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Design and Evaluation of Bioadhesive Ocusert Containing Timolol Maleate for Enhanced Ocular Bioavailability

Gauri Gupta[1], Rahul Sharma[2], Rakesh Sirvi[3]
School of Pharmaceutical Sciences, Jaipur National University, Jagatpura, Jaipur 302017, Rajasthan, India

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ABSTRACT
Ocular drug delivery remains a significant challenge due to the unique anatomical and physiological barriers of the eye, including tear turnover, nasolacrimal drainage, and the impermeability of the corneal epithelium. These factors result in the poor bioavailability of conventional eye drops, necessitating frequent administration and often causing systemic side effects. Timolol maleate, a non-selective β-adrenergic blocker, is widely prescribed for managing intraocular pressure (IOP) in glaucoma and ocular hypertension. Although effective, its current eye drop formulation suffers from rapid precorneal loss and short residence time, limiting therapeutic efficiency. To overcome these limitations, bio adhesive ocular inserts were formulated using biocompatible polymers—chitosan and sodium alginate—employing the solvent casting method.
The formulated inserts were designed to enhance ocular bioavailability, prolong drug contact time, and ensure sustained release of timolol maleate. Various ratios of chitosan and sodium alginate were evaluated to optimize film properties. Each insert was engineered to contain 3 mg of timolol maleate and was shaped to fit within the conjunctival sac. The inserts were subjected to a series of physicochemical and mechanical evaluations including visual appearance, weight uniformity, surface pH, folding endurance, thickness, drug content, swelling index, and bio adhesive strength.
Results indicated that the inserts exhibited uniform weight and thickness, an ideal surface pH close to physiological tear fluid, and excellent folding endurance, indicating good flexibility and mechanical stability. The bio adhesive strength was satisfactory, ensuring effective adherence to the ocular mucosa, which contributes to prolonged residence time. Drug content analysis confirmed uniform distribution and accurate dosing, while swelling studies revealed that the inserts were capable of absorbing tear fluid without rapid disintegration, allowing for sustained drug release.
Additionally, the inserts offered several advantages over conventional eye drops, including reduced dosing frequency, minimal systemic absorption, improved patient compliance, and the potential to bypass corneal barriers via conjunctival-scleral routes. The antioxidant property of timolol maleate further supports its suitability in managing oxidative stress within the trabecular meshwork, a key factor in the pathogenesis of primary open-angle glaucoma.

Key words: Timololmaleate, Glaucoma, Bio-adhesive, Ocular insert, ocusert, Tear film, Bio availabilty

I. INTRODUCTION

The eyes surface is abundant in nutrient, which in turn supports a variety of microorganisms that make up the normal ocular flora [1]. The eye is a fascinating organ. The flow of tears and blinking reflex create a favorable environment and help eliminate foreign particles from the eye.in the context of ocular drug delivery, the eyes protective mechanisms lead to limited drug adsorption and often a brief duration of the therapeutic effects. One contributing factor to the relatively low bioavailability of standard eye drops is the brief contact time with the cornea. When drug solution are applied in drug concentration within 4 to 20 minutes [2]. additionally, the absorption of drugs is influenced by their chemical properties, as the corneas permeability is affected by the molecular size and hydrophobic characteristics of the drugs [3].

A significant challenge in ocular in ocular therapeutics is achieving an optimal concentration at target site. The poor bioavailibity of drugs from ocular formulation is primarily due to factors such as tear production, ineffective absorption, short retention time, and the impermeability of the corneal epithelium. Furthermore, drugs that are either hydrophobic or unstable at the PH levels suitable dor the eye cannot be developed as eye

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drops. Due to the bioavailability challenge associated with the ocular route, many effective drugs still require investigation for their therapeutic potential through topical application. Innovative drug delivery systems may serve as a promising approach to explore the therapeutic potential of these drugs [4-7].

Ocular inserts are characterized as thin, sterile, multilayered device with a solid or semisolid consistency that are impregnated with drugs and specifically designed in size and shape for eye application. These ocular inserts provide numerous benefits, including an extended ocular residence time, slow and consistent drug release, precise dosing, minimized systemic absorption, improved patient compliance, the potential for targeting internal ocular tissues, enhanced shelf life compared to aqueous solution, and the absence of preservatives, which lowers the chances of sensitivity reaction [8-9]. additionally, they offer prolonged drug action and improved bioavailibity [10].

Glaucoma is defined by an elevation in intraocular pressure (IOP) beyond the typical range. There are several types of glaucoma, including open-angle, and congenital forms.

Every form of glaucoma can be categorized into primary and secondary types, which is defined when there is no identified cause for the glaucoma or when underlying ocular or systemic condition contribute to its development [11].

TIMOLOL MALEATE

Timolol maleate is a non-selective beta adrenergic blocker primarily utilized as an eye drop formulation for managing glaucoma and ocular hypertension since it received approval for widespread use in 1978. It has the most extensive history of safety and effectiveness in reducing intraocular pressure (IOP) and is typically administered through standard eye drops one or multiple times daily. Timolol maleate posses unique antioxidant properties that impact the trabecular meshwork (TM) Cells in ocular tissues, particularly in cases of primary open angle glaucoma.

The yound and mature human trabecular meshwork (TM) and a cellular structure made up entirely of DNA, with or without mitochondria, were examined. The final assessment of DNA fragmentation was conducted using a halo test, while DNA breakage was measured based on the levels of 8-hydroxy-20-deoxyguanosine. The function of mitochondria was evaluated using the 3-[4,5-Dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide assay. The antioxidant effects of the drugs dorzolamide and timolol were tested on biopsy samples of TM and TM from human cells that were stimulated with hydrogen peroxide. It was found that timolol demonstrates antioxidant properties even in the presence of mitochondria. Despite this, dorzolamide exhibited greater antioxidant activity when in the presence of mitochondria, which included subcellular fractions and TM cells from young humans, along with functioning mitochondria. The findings distinctly showed that timolol possessed a direct antioxidant effect on intact cells, whereas dorzolamide demonstrated antioxidant activity under oxidative stress when intact mitochondria were present [12].

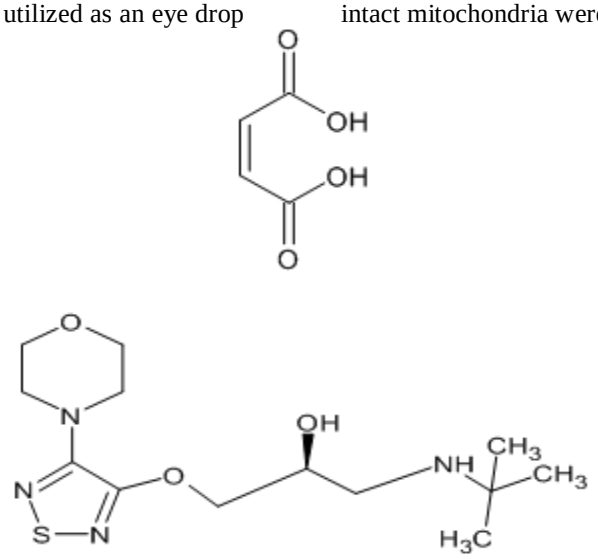

Fig. 1: Structure of timolol maleate

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ANATOMY AND PHYSIOLOGY OF EYE

The human eye is a highly sensitive and intricate organ that demonstrates the anatomy of the human eye. It consists of both anterior and posterior chambers. The front segment comprises the tear film, cornea, pupil, lens, and ciliary body. In contrast, the back segment includes the conjunctiva, sclera, choroid, retina, vitreous humor, and optic nerve. The structure and volume of tears are regulated by orbital glands and epithelial secretions. The cornea, located at the front of the eye, helps to transmit and focus light into the eye. It is categorized into three layers: epithelium, stroma and endothelium. The epithelium consists of five to seven layers of tightly connected cells. The stroma is a dense layer that is primarily water-based. The endothelium maintains the cornea's transparency[13].

The iris is the colored part of the eye that regulates the amount of light that enters. Thepupil, which is the dark central opening in the iris, adjusts its size based on the light available. The lens is a transparent structure that focuses light onto the retina. The ciliary body consists of pigmented and non pigmented ciliary epithelia, a stroma, and ciliary muscles. The capillaries within the ciliary body facilitate communication between the anterior and posterior segments[14]. The vitreous humor is a gel-like,transparent,avascular connective tissue located between the lens of the eye and retina. It consists of 99.9% water with hyaluronic acid,ions and collagen[14]. The conjunctiva is a thin,translucent membrane that lines the interior of the eyelids and protects the sclera's front surface. Three layers make up this mucous membrane: the substasntia propria, which encloses blood vessels, lymphaticvessels, and nerves; the outside epithelium; and the submucosa layer, which is connected to the sclera [15]. The cornea's sclera is continuous. Collagen and mucopolysaccharides make up its composition between the retina and the sclera is a circulatory layer called the choroid. The back of the eye is covered in a thin layer of tissue called the retina, which is made up of glial and neuroglial cells. It generates electrical impulses that travel to the brain via the optic nerve [14].

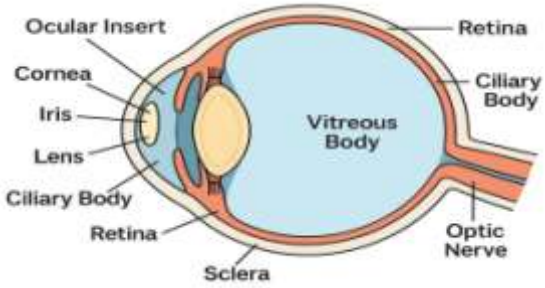

Fig.2 : an eye showing the position of ocular insert

Barriers to effective drug delivery

ANATOMICAL BARRIER

When a dosage form is applied to the skin, it can enter through two pathways: the cornea or the non-corneal route. The cornea is highly compact multilayered structure made up of five layers: epithelium, bowman's membrane, stroma, Descemet's membrane, and endothelium. Among these layers, the epithelium serves as the primary barrier [16].

The non- corneal pathway avoids the cornea and entails passage through the conjunctiva and sclera. This pathway is particularly significant for larger, hydrophilic molecules like peptides, proteins, and siRNA [17].

PHYSIOLOGICAL BARRIER

The tear film serves as the main defense mechanism for the eye. The effectiveness of drugs applied topically is additionally diminished by precorneal factors, which includes drainage of the solution, dilution by tears, turnover of tear, and heightened tearing [18]. The lacrimal fluid is an isotonic aqueous solution that consisted of a blend of protein, including lysozyme, and lipids [19].

COMPOSITION OF TEAR

Tear fluid is made up of salts, carbohydrates, chemical substance, 0.7% protein, and lysozyme. It consists of 98.2% water and 1.8% solids. The organic component include protein (0.67%), NaCl (0.66%) , and non-protein nitrogen (NPN) at 0.05%. urea makes up 0.03%. Additionally, other mineral elements such as

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sodium, potassium, and ammonia comprise 0.79% [20].

BIOADHESIVE OCULAR INSERT: CONCEPT AND ADVANTAGES

Drugs can be administered by the diffusional approach with ocular implants. By removing absorption peaks, the solid dosage form reduce side effects while de levering an ophthalmic drug at relatively steady pace [21].ocular inserts are cutting edge drug delivery systems that eliminate the need for frequent medication administration by releasing medications at predetermined and predictable rates. Ocular inserts are sterile preparations that are placed in the conjunctival sac or cul-de-sac and are made especially for use in the eyes Compared to conventional. Ophthalmic inserts offer various advantages compared to conventional dosage forms, such as prolonged ocular retention, sustained release, accuratedosing, and reduced administration frequency [22]. In ocular inserts, films are placed directly in the cul-de-sac, enhancing ocular bioavailability by prolonging contact time with the corneal tissue and reducing the necessity for frequent administration [23].

Ocuserts are pliable, flat, insoluble devices composed of two layers that encase a drug reservoir and are used commercially for delivering a precise dosage of medication. Each ocusert consists of three components: a central drug reservoir, and an external annular ring that facilitates easy handlingand accurate insertion [24]. The main aim of ocusert development is to deliver a continuous and controlled release of an ophthalmic medication to the eye[25].

HISTORY

The first solid medication was developed in the 1800s by soaking squares of dry filter paper in dry solutions like atropine sulphate and pilocarpine hydrochloride. Small pieces were then cut and placed beneath the eyelids. Later, lamellae emerged as the precursor to contemporary soluble inserts. These lamellae were made from glycerinated gelatin and contained various ophthalmic drugs. Up until the early 1900s, official pharmacopoeias recognized glycerinated gelatin 'lamellae'. Although lamellae were used, they were eventually discontinued when stricter sterility standards for ophthalmic products were established. Currently, there is a renewed interest in ophthalmic inserts [26].

BENEFITS OF OCULAR INSERTS: [27,28,29]

1. Extended contact time with the eye enhances the absorption of medication.
2. Enhanced ocular permeability compared to standard formulations leads to longer-lasting drug effects and increased bioavailability in the eye.
3. Delivering the correct dosage into the eye ensures effectiveness.
4. A reduced incidence of systemic side effects.
5. Less frequent doses are required compared to conventional dodge forms.
6. It is possible to address the effects of regularly using a traditional dosage form.
7. Increased comfort leads to better patient adherence.
8. The handling process is straightforward.
9. Vision and oxygen permeability remain unaffected.
10. Consistent release kinetics.
11. Prepared in a sterile environment.
12. Improved patient adherence due to reduced administration frequency and fewer ocular and systemic side effects.
13. Potential to reach inner ocular tissues via non-corneal pathways (conjunctival scleral routes.)
14. Extended shelf life in a comparison to aqueous solutions.

Generally, all types of ocuserts have three layers.

A central drug reservoir is a slim disc that holds a mixture of medications. The drug is embedded within a polymer, enabling it to disperse from the reservoir. A rate controlling membrane is comprised of two clear discs made from ethylene vinyl acetate, which is a copolymer. This membrane enables a controlled release of the medication from the drug reservoir. An external yearly ring is included for improved handling and precise insertion

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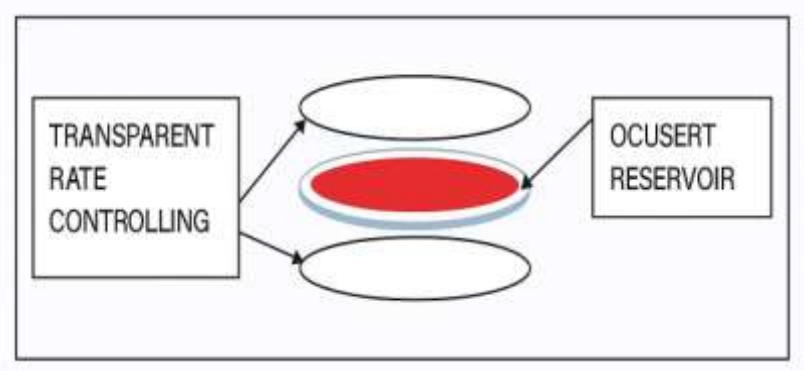

Fig. 3: Diffusional insert

II. MATERIALS AND METHODS

MATERIALS

Timolol maleate was received as a complimentary sample from M.K. Chemicals,Bangalore. Chitosan and sodium alginate were provided as a complimentary sample by S.D scientific and chemicals,Jaipur.

METHODS

The ocular insert that contain bio adhesive timolol maleate were developed using sodium alginate and water-soluble chitosan through a solvent casting method. Solutions of the polymers were created by dissolving sodium alginate and chitosan in varying ratios, along with timolol maleate and glycerin in distilled water.

Chitosan was incorporated into an aqueous solution of sodium alginate while being stirred continuously. The plasticizer was subsequently added, and the drug-polymer mixtured were mixed for 12 hours and left overnight to eliminate any trapped air bubbles. The pH levels of the solutions were observed to be between 5 and 8. The solutions were then deposited into glass rings set on mercury within glass petri dishes. The solvent was allowed to evaporate by placing the petri dishes in an oven set to 40±2℃. The dried films were carefully extracted from the petri dish and then trimmed into oval-shaped inserts with the assistance of a die sharp edges (13.2 mm long and 5.4 mm wide) was utilized.

EVALUATION TESTS [30-35]

1. PHYSICAL APPEARANCE

The visual aspect of the film was analyzed. The hue and texture of the film were noted. The distribution of the drug throughout the film was also examined.

2.Weight Uniformity

The weight variation test was performed by measuring three patches taken from various locations of the same formulation, and their individual weights were obtained using a digital balance. The average value was calculated, and the standard deviation of weight variation was determined based on the mean value.

3.Surface pH determination

Inserts were allowed to swell for 5 hours on agar plate made by dissolving 2% m/v agar in warm simulated tear fluid, consisting of 0.670 g sodium chloride, 0.200 g sodium bicarbonate, 0.008 g calcium chloride, and enough purified water to reach a total of 100 g at pH 7.4 while stirring, and then pouring the mixture into a petri dish to gel at room temperature. The surface pH was determined using pH paper placed on the surface of the swollen patch.

4.Folding endurance

Folding endurance was quantified by the number of times the insert was folded at the same location, either until the specimen broke or visible cracks formed. This test was crucial for assessing the sample's capacity to endure folding and also provided insight into its brittleness. The specimen was folded at its midpoint using the fingers and thumb and then subsequently opened. This action was referred to as a single fold. The procedure was continued until the insert displayed either breakage or cracks at its center.

5.Thickness

The films were assessed for thickness using a micrometer with a sensitivity of 0.001 mm. Ten readings were averaged to obtain the final measurement. The mean thickness and standard deviation were computed.

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6.Bioadhesive strength

The bio adhesive strength of the insert was evaluated using a modified physical balance. The membrane was secured to the open end of a glass vial that was filled with an isotonic phosphate buffer. The vial was positioned at the center of a glass beaker containing STF (pH 7.4,at 37±2℃). In a separate setup, the insert was attached to the undecided of a rubber stopper, which was connected to the level of physical balance. The weight placed on the other side of the balance, necessary to separate the patch from the conjunctival surface, served as the measure of bio adhesive strength.

7.Drug content

The drug concentration was determined by grinding the ocular inserts in 20 ml of phosphate buffer at pH 7.4 using a mortar and pestle. The mixture was filtered, and 1 ml of the resulting solution was taken, diluted and analyzed using a UV-Visible Spectrophotometer(Model-1700, Shimadzu,Japan).

8.Swelling Index

The extent of swelling in the polymer is influenced by the polymer concentration, ionic strength and water availability. To assess the swelling index of the prepared ocular inserts, the initial weight of the insert was recorded before it was immersed in freshly boiled and cooled artificial tear fluid ata pH of 7.4, maintained at a temperature of 37℃. The insert was taken out of the solution every hour, excess surface water was blotted away using filter paper, and the insert was weighed again.

III. CONCLUSION

The development of bio adhesive ocular inserts for controlled timolol maleate delivery presents a promising solution to the challenges faced by conventional eye drop formulations. Traditional treatments suffer from poor bioavailability and require frequent administration, which can lead to patient non-compliance. In contrast, the chitosan and sodium alginate-based ocular inserts developed in this study effectively enhance drug retention and bioavailability by prolonging contact with the eye and enabling sustained drug release. These inserts demonstrated excellent physicochemical properties, including appropriate thickness, bio adhesive strength, swelling behaviour, and consistent drug content.

Timolol maleate, a well-established β-blocker for managing intraocular pressure (IOP) in glaucoma, was successfully incorporated into the ocular insert. The drug's antioxidant properties, especially in protecting trabecular meshwork cells, suggest additional therapeutic benefits beyond IOP reduction. The design of the insert, with its central drug reservoir and rate-controlling membranes, ensures precise dosing and reduces the need for frequent administration, improving patient adherence.

These bio adhesive ocular inserts have the potential to revolutionize glaucoma treatment by addressing the limitations of conventional drug delivery systems, offering both controlled release and enhanced ocular tissue targeting. Overall, this innovative drug delivery approach could improve therapeutic outcomes, reduce systemic side effects, and enhance patient compliance. Future studies and clinical trials will be crucial to validate their efficacy and pave the way for their commercialization.

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