WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 14, Issue 22, 11-20. Review Article ISSN 2277–7105

OPTHALMIC DOSAGE FORM (REVIEW ARITICLE)

Divyani Nagesh Tambe*, Srushti Nandkumar Kalbe*, Srushti Madhukar Davari*, Sneha Chandrakant Hundalekar*, Samaruddhi Balvant Barad*

Shree Saraswati Institute of Pharmacy, Tondavali.

Article Received on 18 Oct. 2025,
Article Revised on 08 Nov. 2025,
Article Published on 16 Nov. 2025,

https://doi.org/10.5281/zenodo.17614518

***Corresponding Author**

Divyani Nagesh Tambe

Shree Saraswati Institute of Pharmacy, Tondavali.

How to cite this Article: Divyani Nagesh Tambe, Srushti Nandkumar Kalbe, Srushti Madhukar Davari, Sneha chandrakant Hundalekar, Samaruddhi Balvant Barad (2025). Opthalmic dosage form (review ariticle). World Journal of Pharmaceutical Research, 14(22), 11–20.

ABSTRACT

Many studies have demonstrated that new and more complex ophthalmic drug forms exhibit advantage over traditional ones and are able to increase the bioavailability of the active substance. The rest of the paper describes recommended *in vitro* and *in vivo* studies to be performed for various ophthalmic drugs forms.

Ocular (eye) dosage forms are sterile pharmaceutical preparations intended for direct application to the eye for treating local or systemic conditions.

reducing the susceptibility of drug forms to defense mechanisms of the human eye, extending contact time of drug with the cornea, increasing the penetration through the complex anatomical structure of the eye, and providing controlled release of drugs into the eye tissues, which allows reducing the drug application frequency. General principles for the development of a topical ophthalmic dosage form intended for application to ocular structures are discussed. Formulation development strategy based on a quality by design (qbd) approach is used as a tool to help formulation scientist develop dosage forms.

INTRODUCTION

Ophthalmic drug forms have been one of the most important and widely developed areas of pharmaceutical technology for dozens of years. The main reason of continuingly strong interest of scientists in these drug forms is the problem of a low bioavailability of medicinal substance after the application to the eyeball. Ophthalmic drug forms have been one of the

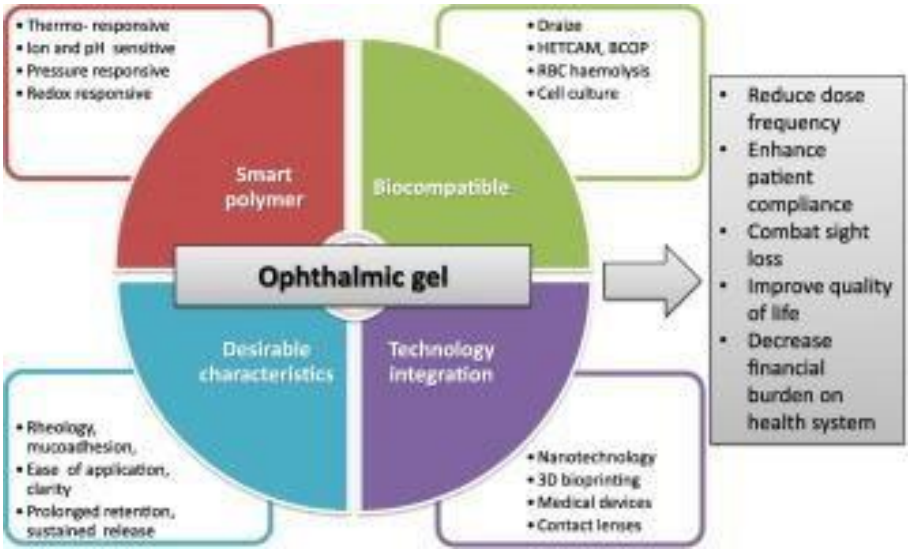
most important and widely developed areas of pharmaceutical technology for dozens of years. The main reason of continuingly strong interest of scientists in these drug forms is the problem of a low bioavailability of medicinal substance after the application to the eyeball.

These forms include solutions, suspensions, ointments, gels, and inserts used for conditions like conjunctivitis, glaucoma, dry eye, post-surgical inflammation, and intraocular infections. Ophthalmic preparations (eye preparations) are sterile, liquid, semi-solid, or solid preparations that may contain one or more active pharmaceutical ingredient intended for application to the conjunctiva, the conjunctival sac or the eyelids. Ophthalmic formulations have been one of the most important and growing areas of pharmaceutical technology for decades. Ophthalmic drug delivery systems may be preferred over other delivery systems despite their potential risks and complications. Additionally, compared with oral drug delivery systems, ocular drug delivery systems may provide better equivalent bioavailability in the eye.

OPTHALMIC GEL

Ophthalmic Gel is an eye lubricant or artificial tears used to relieve dry eyes. This can happen because not enough tears are made to keep the eye lubricated. Ophthalmic Gel is usually taken when needed. Use the number of drops as advised by your doctor. Wait for at least 5-10 minutes before delivering any other medication in the same eye to avoid dilution. Ideal for use as needed, it helps maintain eye moisture, protecting against dryness and discomfort. ophthalmic gelling systems with emphasis on mechanism of gel formation and application in

ophthalmology. Ophthalmic in situ gel is a novel preparation. It can be instilled into the eye as a liquid but gels upon contact with the ocular surface, generating a sustained-release depot of the drug.



A gel is a semi-solid dosage form that can have properties ranging from soft and weak to hard and tough. Gels are defined as a substantially dilute cross-linked system, which exhibits no flow when it is present in the steady state. A gel is defined as a soft, solid or semi-solid-like material consisting of two or more components, one of which is a liquid, present in substantial quantity.

ADVANTAGES

- Extended ocular residence time
- Controlled and sustained drug release
- Comfort & biocompatibility
- Versatility in drug loading
- Stimulus-responsive behavior
- They are easily administered by the nurse
- they are easily administered by the patient himself.

DISADVANTAGES

- The very short time the solution stays at the eye surface.
- Its poor bioavailability.
- The instability of the dissolved drug.
- The necessity of using preservative.

- Limited Drug Loading Capacity

Ophthalmic gels are divided into two categories

gel eye drops and in situ gels. The first exist as viscous solutions before application to the eye and are normally used for dry eyes as a tear substitute. In situ gels, by comparison, are liquids that are applied as drops onto the eye and only after administration undergo a sol-gel-to-gel transition in the conjunctival cul-de-sac following external stimuli, such as pH, temperature, or ions, with a significant improvement in ocular bioavailability.

APPLICATION

- Eye infections, including bacterial, viral and allergic conjuvtivas
- Corneal ulcers
- Dry eye syndrome
- Eye discomfort and symptoms, like redness, dryness, swelling, itching.

IDEAL PROPERTIES

- Effectively overcome ocular barriers.
- Prolong cornral contact time.
- Bioavailability of target tissue.
- It should be non toxic.
- Drug selection criteria
- the drug must be bio chemically pharmacologically potent.
- The drug must be non toxic to both ocular and systemic tissues
- The drug must be sufficient stable that neither significant loss in potency from admonished availability nor little increase in toxicity from byproducts of degradation arises.
- The drug can be either targeted to tissues and location of primary disease stable etiology or to sites responsible for symptomatic response.
- The drug must be sufficient with the dosage form ,and with the tissues exposed to it to achieve an effeetive pharmacokinetic tissue profile.

COMPOSITION /EXCIPIENT

I. Viscosity increasing polymers

Enhancing the viscosity of the vehicle is a technique used to extend the residence time of ophthalmic drugs. Synthetic polymers such as polyethylene oxides, polyacrylates and polyvinyl alcohols, polyesters, polyolefins, collagen, gelatin, and dextran are used to

accomplish this increase in viscosity. An ideal viscosity range of 15– 55 P (P). These compounds, which are classified as bioadhesive hydrogels or in situ forming gels, comprising both polar and non-polar groups, undergo swelling upon water contact, leading to entanglement and adherence to mucin molecules and, therefore, increasing pre-corneal residence time.

II. Solubility enhancers

Different biomaterials have been used as the primary component of ophthalmic formulations to improve drug bioavailability, the most common ones being cyclodextrine. Natural polymers have inherent biocompatibility and minimal toxicity as highlightsmade up of a large number of structural units named monomers, which are associated to each other by polymerization reaction.

III. Penetration enhancer

Penetration-enhancing substances have the property of modifying the permeability of the corneal epithelium, and they can generally be categorized as chelating agents. The primary mechanism involves modifying the stability of the tear film and mucus layer, including membrane fluidization, and temporarily opening tight junctionscorneal epithelial cells are adhered by tight junctions that depend on the availability of Ca2+ ions.

IV. Buffering agents

A buffer system is composed of different compounds responsible for maintaining the acid-base balance of a solution or formulation, by resisting a change in ph when acids or bases are added. E calcium and phosphate present in the physiological tear film coexist in a delicate equilibrium, which may be disturbed by the use of eye drops with a high concentration of these ions. The optimum ph of an ophthalmic formulation is 7.2 ± 0.2, but the buffering capacity of the lacrimal film tolerates ph ranging from 3.5 to 8.5.

V. Preservatives

Pharmaceutical products, without preservation, are easily susceptible to be contaminated with mold, fungi, and bacteria, leading to spoilage and greater risk of infection to the patient. Benzalkonium chloride (bak) is a quaternary ammonium compound that lyses the cell membranes of microorganisms, and it is by far the most used preservative in ophthalmic preparations, present in about 70 % of eye drops. The use of preservatives as an adjuvant is practically imperative to extend the shelf-life of these formulations and to ensure their

sterility.

MANUFACTURING

A. Formulation development

The process begins with the development of a specific formulation to treat an eye problem. This includes the appropriate choice of active agents, stabilizers, and preservatives that support the functional aspect, efficiency and shelf-life.

B. Quality Control And Testing

The formulation is subjected to critical testing and quality control systems prior to production. Testing also takes into account the contamination of the product.

C. Manufacturing and Sterilization

They are manufactured under cleanroom conditions to achieve sterility. The production steps include accurate mixing, filling and sealing, packing of the products. Following manufacturing, the next step is sterilization. This is so important since it helps to remove any possible microbial contaminations.

D. Packaging

The controlling factors of ophthalmic product packaging are its protective function and ensuring correct doses of the end product. Based on sterility and product compatibility, appropriate packaging materials are selected.

E. Final Quality Assurance

After the closing procedure the distributed unit goes through a final quality assurance stage. This includes packaging specifications including the integrity of the package, final sterility evaluation, etc.

MARKEDED FORMULATION

The ophthalmic gel market is witnessing significant growth fueled by the increasing prevalence of ocular diseases like dry eye syndrome, conjunctivitis, and blepharitis. The aging global population is a major driver, as older individuals are more susceptible to these conditions.

Examples

1. **Gancigel opthelic gel**

An antiviral for treating viral infection of the eye.

2. **Ocuheel opthelmic gel**

Used to treat viral infection, such as cytomegalovirus retinitis, particularly in immunocompromised patints.

3. **Optimoist opthelmic gel**

An eye lubricant that helps relieve dry eyes by providing lubrication and soothing irritation.

4. **Dpnol opthelmic gel**

Used to treating eye injuries and inflammation ,promoting wound healing after surgeries.

EVALUATION

The evaluation of ophthalmic liquid crystal in situ gels involves several crucial aspects to assess their suitability as drug delivery systems.

i. Physical characteristics

The appearance, pH, viscosity, and clarity of the liquid crystal in situ-gels are evaluated to ensure their uniformity and suitability for ocular application.

ii. In Vitro Release Profile

A modified Franz diffusion cell is used to study the release profile of the drug from the liquid crystal in situ-gel formulation.

iii. Drug Release Kinetics

In vitro release studies using diffusion cells provide valuable insights into the drug release profile from the liquid crystal in situ-gel. These studies help understand the sustained release behavior and optimize the formulation for desired therapeutic outcomes.

iv. Mucoadhesive Properties

The mucoadhesive properties of the liquid crystal in situ-gel are evaluated to ensure its residence on the ocular surface for an extended duration. Techniques such as texture analysis and ex vivo models are utilized to measure the adhesive strength and duration.

v. Stability

The stability of the formulation is evaluated under different storage conditions, such as temperature and light exposure. Changes in appearance, pH, viscosity, and drug content are monitored over a specified period.

vi. Compatibility

Compatibility studies are conducted to assess any interactions between the liquid crystal in situ-gel formulation and common ophthalmic excipients. The stability and integrity of the formulation are evaluated after combining with excipients.

vii. Ocular Irritation Potential

The ocular irritation potential of the liquid crystal in situ-gel is evaluated through in vitro or ex vivo models to assess its safety and compatibility with ocular tissues. These studies aid in identifying any potential inflammation or irritation that could arise from the formulation.

RESULT AND DISCUSSION

A. Gel strength

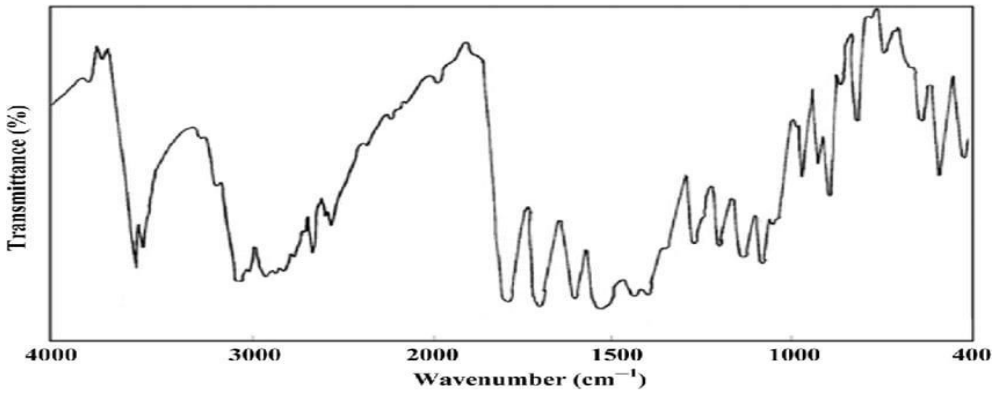
Assessment of mucoadhesive force is an important parameter as it provides insight into the retention of formulation on the mucous membrane . The gel strength as well as adhesive force of M1-M8 were determined using texture analyzer. It is apparent from the data in that the gel strength varied considerably among the gels tested.

B. Identification of drug by FTIR

Infrared (IR) light is electromagnetic radiation with longer wavelength of light, extending from the nominal red edge of Use visible span74) 83 nm. This range of wavelengths corresponds to a frequency range of approximately 800 down to 1 THz, and includes most of the thermal radiation emitted by objects near Infrared.

a FTIR transmittance spectrum of Moxifloxacin HCl was obtained from a KBr pellet and interpreted following characteristic absorption bands FTIR spectra of Moxifloxacin HCl showed aromatic C-C stretching at 1621, 1515 and 1454 cm-1 and C-H bending for substituted benzene at 873 cm-1.

light is emitted or absorbed by molecules when they change their rotational vibration movement.



C. Sterility testing

Sterility test was performed using the membrane filter through which it was filtered, the filter was cut in 2 and directly incubated in fluid thioglycolate media and no visible Microbial Growth was seen.

D. Stability testing

The product was kept for 1 month and tested for various parameters as per Various ICH guidelines at Temp 40 oC and RH 75 ± 5%. ICH Q1A – Stability testing of new drug substances and Products ICH Q1B – Photo stability testing of new drug substances and products.

E. *Ex vivo* permeation

Goat's cornea was selected for the *ex vivo* drug permeation investigations for the design of experimental batches because it is multi-layered as well as simulate the condition of the human corneal membrane. The cumulative amount of moxifloxacin penetrated via the cornea membrane from both MH7 and control are depicted.

F. Ocular irritation

Eye irritation score from individual rabbits was added to get the total irritation score that was subsequently divided by the total number of rabbits used for the ocular irritancy test to obtain the final eye irritation score.

G. Stability

Stability data suggests no significant variation in gelling capacity, pH and viscosity of MH7 during storage. The *in vitro* drug release data after six-month stability cycles were evaluated by t-test considering two sample having equal variances. The observed *t* test value of 0.072 is well below the *t* critical value of 1.76, hence, demonstrates no statistically significant

difference in MH7 after specified stability period.

DISCUSSION

The process for evaluating the manufacture of in-situ ophthalmic gel in-vivo was obtained based on the findings of the literature search that was carried out, and the results of this evaluation are presented. Polymers and mechanism details are distinct for each technique, which results in various outcomes.

CONCLUSION

Use of water soluble and biodegradable polymers makes the in situ ophthalmic gel more acceptable because minimum chances of irritation. in recent years, pharmaceutical research has focused attention on the development of new drug administration approaches aimed at increasing the ocular residence time, to provide a prolonged pharmacological action, thus improving both bioavailability and patient safety, and therefore minimizing side effects.

The formulation and evaluation of these systems play a pivotal role in optimizing their performance and therapeutic efficacy. many efforts have been made to develop a delivery system with prolonged residence time in the ocular region, which could ultimately result in the increased ocular bioavailability by making many changes and modifications in the product formulation and product content.

REFRENCES

1. Savita Gambhire, Karuna Bhalerao, Sushma Singh, In-situ hydrogel: different approaches to ocular drug delivery, International Journal Of pharmacy and pharmaceutical sciences, 2013.
2. International journal of pharmaceutical research and application, may – june 2022; 7(3): 508-522.
3. Tinu T S, Litha Thomas1, Anil Kumar B: Int. J. Pharm. Sci. Rev., 2013; 30: 176-183.
4. Gupta, A., Formulation and Evaluation of In Situ Ophthalmic Drug Delivery System. international Journal of Pharmaceutical & Biological Archive, 2012; 3(4): 715-718.
5. Snehalnikode, gauri dixit and kanchanupadhya: in situ gel: application and uses of polymers: world journal of pharmacy and pharmaceutical sciences, 2016; 5(7): 1638-1658.