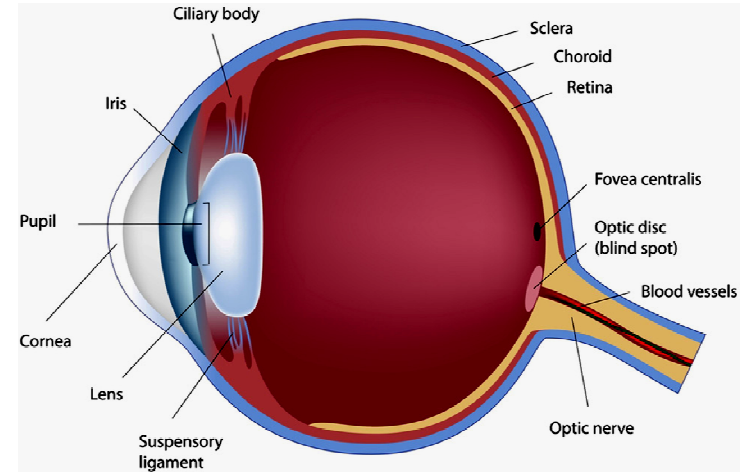
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Ideal Requirements:

1. Sterility, clarity, buffer, buffer capacity and pH, tonicity, viscosity, stability, comfort, additives, particle size, packaging and preservatives
2. The buffer system must be considered with tonicity and comfort in mind.
3. Stability can be related with pH, buffer and packaging.
4. Sterilization important in terms of stability and packaging.
5. Solutions must be free from foreign particles.
6. Solutions pH must be optimum.
7. More than one sterilization methods are employed.
8. Sterile solutions, suspension and ointments usually contain antimicrobial preservatives.

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Anatomy & Physiology of Eye:



Anatomy & Physiology of Eye: CONTD...

- The **sclera**: The protective outer layer of the eye, referred to as the "white of the eye" and it maintains the **shape of the eye**.
- The **cornea**: The front portion of the sclera, is transparent and allows light to enter the eye.
- The cornea is a powerful **refracting surface**, providing much of the eye's focusing power.

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Anatomy & Physiology of Eye: CONTD...

- The **choroids** is the second layer of the eye and lies between the sclera and the retina.
- It contains the **blood vessels** that provide **nourishment to the outer layers** of the retina.
- The **iris** is the part of the eye that gives it color.
- It consists of **muscular tissue** that responds to surrounding light, making the pupil opening in the center of the iris, larger or smaller depending on the brightness of the light.

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Anatomy & Physiology of Eye: CONTD...

- The **lens** is a transparent, biconvex structure, encased in a thin transparent covering. The function of the lens is to refract and focus incoming light onto the retina.
- The **retina** is the innermost layer in the eye. It converts images into electrical impulses that are sent along the optic nerve to the brain where the images are interpreted.
- The **macula** is located in the back of the eye, in the center of the retina. This area produces the sharpest vision.

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Anatomy & Physiology of Eye: CONTD...

- The inside of the eyeball is divided by the lens into two fluid-filled sections.
- The larger section at the back of the eye is filled with a colorless gelatinous mass called the **vitreous humor**.
- The smaller section in the front contains a clear, water-like material called **aqueous humor**.
- The **conjunctiva** is a mucous membrane that begins at the edge of the cornea and lines the inside surface of the eyelids and sclera, which serves to lubricate the eye.

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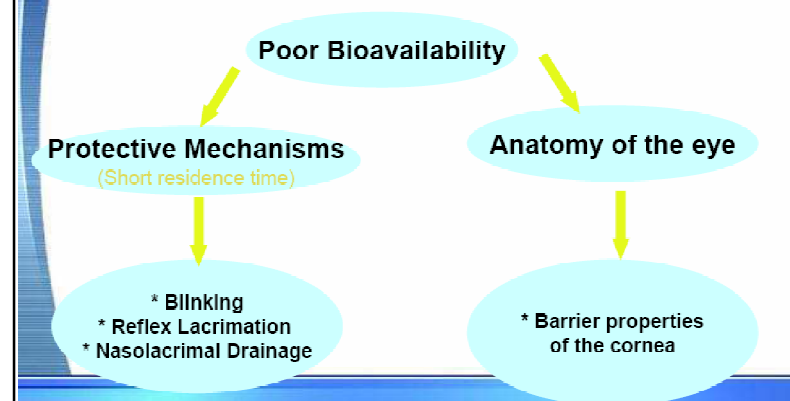
Bioavailability:

- Under normal conditions **human tear volume** averages about **7 μ L**.
- The estimated maximum **volume of cul-de-sac** is about **30 μ L**.
- Many commercial eyedrops range from 50-75 μ L in volume to minimize drainage loss.

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Bioavailability: CONTD...

♣Drug delivery in ocular therapeutics is a challenging problem.



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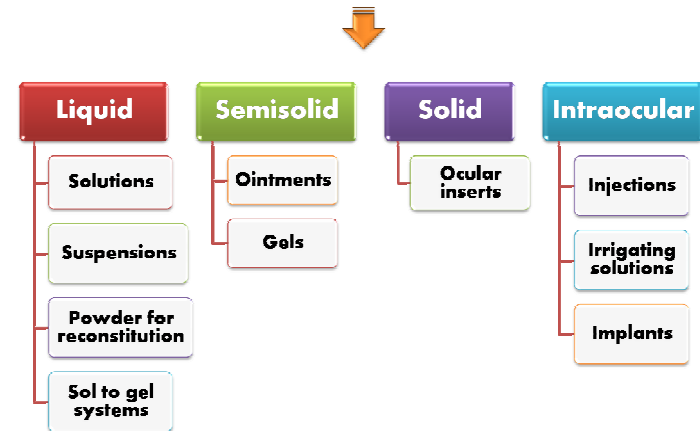
Bioavailability: CONTD...

• Corneal Absorption:

1. Drugs administered by instillation must penetrate the eye & do so **primarily through the cornea**.
2. Corneal absorption is much **more effective** than scleral and conjunctival absorption.
3. Many ophthalmic drugs are **weak bases** and are applied into eye as aqueous solutions of their salts.
4. Depending upon pH, drug gets dissociated and pass through cornea, iris and ciliary body to the site of its pharmacological action.
5. Since, cornea is a membrane including **both hydrophilic and lipophilic layers**.
6. Most effective penetration is obtained with drugs having both lipid and hydrophilic properties.

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Classification of Ophthalmic Products:



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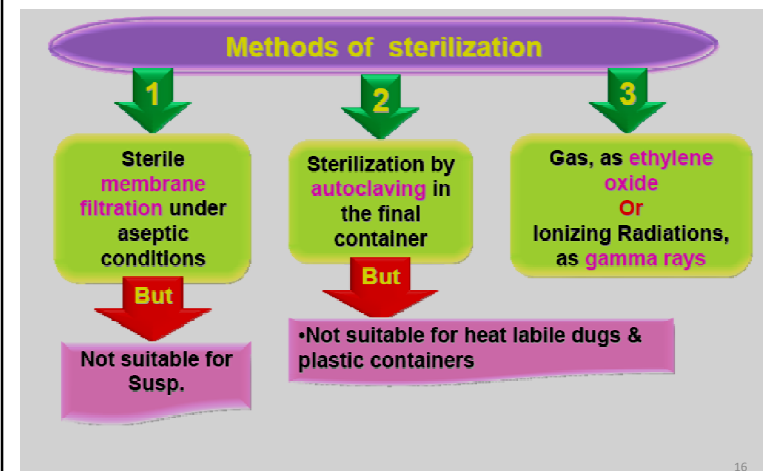
General Safety Considerations:

1. **Sterility**
2. **Ocular Toxicity & Irritation**
3. **Preservation & Preservatives**

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General Safety Considerations: CONTD...

1. Sterility



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General Safety Considerations: CONTD...

1. A sterile suspension, bottle, caps, dropper tips may be sterilized by using ethylene oxide or gamma radiation;
2. A suspended solid may be sterilized by dry heat, gamma radiation, or ethylene oxide;
3. A aqueous portion of composition may be sterilized by filtration;
4. A compounding is completed under aseptic conditions.
5. This sterile manufacturing process must then be validated to prove that NMT 3 containers in a lot of 3000 containers (0.1%) are non-sterile.

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General Safety Considerations: CONTD...

2. Ocular Toxicity & Irritation

1. **Albino rabbits** are used to test the ocular toxicity and irritation of ophthalmic formulations.
2. The procedure based on the **examination of the conjunctiva, the cornea or the iris.**
3. **E.g. USP procedure for plastic containers:**
 1. Containers are cleaned and sterilized as in the final packaged product.
 2. Extracted by submersion in saline and cottonseed oil.
 3. Topical ocular instillation of the extracts and blanks in rabbits is completed and ocular changes examined.
4. A modified '**Draize test**': official method for evaluation of acute ocular irritancy in rabbits.

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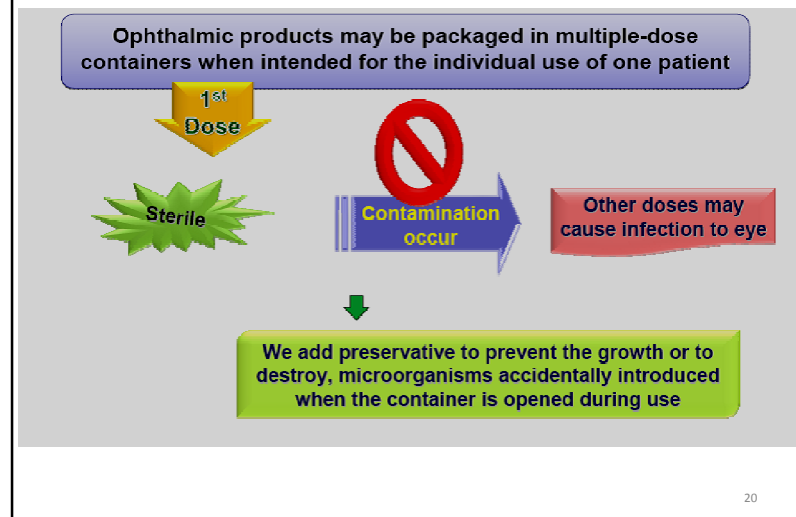
General Safety Considerations: CONTD...

3. Preservation & Preservatives

1. Preservatives are included in multiple-dose eye solutions for maintaining the product sterility during use.
2. Preservatives **not included in unit-dose package.**
3. The use of preservatives is prohibited in ophthalmic products that are used at the of eye surgery because, if sufficient concentration of the preservative is contacted with the corneal endothelium, the cells can become damaged causing clouding of the cornea and possible loss of vision.
4. **So these products should be packaged in sterile, unit-of-use containers.**
5. The most common organism is *Pseudomonas aeruginosa* that grow in the cornea and cause loss of vision.
6. *Staphylococcus aureus* is responsible for most bacterial infections of the eye.

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General Safety Considerations: CONTD...



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General Safety Considerations: CONTD...

Examples of Preservatives:

1- Cationic Wetting Agents:

- **Benzalkonium chloride (0.01%):**
- It is a **quaternary ammonium compound** and most **widely used** preservative.
- It is generally used **in combination with 0.01-0.1% disodium edetate (EDTA)**. The chelating, EDTA has the ability to render the resistant strains of *P. aeruginosa* more sensitive to benzalkonium chloride.

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General Safety Considerations: CONTD...

2- Organic Mercurials:

- When Benzalkonium chloride could not be used in a particular formulation, one of the following organic mercurial's is used:
 - Phenylmercuric nitrate: 0.002-0.004%
 - Phenylmercuric acetate: 0.005-0.02%.
 - Thiomersal: 0.01-0.02%

3- Alcohol Substitutes:

- Chlorobutanol(0.5%). Effective only at pH 5-6.
- Phenylethanol (0.5%)

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General Safety Considerations: CONTD...

5. Methyl & Propyl Paraben:

- They are used in combination, with methyl paraben (0.03-0.1%) and propyl paraben (0.01-0.02%)
- Parabens have also been shown to promote corneal absorption.

6. Cetrimonium Chloride:

- Used in dry eye treatment (0.01%)

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Sterilization:

1. **Moist heat sterilization**
2. **Membrane filtration**
3. **Gaseous sterilization**
4. **Radiation sterilization (^{60}Co)**

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Artificial Tears:

- **Artificial tears** are lubricant eye drops used to **treat the dryness and irritation** associated with deficient tear production in **Keratoconjunctivitis Sicca (dry eyes)**.
- They are also used **to moisten contact lenses** and in eye examinations.
- Artificial tears are **available over-the-counter**.
- Artificial tears are supplemented with other treatments in moderate to severe forms of dry eyes.
- Application of artificial tears every few hours can provide temporary relief from the symptoms of dry eyes.
- **Hydroxypropylcellulose** stabilizes and thickens the precorneal tear film and prolongs the tear film breakup time.

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Composition of Tears:

- Preparations contain **Carboxymethylcellulose, Polyvinyl alcohol, Hydroxypropyl methylcellulose (a.k.a. HPMC or hypromellose), Hydroxypropylcellulose and Hyaluronic acid (a.k.a. Hyaluronan, HA)**.
- They contain **water, salts and polymers but lack the proteins** found in natural tears.
- Patients who use them more frequently than once every three hours should choose a brand without preservatives or one with non-irritating preservatives.
- Besides lubricating your eyes, some artificial tears contain electrolytes.
- These additives may promote healing of the surface of the eyes.
- Artificial tears may also contain thickening agents, which keep the solution on the surface of your eyes longer.

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Additives:

- The inactive ingredients in ophthalmic solution and suspension dosage forms are necessary to perform one or more of the following functions:
 - **Adjust concentration and tonicity**
 1. Buffer and adjust pH,
 2. Stabilize the active ingredients against decomposition ,
 3. Increase solubility,
 4. Impart viscosity
 5. Act as solvent.

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Additives: CONTD...

1- Tonicity and Tonicity-Adjusting Agents:

1. The pharmacist should adjust the tonicity of an ophthalmic correctly (i.e. exert an osmotic pressure equal to that of tear fluid, generally agreed to be equal to 0.9% NaCl).
2. A range of 0.5-2.0% NaCl equivalency does not cause a marked pain response and a range of about 0.7-1.5% should be acceptable to most person.
3. Commonly tonicity adjusting ingredients include: **NaCl, KCl, Buffer salts, Dextrose, Glycerin, Propylene Glycol, Mannitol.**

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Additives: CONTD...

Isotonicity:

Lacrimal fluid is isotonic with blood having an isotonicity value corresponding to that of 0.9% NaCl solution

Ideally, an ophthalmic solution should have this isotonicity value

But

The eye can tolerate isotonicity from 0.6% to 2% NaCl without marked discomfort

Some ophthalmic solutions are necessarily hypertonic in order to enhance absorption and provide a concentration of the active ingredient strong enough to exert an effective action.

Additives: CONTD...

2- pH Adjustment and Buffers:

pH adjustment is very important as pH affects

- 1- To render the formulation more stable
- 2- The comfort, safety and activity of the product.

Eye irritation → Increase in tear fluid secretion
↓
Rapid loss of medication.

- 3- To enhance aqueous solubility of the drug.
- 4- To enhance the drug bioavailability
- 5- To maximize preservative efficacy

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Additives: CONTD...

- Ideally, every product would be buffered to a pH of 7.4 (the normal physiological pH of tear fluid).
- When necessary they are buffered adequately to maintain stability within this range for at least 2 years.
- If buffers are required their 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 the physiological range .

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Additives: CONTD...

Normal tears have a pH of about 7.4 and possess some buffer capacity.

So

Any formulation having different pH than 7.4 will be neutralized by normal buffer of tears.

But

Most alkaloidal salts precipitate as the free alkaloid at this pH. And many drugs are chemically unstable at pH levels approaching 7.4.

So

For this reason, the buffer system should be selected that is **nearest to the physiological pH of 7.4** & does not cause **precipitation** of the drug or its **rapid deterioration**.

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Additives: CONTD...

3- Stabilizers & Antioxidants:

- Stabilizers are ingredients added to a formula to **decrease the rate of decomposition** of the active ingredients.
- **Antioxidants are the principle stabilizers** added to some ophthalmic solutions, primarily those containing epinephrine and other oxidizable drugs.
- **Sodium bisulfite or metabisulfite** are used in concentration up to 0.3% in epinephrine hydrochloride and bitartrate solutions.
- The several antioxidant system have been developed: These consists of **ascorbic acid and acetylcysteine and sodium thiosulfate** .

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Additives: CONTD...

4- Surfactants:

- The order of surfactant toxicity is :

Anionic > Cationic >> Non-ionic

- 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 or Tween 20 and 80).

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Additives: CONTD...

5- Viscosity-Imparting Agents:

- **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 filtration more difficult.
- Commercial viscous vehicles are :
 1. **Polyvinyl Alcohol (liquifilm)**
 2. **Hydroxypropyl Methylcellulose**

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Additives: CONTD...

6- Vehicles:

- 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 are extremely sensitive to moisture.
- When oils are used as vehicles in ophthalmic fluids, they must be of the highest purity.

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Packaging:

- Plastic containers for ophthalmic preparations are made from **plastic composed of a mixture of homologous compounds having a range of molecular weights**.
- Such plastics frequently contain other substances such as **residues from the polymerisation process, plasticisers, stabilisers, antioxidants, lubricants and pigments**.
- The plastic bottle and dispensing tip is made of **low-density polyethylene (LDPE) resin**, which provides the necessary flexibility and inertness.
- The cap is made of harder resin than the bottle.

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Packaging: CONTD...

- A special plastic ophthalmic package made of **polypropylene** is introduced. The bottle is filled then sterilized by steam under pressure at 121°C.
- For deciding the suitability of a plastic for use as a container for ophthalmic preparations, factors such as **the composition of the plastic, processing and cleaning procedures, contacting media, adhesives, adsorption and permeability of preservatives, conditions of storage, etc. should be evaluated by appropriate additional specific tests**.

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Packaging: CONTD...

- Plastic containers for ophthalmic preparations comply with the following tests.
 - Leakage test;
 - Collapsibility test;
 - Clarity of aqueous extract;
 - Non-volatile residue and
 - Eye irritation tests.
- **Powder for reconstitution also use glass containers**, owing to their heat-transfer characteristics, 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.

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Isotonicity:

1. Solutions containing the same concentration of particles and thus exerting equal osmotic pressures are called **iso-osmotic**.
2. A 0.9% solution of NaCl (Normal Saline) is iso-osmotic with blood and tears.
3. The term **isotonic**, meaning equal tone, is sometimes used interchangeably with the term iso-osmotic.
4. The clinical significance of all this is to insure that isotonic or iso-osmotic solutions **do not damage tissue or produce pain when administered**.
5. Solutions which contain fewer particles and exert a lower osmotic pressure than 0.9% saline are called **hypotonic** and those exerting higher osmotic pressures are referred to as **hypertonic**.

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Isotonicity: CONTD...

6. **Hypotonic** solution produces painful **swelling** of tissues as water passes from the administration site into the tissues or blood cells.
7. **Hypertonic** solutions produce **shrinking** of tissues as water is pulled from the biological cells in an attempt to dilute the hypertonic solution.
8. The eye can tolerate a range of tonicities as low as **0.6% and as high as 1.8% sodium chloride solution**.
9. Several methods are used to adjust isotonicity of pharmaceutical solutions:
 1. **Sodium chloride equivalent method**
 2. **Freezing point depression method**
 3. **The isotonic solution V-value method**

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Isotonicity: CONTD...

Calculations to Prepare Isotonic Solutions:

- Comparison of depression in freezing point, a colligative property, between solutions is used.

Non Electrolyte:

- 1 gm molecular weight of a non electrolyte in 1000gm of water causes depression in freezing point of 1.86°C of pure water.
- Lachrymal fluid and blood have freezing point of - 0.52°C

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Isotonicity: CONTD...

- No. of gms (X) of Non-electrolyte per 1000 gms of water used to form a isotonic solution is given by:

$$X = \frac{0.52 \times \text{Mol. wt.}}{1.86}$$

- **Example:** Boric acid's **Mol. Wt. = 61.8 gms**

X = 17.3 gms i.e., 17.3 gms of boric acid in 1000gms of water should produce a solution isotonic with tears and blood.

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Isotonicity: CONTD...

Electrolyte:

- **More is the dissociation, less is the quantity of electrolyte required to produce same osmotic pressure.**
- **Calculation involve a dissociation factor (i)**
- Following (i) values are used generally:

Substances that dissociate into 2 ions = 1.8

Substances that dissociate into 3 ions = 2.6

Substances that dissociate into 4 ions = 3.4

Substances that dissociate into 5 ions = 4.2

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Isotonicity: CONTD...

- No. of gms (X) of Electrolyte per 1000gms of water used to form a isotonic solution is given by:

$$X = \frac{0.52 \times \text{Mol. wt.}}{1.86 \times i}$$

- Example:** NaCl Mol. Wt. = 58.5 gms; (i) = 1.8

X = 9.09 gms i.e. 9.09 gms of sodium chloride in 1000gms of water should produce a solution isotonic with tears and blood

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Isotonicity: CONTD...

NaCl Equivalent Method:

- One of the most widely used method.
- The NaCl equivalent (E)** is the amount of NaCl which has the same osmotic effect (based on number of particles) as 1 gm of the drug.

- ❖ Calculate the amount of NaCl required to make the following ophthalmic solution isotonic.

R_x
Atropine Sulfate 2%
NaCl qs
Aqua. dist. q.s. ad. 30 ml
Mft Isotonic Solution
(E of Atropine Sulphate 0.13 g)

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Isotonicity: CONTD...

- 1. Determine the amount of NaCl to make 30 ml of an isotonic solution

$$\frac{0.9 \text{ g}}{100 \text{ ml}} = \frac{X}{30 \text{ ml}} \quad X = 0.27 \text{ g} \quad \dots\dots\dots \text{Eq.(1)}$$

- 2. Calculate the contribution of atropine sulfate to the NaCl equivalent

$$\begin{aligned} 30 \text{ ml} \times 2 \text{ g}/100 \text{ ml} &= 0.6 \text{ g atropine sulfate} \\ E \text{ atropine sulfate} &= 0.13 \\ 0.6 \text{ g} \times 0.13 &= 0.078 \text{ g} \quad \dots\dots\dots \text{Eq.(2)} \end{aligned}$$

- 3. Determine the amount of NaCl to add to make the solution isotonic by subtracting (2) from (1)

$$0.27 \text{ g} - 0.078 \text{ g} = 0.192 \text{ g or } 192 \text{ mg}$$

- Other substances may be used, in addition to or in place of NaCl, to render solutions isotonic. This is done by taking the process one step further and calculating the amount of the substance that is equivalent to the amount of NaCl calculated in step 3.

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Isotonicity: CONTD...

- ❖ Calculate the amount of NaCl required to make the following ophthalmic solution isotonic.

R_x
Dexamthasone Sodium Phosphate 0.1%
NaCl qs
Aqua. dist. q.s. ad. 30 ml
Mft Isotonic Solution
(E of Dexamethasone Sodium Phosphate 0.18 g)

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Isotonicity: CONTD...

- 1. Determine the amount of NaCl to make 30 ml of an isotonic solution

$$\frac{0.9 \text{ g}}{100 \text{ ml}} = \frac{X}{30 \text{ ml}}$$

$$X = 0.27 \text{ g}$$

- 2. Calculate the contribution of Dexamthasone Sodium Phosphate to the NaCl equivalent

$$30 \text{ ml} \times 0.1 \text{ g}/100 \text{ ml} = 0.03 \text{ g}$$

E of Dexamethasone Sodium Phosphate = 0.18 g

$$0.03 \times 0.18 = 0.0054 \text{ g}$$

- 3. Determine the amount of NaCl to add to make the solution isotonic by subtracting (2) from (1)

$$0.27 \text{ g} - 0.0054 \text{ g} = 0.2646 \text{ g}$$

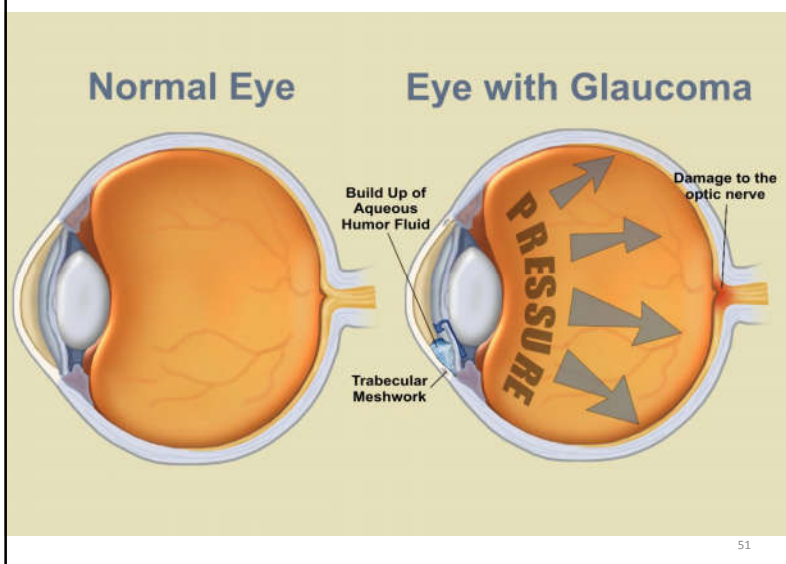
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Glaucoma & Its Management:

1. Glaucoma is a common eye condition in which vision is lost because of damage to the optic nerve.
2. The optic nerve carries information about vision from the eye to the brain.
3. In most cases, the optic nerve is damaged when the pressure of fluid inside the front part of the eye rises.
4. However, glaucoma-related eye damage can occur even when the fluid pressure is normal.

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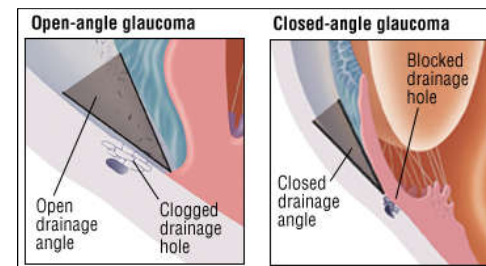
Glaucoma: CONTD...



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Glaucoma: CONTD...

- **Open angle glaucoma (most common)**, fluid circulates freely in the eye and the pressure tends to rise slowly over time. Gradual loss of vision is usually the only symptom.
- **Closed angle glaucoma**, develops suddenly and usually causes eye pain and redness. In this form of glaucoma, pressures rise quickly because normal fluid flow within the eye becomes blocked. This happens when a structure called the angle (where the iris and cornea meet) closes.



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Glaucoma: CONTD...

1. **Glaucoma treatment** often starts with prescription eyedrops.
2. They decrease eye pressure by improving how fluid drains from your eye or by decreasing the amount of fluid your eye makes.
3. Prescription eye drop medications include:
 - 1) Prostaglandins
 - 2) Beta blockers
 - 3) Alpha-adrenergic agonists
 - 4) Carbonic anhydrase inhibitors
 - 5) Miotic or cholinergic agents
4. Other treatment options:
 - 1) Laser therapy
 - 2) Filtering surgery
 - 3) Drainage tubes
 - 4) Electrocautery

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Evaluation of Ophthalmics:

1. **Sterility Test**
2. **Clarity Test**
3. **Leaker Test**
4. **Metal particles in ophthalmic ointment**

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Evaluation: CONTD...**1. Sterility Test:**

Two basic methods for sterility testing:

I) Direct Inoculation Method:

It involves the direct introduction of product test samples into the culture media.

II) Membrane filtration Method:

It involves filtering test sample through membrane filter, washing the filter with fluid to remove inhibitory property and transferring the membrane aseptically to appropriate culture media.

Detection of contamination used to two culture media:-

A) Soybean-casein digest medium:- Incubated at 20 to 25°C

B) fluid thioglycollate medium:- Incubated at 30 to 35°C on 7 Days

Evaluation: CONTD...**2. Clarity Test:**

Ophthalmic Solution by definition contain no undissolved ingredients and are essentially free from foreign particles .

➤ Visual Inspection:

Under a good light, baffled against reflection into the eye and viewed against a black and white background with context set in motion with swilling action.

➤ **Instrumental method:** It is utilizing the principle of light scattering, light absorption and electrical resistance to obtain particle count and size distribution – destruction of product units- only for quality control testing.

Instrumental method utilizing video image projection detects moving particles without destruction of product units-used for inline detection.

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Evaluation: CONTD...

3. Leaker Test:

- Select 10 tubes of the ointment with seals applied when specified.
- Thoroughly clean and dry the exterior surfaces of each tube with an absorbent cloth.
- Place the tubes in horizontal position on a sheet of absorbent blotting paper in an oven maintained at temperature of 60 ± 3 for 8 hours.
- No significant leakage occurs during or at the completion of the test.
- If leakage is observed from one, but more than one of the tubes repeat the test with 20 additional tubes of the ointment.
- The requirement is met if no leakage is observed from the first 10 tubes tested or if leakage is observed from not more than one of 30 tubes tested

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Evaluation: CONTD...

4. Metal Particles in Ophthalmic Ointment:

- Extrude as completely as practicable the content of 10 tubes individually into separate, clear, flat-bottom, 60-mm petridishes that are free from scratches.
- Cover the dishes and heat at 85°C for 2 hours, increasing the temperature slightly if necessary to ensure that a fully fluid state is obtained.
- Taking precautions against disturbing the melted sample, allow each to cool to room temperature and to solidify.
- Remove the covers and invert each petridish on the stage of suitable microscope adjusted to furnish 30 times magnification and equipped with an eye pieces micrometer disk that has been calibrated at the magnification being used.

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Evaluation: CONTD...

- Examine the entire bottom of the petridish for metal particles.
- Count the number of metal particles that are $50\mu\text{m}$ or larger in any dimension. The requirements are met if the total number of such particles in all 10 tubes does not exceed 50 and if not more than 1 tube is found to contain more than 8 such particles.
- If these results are not obtained, repeat the test on 20 additional tubes.

The requirements are met if the total number of metal particles that are $50\mu\text{m}$ or larger in any dimension does not exceed 150 in all 30 tubes tested and if not more than 3 of the tubes are found to contain more than 8 such particles each.

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Question Bank

2 Marks

1. Define ophthalmic products. Give any four ideal requirements for ophthalmic preparations.***
2. Give composition of tears.
3. Enlist different evaluation parameters for eye ointment.
4. Enlist different evaluation parameters for eye drops.
5. Classify ophthalmic preservatives with one example.*
6. Classify ophthalmic products.
7. State different steps involved in calculation of isotonicity by NaCl equivalent method.
8. Give ideal characteristics for ophthalmic products.

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5 Marks

1. Discuss anatomy & physiology of eye.***
2. Define antimicrobials. Classify ophthalmic preservatives with examples. Comment on organic mercurial's used as ophthalmic preservatives.***
3. Define isotonicity. Give difference between hypertonicity and hypotonicity. How many grams of sodium chloride is required in compounding following prescription ?

Rx

Pilocarpine Nitrate – 0.3gm

Sodium chloride – q.s

Purified water – 30 ml

Make an isotonic solution.

Note : Sodium chloride equivalent of pilocarpine nitrate is 0.23.

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The End

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**You have to fight
through
the bad days
in order to
earn
the best days.**

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