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Review Article

Ocuserts: A novel ocular drug delivery system

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Abstract

Ocular drug delivery poses significant challenges due to the unique anatomy and physiology of the eye. Conventional dosage forms, such as eye drops, often suffer from poor bioavailability, short residence time, and frequent dosing. To overcome these limitations, ocular inserts have emerged as a promising solution. These inserts provide sustained and controlled drug release, increasing the contact time with the ocular surface and enhancing bioavailability. This review discusses the advantages and disadvantages of ocular inserts, their classification, mechanism of drug release, formulation methods, and evaluation parameters. Ocular inserts offer several benefits, including improved patient compliance, reduced dosing frequency, and increased therapeutic efficacy.

Keywords: Eye, Ocuserts, Controlled release, Corneal contact, Bioavailability

1. Introduction:

Ophthalmic inserts offer many advantages over conventional dosage forms such as increased ocular residence, sustained release, accurate dosing, and reduced dose frequency [1]. Ophthalmic preparations are sterile, specialized dosage forms that can be applied topically to the exterior of the eye, administered intraocularly or periocularly, or used in combination with an ophthalmic device [2]. Ophthalmic preparation is employed for local therapy rather than systemic treatment owing to the high concentration of medications in the eye's blood [3]. "Drug absorption in the eye is hindered by protective mechanisms and factors like tear drainage, metabolism, and limited corneal permeability, making it challenging to achieve effective drug delivery" [4]. The drug delivery system for eye gives many challenges, tasks and lots of opportunities to the researchers. Although ophthalmic drug delivery is one of the most challenging endeavours which is facing by the pharmaceutical researchers. For ocular drug delivery one of the major challenge is to maintain and obtain a therapeutic level at the site of action for desired period of time. The anatomy, physiology and biochemistry of the eye render this organ exquisitely impervious to foreign substance [5]. Because of the nature of the disease and the obstructions on the ocular surface, particularly in the posterior region, treating ocular diseases is difficult for scientists. By altering viscosity and using polymers, researchers have attempted to enhance the absorption of ocular medications in recent years 6. Many ophthalmic formulations like solutions, suspensions, ointments suffer from the drawbacks like precorneal elimination, high variability in efficiency and blurred vision. The major problem associated with these conventional dosage forms is the bioavailability of drug [7].

2. Human eye:

Eye is an essential part of human body which is about an inch in diameter. Eye is specialized for sight through an arrangement of multiple tissues that functions to focus, transmit, and detect incoming light. The front part of the eye includes the iris, cornea, pupil, sclera, and conjunctiva (a thin layer of a tissue covering the front of the eye, except the cornea) [8]. Thus there is a need of controlled drug delivery system to prolong the pre-corneal resistance time along with a therapeutic effect [9]. To achieve a therapeutic drug concentration in the eye via local or systemic pathways, a number of ocular obstacles must be removed. The blood ocular barrier (BOB) regulates the composition and eye pressure of aqueous humor by controlling its inflow and outflow. The administration of ocular drugs is impeded by physiological and anatomical limitations [10–11].

1) Physiological barriers, which include,

- Tear turn over

- Naso lachrymal drainage
- Blinking action of the eye

2) Static and dynamic anatomical barriers oversee preventing medications from entering the anterior region of the eye. Among the static barriers are-

- Corneal epithelium
- Stroma
- Blood aqueous barrier (BAB)

3) Dynamic barriers include,

- Conjunctival blood
- Lymph flow
- Tear drainage [12]

2.1 Absorption of drugs in the eye

Increasing the duration of an eye drug's interaction with the corneal surface can enhance its therapeutic efficacy. In order to prolong the length of drug eye contact, preparations are made more viscous or the medicine is produced as an ointment that is insoluble in water. Unfortunately, these dose forms do not produce consistent drug bioavailability and only provide a somewhat maintained drug-eye contact compared to eye drop solutions. Throughout the course of the therapy, repeated medication is still necessary. The eye drop dosage form is simple to use, but it has an intrinsic disadvantage in that only 1–10% of the entire dose is bioavailable because the majority of the instilled volume is removed from the precorneal area. Conjunctival absorption, quick solution drainage caused by gravity, induced lachrymation, blinking reflex, limited corneal permeability, and regular tear turnover are the main causes of this [13].

2.2 Ophthalmic preparations

Sterile liquid, semi-solid, or solid therapies for the conjunctiva or eyelids are known as ophthalmic preparations [14]. Conjunctivitis, bacterial keratitis, corneal ulcers, and other eye conditions are all cured by ophthalmic drugs. Ointments, eyedrops, suspensions, and other forms of ocular medicine delivery are frequently used. Although widely used, these conventional dosage forms have several disadvantages, such as a shorter duration of action, shorter corneal contact time, poor absorption, frequent dosing, and noncompliance from patients. When eye drops is topically administered then only less than 5% of administered dose is absorbed [15].

The blank polymeric patches were prepared using PVA and HPMC alone by solvent casting technique The matrix controlled inserts were prepared by solvent casting technique [16,17]. for efficient ocular drug delivery with eye drops, high corneal permeation with longer drug cornea contact time is required. Several efforts have been made toward improving precorneal residence time and corneal penetration [18]. Micro-structured reservoir-based systems offer a number of advantages. To control dose form, these technologies can be used both within and outside the body. It enhances distribution time and dosage form stability. In contrast to sustained-release, it can help with zero-order medicine distribution. Precise distribution was aided by advancements in reservoir drug delivery [19].

3. Ocuserts

First developed in the United States of America in 1975, the Ocusert system was produced by the "Alza Corporation." This flat, flexible, solid, semisolid device consists of a drug reservoir and a rate-controlling membrane. The primary objective of ocusert development is the continuous, controlled administration of an ophthalmically active drug to the eye [20]. Sterile controlled-release formulations known as occuserts prolong the duration of pharmaceutical residence and stop nasolacrimal leaking [21]. They are solid or semisolid, sterile preparations intended for ocular administration. Ocusert is a drug reservoir sandwiched between two microporous membrane sheets. Lachrymal fluid penetrates the membrane, controlling medication release. Internal pressure is high enough to force medication from the reservoir. Diffusion controls medication delivery rate [22].A drug reservoir called an occusert is positioned between two sheets of microporous membrane. By penetrating the membrane, lachrymal fluid regulates the release of medications. Medication can be forced out of the reservoir due to the high internal pressure. The pace of drug distribution is regulated by diffusion [23]. Two sheets of microporous membrane are sandwiched by an occusert, a drug reservoir. Lachrymal fluid controls the release of drugs by piercing the membrane. Because of the high internal pressure, medication may be driven out of the reservoir. Drug delivery by ocular inserts based on diffusion mechanism has been established. By preventing absorption peaks, a solid dosage form like this one minimizes adverse effects by delivering an ophthalmic medicine at a very constant rate [24]. Ocuserts increase patient compliance by prolonging the duration of medication, enhancing bioavailability, and reducing dosing frequency. Ocular administration is made possible by the medication's-controlled release. Ocuserts help patients and physicians save time [25]. To guarantee a prolonged release appropriate for topical eye therapy, ophthalmic inserts aid in extending the duration of contact between the preparation and the conjunctival tissue [26].

3.1 Advantages of ocuserts

Various advantages of ocuserts are as follows:

1) Increased contact time with the ocular surface can be obtained and hence bioavailability is also increased.
2) Sustained and controlled drug delivery can be achieved.
3) Due to extended drug release, better efficacy is obtained.
4) Accurate dosing can be done.
5) Less systemic side effects.
6) Less frequent dosing is required unlike conventional dosage form.

7) Overcoming the effects of repeated administration of a conventional dosage form is possible.
8) Increased comfort and patient compliance.
9) Handling is easy.
10) Vision and oxygen permeability are not interfered.
11) Reproducible release kinetics.
12) Sterile preparation.
13) A stable drug delivery system and better therapeutic performance of the formulation can be obtained.
14) Due to the lack of water in the formulation, shelf life is improved when compared to aqueous solutions.
15) Barriers like drainage, lacrimation, conjunctival absorption, etc. can be avoided [3, 27].

3.2 Disadvantages of ocuserts

Various disadvantages of ocuserts are as follows:

1) A significant drawback of ocular inserts lies in their 'solidity'; patients, frequently hypersensitive, see them as foreign objects in the eye. This may represent a significant physical and psychological obstacle to user acceptance and compliance.
2) Occasional inadvertent loss during sleep or while rubbing the eyes.
3) Their interference with vision.
4) The challenging placement and removal of the ocular inserts, particularly for insoluble types.
5) The medicinal solution comes into contact with the eye surface for just a short period of time.
6) Insufficient bioavailability.
7) Instability of dissolved drugs [28,29].

3.3 Classification of ocuserts

The ocuserts have been classified, based on their physicochemical behavior as given below;

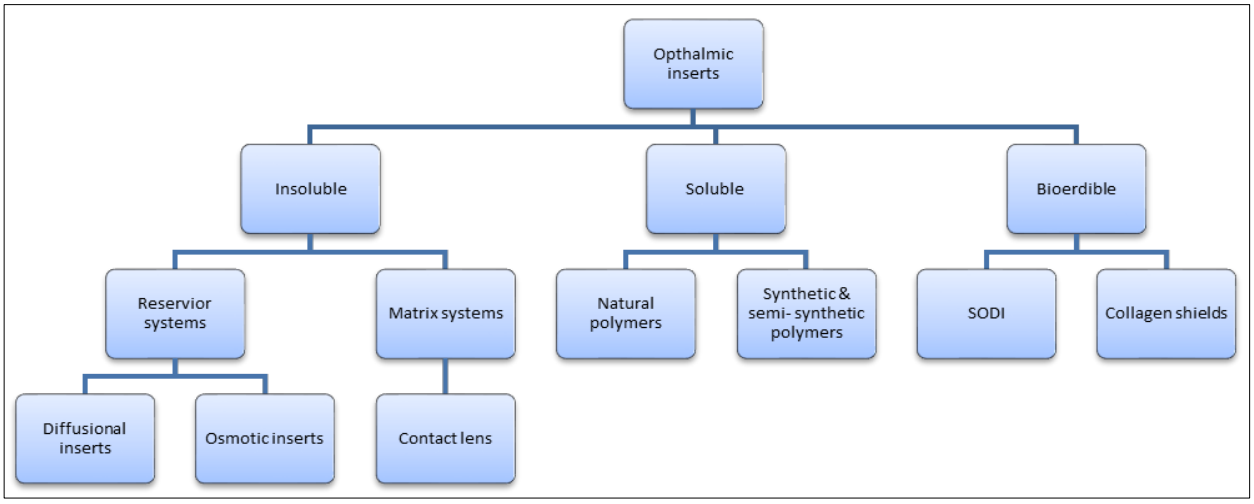

Figure 1: Classification of ocusert [6].

3.3.1. Insoluble ocuserts

Drugs are administered using this kind of delivery system in a variety of methods and at a regulated pace; however, the system must be withdrawn once it is empty.

Insoluble ocuserts are divided into 2 categories:

Reservoir system

In this system, diffusion or osmosis release drugs. It may be colloid, gel, semisolid, liquid, solid matrix, or carrier.

Diffusional inserts

In this form, drug release is diffusional. The ocular insert is a permeable membrane medication delivery method.

Osmotic inserts

These can be divided into two types and comprise a central component encircled by a part:

Type 1 - The innermost part is a polymer-enclosed drug reservoir that might include an osmotic solute. The perimeter is made up of an insoluble, semi-permeable polymeric membrane. Osmotic pressure causes medication leakage from matrix apertures.

Type 2 – The center of this type has two compartments. The osmotic solute is in one compartment and the medication is in the other. The solute compartment is surrounded by a semi-permeable membrane. There is no airflow in the medicine section.

Matrix systems

Contacts and insoluble eyewear are part of this system. Solids, aqueous preparations, or water are stored in a three-dimensional matrix. Hydrophilic or hydrophobic cross-linked polymers, such as those found in vision correction contact lenses, are present in this system. This system releases medications while correcting vision [3].

3.3.2. Soluble ocuserts

Soluble inserts are homogenous polymeric ocuserts that deliver the medication into the eye over time. Dissolution

and erosion result from the hydrolysis of chemicals or enzymes. The drug content of the ocusert is released as a result of swelling and chain relaxation brought on by tear fluid penetration, which leads to drug diffusion. After administration, removal is not required [4, 30].

They can be further separated into two groups based on the kind of polymer source:

Natural polymers: Soluble ophthalmic inserts are made using collagen. Before applying, the occusert is soaked, dried, and then rehydrated. The concentration of the preparation, soaking duration, and binding agent concentration all affect how much medication is in the ocusert. When the collagen degrades, the drug is released [6].

Synthetic and semi-synthetic polymers: Semisynthetic and synthetic materials are used to make ophthalmic inserts. It can be made from synthetic polymers like polyvinyl alcohol and cellulose derivatives. Applying eudragit to the ocusert could cause a delay in release [6].

3.3.3. Bio-erodible ocuserts

Polyester derivatives and cross-linked gelatin are used in bioerodible ocuserts. The main advantage of these polymers is that their final structure can be altered during production or by including cationic or anionic surfactants to prevent erosion [30]. Among them are:

Soluble ophthalmic drug insert (SODI): SODI is a small oval wafer, which is made to use in weightless conditions as eye drops cannot be used in these conditions [31].

Collagen shields: Bone, tendons, ligaments, and skin all contain collagen. About 25% of the proteins in mammals are made by it. Catgut suturing is one of the many biological applications for this intestinal collagen protein. Blunt forceps and an anesthetized cornea are required for this implantation [32].

4. Mechanism of drug release

Depending on the type of ocusert, one of the following techniques may be used to release the drug:

- Diffusion
- Osmosis
- Bioerosion [33, 34]

5. Formulation methods of ocuserts

5.1. Solvent casting method- Solvent casting is used to create ocuserts because of its affordability and ease of use. This process looks at the polymer's rheological characteristics because they affect things like ocusert thickness, drying rate, and uniformity. Because polymer mixing may result in air bubbles, de-aeration is required. After sufficient mixing, polymers are cast onto the appropriate substrate. The ocusert film is left behind as the mixture dries and the solvent evaporates. Ocusert films are then cut to the appropriate length [35].

5.2 Glass substrate technique- Thin films are created using glass substrate technology. A drug reservoir film is created using a transparent polymer solution. The drug is mixed into the polymer solution by vortexing it. Plasticizer is added after the drug dissolves. A glass mold is filled with the solution, which is then dried to create films. It takes a day to dry at room temperature. After drying, the films are cut to size and put away [34].

5.3 Melt extrusion technique- Melt extrusion is an alternative for solvent casting. It's utilised for non-organic solvents. In this process, polymers and other components are melted and then passed through a die to prepare films. The films are then trimmed. This approach isn't for thermolabile substances [35].

6. Evaluation parameters for ocuserts

6.1. Organoleptic characteristics- Ocuserts are assessed based on their organoleptic characteristics, which include color, texture, look, and odor.

6.2. Uniformity of thickness-The even dispersion of components is made possible by the ocusert's consistent thickness. Uniform thickness is measured using a micrometre screw gauge [35, 36].

6.3. Uniformity of weight- The homogeneity of the ocusert demonstrates the consistency of its components. For every batch, three ocuserts are weighed. Weight averages are noted [37].

6.4. Drug content- Drug content quantifies each formulation's active ingredients. 10 ml of STF is used to dissolve the occusert. After appropriate dilutions, the absorbance value is estimated using a UV visible spectrophotometer [37].

6.5. Swelling index- The swelling or water-absorption properties of a formulation are measured by the swelling index. Four milliliters of STF are mixed with weighed occusert. The ocusert is taken out after five minutes, and any extra fake tear fluid is weighed [38]. The following formula can be used to determine the percentage swelling index.

$$\% \text{ Swelling Index} = \frac{(\text{Weight of swollen ocusert after time t} - \text{ Initial weight of ocusert})}{\text{Initial weight of ocusert}} \times 100$$

6.6. % Moisture absorption- The physical stability of ocuserts in moist conditions is measured by the moisture absorption test. Three ocuserts are placed in aluminum chloride desiccators following the weighing of each batch. The ocuserts are weighed once more after three days. [39] The following formula is used to calculate the percentage of moisture absorption**:**

$$\% \text{ Moisture absorption} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

6.7. Folding endurance- This test determines the ocusert's resistance to folding**.** This is accomplished by repeatedly folding the film until it breaks. Folding endurance is the amount of times a film can be folded without breaking [40]**.**

Surface pH- In a closed petri plate with 1 milliliter of distilled water, the occusert is left to swell for 30 minutes

at room temperature. The surface pH is measured with a digital pH meter [39].

6.8. In-vitro drug release study- The diffusion cell method is used to determine the drug release. A pre-hydrated cellophane membrane lines an open cylinder that serves as a donor compartment. Simulated tear fluid hits the membrane's ocusert. The simulated tear fluid is mixed and maintained at 37 ± 0.5ºC using a magnetic stirrer. One milliliter of the receptor compartment is spectrophotometrically analyzed after a predetermined amount of time. For each sample, artificial tear fluid is added [41].

6.9. Ex-vivo permeation studies- This study utilizes diffusion cells. Goat cornea is extracted from the eye and put on a diffusion cell so the corneum side remains in touch with the donor ocusert. A magnetic stirrer is used to mix artificial tear fluid at 37 ± 0.5 ºC. Following specific timings, a spectrophotometric analysis is performed on 1 milliliter of the receptor compartment. Artificial tear fluid is used in place of each sample [42].

6.10. Sterility test- A sterility test is conducted to identify the presence of viable microorganisms in the all-injectable formulation of each batch. Sterility is an essential need for all ophthalmic preparations.

Two primary techniques exist for sterility testing.

1) Membrane Filtration Technique

2) Direct inoculation technique [43].

6.11. Stability study- Stability tests can be performed on ocular implants in accordance with ICH recommendations**.** For two months, the ocular inserts should store at 40°C and 75% relative humidity. After that it's physical appearance, drug content, and in vitro drug release tests can be evaluated [44].

7. Conclusion:

Ocular inserts have the potential to revolutionize ophthalmic drug delivery by providing sustained and controlled release of medications, improving bioavailability, and reducing dosing frequency. These inserts can be classified into insoluble, soluble, and bio-erodible types, each with its own advantages and disadvantages. The formulation methods and evaluation parameters for ocular inserts are critical to ensure their safety, efficacy, and patient compliance. While ocular inserts offer several benefits, challenges such as patient acceptance and insert placement/removal need to be addressed. Further research is necessary to develop more effective and patient-friendly ocular inserts, which can improve the treatment outcomes for various ophthalmic disorders. With continued advancements in technology and materials, ocular inserts are poised to play a significant role in the future of ophthalmic drug delivery.

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