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Review Article

A Quick Reference to the Decade's Literature Reviewed on Ocular Films

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ABSTRACT

The study outlines the review of ocular films and polymers so far used by quick reference for the researchers. There is extensive research going on in the name of finding an accurate polymer that helps delay the release of drugs in ocular drug forms. The ocular film is a good idea if implemented properly, but finding a suitable polymer is a gargantuan task that has yet to be accomplished. Till now, researchers have extensively studied and compiled in the interest of reviewing all the available ocular films. To research and compile previous works on ocular films. Various sources of information collected were from the internet and research journals, which have been employed. Thanks to the extensive article collection of the team, it was possible to study and review all the available ocular films in the research. The article summarizes the ocular films' general preparation methods and evaluation tests. Ophthalmic preparation methods and eye diseases were discussed. The combination of drugs with polymers was discussed. This will help in a quick review of drugs and polymers that were successfully tried in making ocular films and the common evaluation approaches.

Keywords: Evaluation, Eye, Film, Ophthalmic, Polymer.

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INTRODUCTION

The ocular drug delivery system is a dosage form. It is used again for disorders that will cause infections in the eyes. The prolonged contact of the drugs with the eye will increase the therapeutic efficacy and bioavailability of ocular drugs.[1] The development of newer, more sensitive diagnostic techniques and therapeutic agents gives urgency to the development of the most successful and advanced ocular drug delivery systems. The eye will be infected easily because it is sensitive and located on the surface of the body. The medication is to be repeated throughout the eye and is composed of a transparent cornea, lens, and vitreous body without blood. The main bulk of the eye (the cornea) is made up of crisscrossing layers of collagen and is bound by elastic lamina on both the front and back. The cornea is richly supplied with free nerve endings. The transparent is continued posteriorly into the opaque white sclera. It consists of tough fibrous tissue. Both the cornea and sclera withstand the tension constantly maintained in the eye. The eye is constantly cleansed and lubricated by the lacrimal apparatus, which consists of four structures, e.g., lachrymal glands, lachrymal canals, the lacrimal sac, and the nasolacrimal duct. The physiological barriers to diffusion and productive absorption of topically applied drugs exist in the precorneal and corneal spaces. The eye is a slightly asymmetrical globe, about an inch in diameter, which helps in viewing the world around the living being, hence the term "photoreceptors".[2] The eyes contain lachrymal glands which produce tears to lubricate the surface of the eyeball. Wash away dust particles falling on the surface of the eyeball. It helps in killing germs, thus preventing infection. Communicate emotions.

The human eye faces many obstacles viz., Astigmatism, cataracts, cat eye syndrome, colour blindness, conjunctivitis, diabetic retinopathy, glaucoma, haemolacria, heterochromia, hyperopia, macular degeneration, myopia, optic neuritis, presbyopia, polycoria and so on goes the list of eye infections that start from harmless dry eyes and lead to loss of vision.

Ophthalmic Dosage Forms

The ophthalmic dosage forms are ranged as follows.

Eye solution

Eye solutions are conventional ophthalmic dosage forms that are commonly used for every eye condition, but they come with their demerits, inclusive of drainage of medication out of the eye very

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easily, drug loss by tear fluid, low bioavailability of the drug in the eye, and regular instillation of eye drops.

Suspension

They are biphasic ophthalmic dosage forms that are administered into the eye for drug delivery. They come in handy to administer potent drugs and reduce the frequency of administration, but they can cause eye irritation,[3] which is a considerable aspect of the criteria of the eye.

The ointments

Eye ointments are not widely used or appreciated for their problems of causing blurring of vision and disturbing the eye while they are in the eye because of their semi-solid nature, so they get less patient compliance as they irritate the user.

Liposomes

These are controlled drug-release dosage forms that can stay for longer times in the eye and require less attention to be paid,[4] but they have more shortcomings than uses, like stability issues, not reproducibility, and chances of rapid clearance.

Implants

The implantation of the drug concept, though it seems to appease anyone, the complex process of implantation of the drug will make anyone averse to getting an implant.

Pro drugs

Prodrugs have a long residence time, which increases bioavailability, but they can also be responsible for some metabolic problems too.

Hydrogels

They have issues with the dosage forms themselves, like temperature, pH, and ionic strength.

Microemulsions

Toxicity at higher concentrations, surfactant or co-surfactant selection, and aqueous/organic phase affecting its stability are some of the major drawbacks to using this dosage form.

Nano-suspensions

Only poorly soluble drugs comply with this dosage form, narrowing the spectrum of availability of drugs.

Cyclodextrins

Alone, cyclodextrins are not significant dosage forms; they function well as penetration enhancers.

Gene therapy

It can raise serious ethical questions as well as immune issues for the patient.

Advantages of Ocular Films

The merits of ocular films were summarized as follows

- Biodegradability or solubility in the eye.
- Comfortable.
- Controlled release.
- Ensure effective drug concentration in the eye.
- More accurate pharmaceutical dosing and fewer systemic side-effects.
- More contact.
- More shelf life.
- Prolonged delivery.
- Prolonged retention of devices.
- Reduced dose frequency.

PREPARATION OF OCULAR FILMS

Ocular films were prepared by the solvent casting evaporation technique by utilizing different polymers. Distilled water, ethanol, or hydroalcoholic solvent can be used as a solvent for casting. A solution is prepared using a 30% w/w plasticizer of dry polymer (glycerin, triethyl citrate, and polyethylene glycol 400) along with (2% w/v suitable polymer) through magnetic stirring and added to the polymer solution while in stirring condition to produce flexible films. This solution protects the ocular films by protecting the polymeric inserts from turning brittle upon storage.[5] The weighed amount of suitable drug was added to the above solution and stirred for 30 minutes to obtain uniform dispersion. After proper mixing, 10mL of the casting solution was poured into a clean glass petri dish (area of 15.9 cm^2) and covered with an inverted funnel to allow slow and uniform evaporation at room temperature for 48 hr. (The obtained films were then dried in a desiccator over fused calcium chloride at room temperature). The dried films were cut into pieces of a definite size (1 cm^2), containing 600 g/cm^2).

EVALUATION OF OCULAR FILMS

Physical characterization

The physical characteristics of ocular films were evaluated as colour, texture, flexibility, and appearance.

Uniformity of weight

The 3 films from a batch are weighed individually using a digital balance; the mean weight of the films is recorded.

Uniformity of thickness

A Vernier Calliper is used to measure the thickness of 3 randomly selected formulations.

Weight variation

The average weight of 20 films weighed on a batch's digital balance is considered the film's original weight.

Tensile Strength

A tensile strength instrument is used to test the tensile strength of ocular films. The 3 films were selected from a batch and the d average of their tensile strengths is considered the original tensile strength. One end of the ocular film is placed between adhesive strips and the other end of the ocular film is held between another set of adhesive strips with a pin sandwiched between them. A small piercing was made on the adhesive strips near the pin and a hook was inserted into the hole.[6] The hook is used to tie a thread and pass it over a pulley to attach a small pan on its end intended for holding weights. A small pointer was attached to the thread, which travelled over the graph fixed on a base plate to give the reading of braking force. Slowly, weights were added to the pan until the film was broken. The weight required to break the film is called the breaking force, and the elongation achieved by the film before breaking is determined by the graph. Tensile strength is calculated using eq.1.

$$\text{Tensile power} = \frac{\text{break force}}{ab\left(1 + \frac{\Delta l}{L}\right)} \quad (1)$$

Where, A = film width; B = film thickness; L = strip length; ΔL = Change in length of the strip while breaking

Using the above, another parameter can also be determined called "%Elongation at the Breakthrough eq.2.

$$\% \text{ Length at break} = \frac{I_b - I_0}{I_0} \times 100 \quad (2)$$

Where I_0 = Film's original length; I_B = length of a film at the break when stress is applied.

Folding endurance

The number of times a film can be folded in the same place until the strip breaks are called "folding endurance."[7] A small strip of film (2x2 cm) is taken to perform this test. The strip is folded in the same place until the strip breaks, thus the number of times the strip can be folded without breaking is noted.

Eye Irritation Test

The institutional Animal Ethics Committee (IAEC) approved their use in this study. Prepared ocular films are placed in the lower cul-de-sac of the eye and tested twice a day for 7 days and checked regularly, by removing the films using a swab, for irritation, redness, swelling, or haziness.

Table 1: The polymers and drug combinations earlier employed in ocular films.

Drug	Polymer	Reference
Vildagliptin	Polyethylene glycol (PEG)- 400	Souvik *et al.*, 2021[11]
Dexamethasone sodium phosphate	Hydroxy Propyl methyl cellulose (HPMC)-K4M and ethyl cellulose (EC)	Ahad *et al.*, 2021[12]
Sulbactam	HPMC K4M, Polyvinyl alcohol (PVA), and EC	Monika *et al.*, 2020[13]
Azithromycin	HPMC, Hydroxyethyl cellulose (HEC), and Eudragit	Shiva *et al.*, 2020,[14]
Erythromycin	Gelatin, HPMC, and EC	Samanvitha *et al.*, 2020[15]
Erythromycin	Gelatin and HPMC	Shaik *et al.*, 2020[16]
Tobramycin	PVA and polyvinyl pyrrolidone (PVP)	Qin *et al.*, 2019[17]
Ciprofloxacin HCl	HPMC	Hamdy and Aya 2019[18]
Cyclosporine	hydroxypropyl-β-cyclodextrin (HPβCD)	Maria *et al.*, 2018[19]
Cetirizine HCl	HPMC and PVA	Syed *et al.*, 2018[20]
Triamcinolone Acetonide	Eudragit S100 and Zein	Shahla *et al.*, 2018[21]
Ciprofloxacin HCl	plantago ovata	Ayushi and Shikha, 2018[22]
Ciprofloxacin HCl, and prednisolone sodium phosphate	Polyethylene oxide N10	Sai *et al.*, 2017[23]
Dexamethasone	2-(hydroxyethyl) methacrylate (HEMA) and 2-methacryloyl-oxyethylene phosphorylcholine (MPC)	Athmar *et al.*, 2017[24]
Carboxymethylated Hyaluronic acid	poly(ethylene glycol) diacrylate (PEGDA)	Hee *et al.*, 2017[23]
Ofloxacin and dexamethasone	HPMC	Sravanthi 2017[25]
Moxifloxacin	poly(L-lactide-co-ε-caprolactone) (PLC)	Dulcia *et al.*, 2016.[26]
Cyclosporine-A	HPMC and xanthan gum (XG)	Zahraa *et.al.*, 2016.[27]

Fluconazole	PVA, PVPK-30, HPMC	Viswanath *et al.*, 2015[28]
Timolol maleate	Guar gum	Sunil *et al.*, 2015[29]
Betaxolol HCl	Gelatin	Kulkarni *et al., 2015* [30]
Valacyclovir HCl	HPMC E15 LV and PVP	Naga *et al.*, 2014[31]
Sodium Cromoglycate	HEC	Pai *et al.*, 2014.[32]
Ketorolac tromethamine	Gelatin, HPMC, and EC	Apparao and Veera *et al.*, 2014[33]
Moxifloxacin	PEGDA	Hee *et al.*, 2014[34]
Aceclofenac	HPMC and EC	Vivek *et al* ., 2013[35]
Betaxolol HCl	polyethylene oxide (PEO)	Gevariya *et al.*, 2013[36]
Ciprofloxacin	HPMC and PVA	Nayan and Shalini, 2013[37]
Ofloxacin	PVA	Deepak *et al.*, 2012[38]
Ofloxacin	Guar gum	Sunil *et al.*, 2012[39]
Betaxolol HCl	Gelatin and Chitosan	Ashture *et al.*, 2012[40]
Papain and Urea	PVA	Romanovskaya *et al.* 2012,[40]
Levobunolol HCl	EC and Eudragit RL100	Manjunatha and Giriraj, 2012[41]
Azithromycin	Carbopol, and HPMC	Ritu *et al.*, 2011[42]
Acyclovir	HPMC, PVA and eudragit	Prasoon *et al.*, 2011.[43]
Ciprofloxacin HCl	MC, HPMC, Hydroxypropyl cellulose (HPC), and Eudragit RS100	Mohamed *et al.*, 2011[44]
Brimonidine	PVP K-90	Mona and Azza, 2011[45]
Gatifloxacin	HPMC, MC, sodium carboxy methyl cellulose, and gelatin	Ajay *et al.*, 2010[46]
Moxifloxacin HCl	Gelatin and glycerin	Patel *et al.*, 2010[47]
Ciprofloxacin HCl	Gelatin	Mundada and Shrikhande, 2009.[48]
Brimonidine Tartrate	EC, and PVP-K30	Patel *et al.*, 2009[49]
Chloramphenicol	Cellulose acetate and cellulose acetate butyrate	Nilay *et al.*, 2008[50]
Gatifloxacin	Sodium alginate and chitosan	Mehra and Mishra 2008[51]
Ofloxacin	Eudragit RS 100 and EC	Karthikeyan *et al.*, 2008[52]
Ofloxacin	HPMC, MC, PVP, and PVA	Sreenivas *et al.*, 2006.[53]
Pefloxacin mesylate	Eudragit RS 100 and Eudragit RL 100	Yasmin *et al.*, 2005[54]
Cromolyn Sodium	PVA and sodium alginate with glycerin and PEG 400	Dandagi *et al.*, 2004[55]
Norfloxacin	HPMC and EC	Venkateshwar and Somashekar, 2004[9]
Pefloxacin mesylate	HPC, HPMC, PVP, and PVA	Bharat and Hiremath, 1999.[56]
Diclofenac sodium	HPMC and PVP, Eudragit RL PO, and Eudragit	Zahra *et al.*, 1990[57]

Method of sterilisation and sterility test

All the films are sterilized under UV radiation for 30 min. The irradiated films are advised to be tested for sterility as per Indian Pharmacopoeia for any pieces of evidence of viable forms of bacteria, fungi, or any other microorganism in or on the ocular films, accounting for accidental contamination of ocular films.

The drug content determination

The samples of ocular films from each batch are collected and dissolved in isotonic phosphate buffer pH 7.4 (tear fluid) into the volumetric flask. The absorbance of the solution is measured spectrophotometrically after the solution is filtered and diluted.[8] The mean drug content of films was determined by considering the concentration of the solution and the number of films dissolved.

Swelling index examination

A swelling index test is performed to measure the hydrophilicity and hydration of films. The swelling test is specifically performed because the swelling of the polymer matrix affects the release of the drug. To perform this test, 3 films of each formulation are selected randomly, then weighed, put in a mesh basket, and inserted into phosphate buffer saline of pH 7.4 at a temperature of 32±0.5°C.[9] For every 90 min, the films are removed and wiped

with lint-free tissue to remove the case of any excess surface phosphate buffer saline. They are then weighed later and returned to the same container.

The swelling index was calculated using eq.3.

$$\text{Swelling index} = \frac{W_t - W_0}{W_0} \text{ X } 100 \text{--- (3)}$$

Where, W_0 = initial weight; W_t = weight at time't'

In vitro drug release study

The vial method is followed to evaluate *in vitro* drug release from different ocular films. Each film is placed in a vial of 10ml of simulated tear fluid (pH 7.4) prepared at 37±0.5°C. The vials are then placed in a shaker. The shaker is advised to set a minimum shaking speed to simulate blinking. Samples were withdrawn at specific intervals while the equivalent amount of fresh fluid was added to the shaker.[10] The withdrawn samples are diluted using pH 7.4 isotonic phosphate buffer and measured using a UV spectrophotometer at their respective wavelengths. The successful attempts on ocular films with their corresponding drug and polymers were shown in Table 1.

CONCLUSION

According to the study, a suitable polymer that aids in the creation of ocular films has been discovered. According to the study, since last December, many different polymers have been attempted to create ocular films. All of the available ocular films have so far been thoroughly examined and collated by researchers with the intention of examining them. The writers were successful in locating the data in reliable peer-reviewed publications from a variety of sources. This review focuses on the standard techniques for ocular film preparation and testing. A brief overview of the medications and polymers that have been employed effectively in the creation of ocular films will be given in this review, along with a list of typical evaluation techniques.

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