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Research

Formulation and Evaluation of Ophthalmic Emulgel Using Tobramycin and Dexamethasone

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Abstract:
In this study, a combination of medications will be chosen to create emulgel that can be administered via the ocular route. Patient compliance, treatment adherence, and resident time in ocular tissues may all be enhanced by the new combination's simultaneous administration and prolonged release of the two medications. Gel and emulsion will be combined to create Emulgel. After being produced independently, the gel and emulsion are combined. The aqueous phase and oil phase are separated and combined to create the emulsion. We have chosen tobramycin and dexamethasone as the APIs for this emulgel. They are used in conjunction with corticosteroids and antibiotics. It is used to the eye to stop long-term harm that could result from specific eye issues. The produced formulation is assessed using physical examination, pH measurement, rheological analysis, drug content determination, spreadability, diffusion analysis, in-vitro drug release kinetic analysis, and antibacterial activity. Optimized emulgel formulation may enable simultaneous and prolonged release of the two medications. Patient compliance and, consequently, therapy adherence may be enhanced by the ability to administer hydrophilic and hydrophobic drugs using the same formulation without the need for two drops.

Keywords: antibiotics, ophthalmic medication administration, emulgel.

Introduction:

Ocular drug delivery remains a significant challenge due to the unique anatomy and physiology of the eye. Protective mechanisms such as blinking, tear turnover, nasolacrimal drainage, and corneal barriers reduce drug residence time and limit bioavailability. Conventional ophthalmic dosage forms like eye drops and ointments often suffer from poor drug absorption and require frequent administration, leading to reduced patient compliance.

To overcome these limitations, novel drug delivery systems such as ophthalmic emulgels have gained attention. An emulgel is a combination of emulsion and gel systems, offering the advantages of both. It enhances drug stability, improves bioavailability, prolongs residence time, and provides better patient comfort due to its non-greasy and easily spreadable nature. Emulgels are particularly useful for incorporating both hydrophilic and lipophilic drugs, making them suitable for ophthalmic applications.

Tobramycin is a broad-spectrum aminoglycoside antibiotic widely used in the treatment of bacterial eye infections such as conjunctivitis and keratitis. Dexamethasone, a potent corticosteroid, is used to reduce inflammation, redness, and swelling associated with ocular conditions. The combination of Tobramycin and Dexamethasone provides a synergistic therapeutic effect by simultaneously addressing infection and inflammation, thereby improving treatment outcomes.

The present study aims to formulate and evaluate an ophthalmic emulgel containing Tobramycin and Dexamethasone to enhance ocular drug delivery. The objectives include the development of a stable and effective formulation, evaluation of its physicochemical properties, assessment of drug release behavior, and determination of its suitability for ophthalmic use.

Material and Methods

Materials:

Dexamethasone and Tobramycin were used as active pharmaceutical ingredients. Polyethylene glycol was used as an emulsifying agent, castor oil served as the oil phase, ethanol was used as a solvent, and benzalkonium chloride was used as a preservative. All the materials used were of analytical grade.

Methodology

Emulgels are prepared by combining two immiscible liquids (oil and aqueous phases) using an emulsifying agent to form a stable emulsion, which is then incorporated into a gel base. Gels enhance viscosity, consistency, and uniformity without altering other properties, and are formed by the swelling of polymers in a liquid medium.

The preparation of emulgel involves three main steps: preparation of the emulsion phase, preparation of the gel phase, and incorporation of both phases.

For the emulsion phase, Dexamethasone (100 mg) was dissolved in castor oil (3 g) to form the oil phase based on solubility studies. The aqueous phase was prepared by dissolving Tobramycin (500 mg), polyethylene glycol (emulsifying agent), and benzalkonium chloride (preservative) in distilled water. Both phases were heated separately to 70°C and then the oil phase was gradually added to the aqueous phase with continuous stirring at 1500 rpm to form an oil-in-water emulsion. The emulsion was then cooled to room temperature.

The gel phase was prepared by dispersing the gelling agent in glycerol, allowing it to swell and form a uniform gel base. Finally, the prepared emulsion was mixed with the gel using a high-speed mixer at 1500 rpm for 15 minutes to obtain a smooth and homogeneous emulgel formulation.

Evaluation Parameters

1. Physical Appearance

The prepared ophthalmic emulgel was visually inspected for color, clarity, homogeneity, consistency, and presence of any phase separation or grittiness.

2. pH Determination

The pH of the formulation was measured using a calibrated digital pH meter. The electrode was immersed in the emulgel sample, and readings were recorded at room temperature. The pH was maintained within the ocular acceptable range (approximately 6.5–7.5).

3. Viscosity

Viscosity of the emulgel was determined using a Brookfield viscometer at suitable spindle speed and temperature. The sample was placed in the viscometer, and readings were recorded to evaluate flow behavior.

4. Spreadability

Spreadability was determined using the glass slide method. A known quantity of emulgel was placed between two glass slides, and a specified weight was applied. The time taken for the slides to separate was recorded. Spreadability was calculated using the formula:

$S=M\times LTS=TM\times L$

Where:

S = Spreadability

M = Weight applied

L = Length of glass slide

T = Time taken

5. Drug Content Uniformity

A known quantity of emulgel was dissolved in a suitable solvent (e.g., phosphate buffer), filtered, and analyzed using UV spectrophotometry. The absorbance was measured, and drug content was calculated using a calibration curve.

6. In-vitro Drug Release Study

The drug release study was carried out using a Franz diffusion cell. A suitable membrane (e.g., dialysis membrane) was mounted between donor and receptor compartments. The receptor compartment was filled with simulated tear fluid or phosphate buffer (pH 7.4) and maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined time intervals and analyzed spectrophotometrically, replacing with fresh medium each time.

7. Sterility Testing

Sterility testing was performed as per pharmacopeial standards. The formulation was inoculated into fluid thioglycollate medium (for

bacteria) and soybean-casein digest medium (for fungi) and incubated for specified periods. The absence of microbial growth indicated sterility.

8. Ocular Irritation Test

The ocular irritation test was carried out using suitable animal models (e.g., rabbit eye model). The formulation was instilled into the eye, and signs of irritation such as redness, swelling, or tearing were observed over a specific period.

9. Stability Studies

Stability studies were conducted according to ICH guidelines by storing the formulation at different conditions (e.g., 25°C/60% RH and 40°C/75% RH). Samples were evaluated at regular intervals for physical appearance, pH, viscosity, and drug content.

The preformulation studies confirmed that Tobramycin and Dexamethasone possess suitable physicochemical properties for incorporation into an O/W emulgel system, with clear phase selection based on solubility behavior. The melting point analysis verified the purity of both drugs, while FTIR studies confirmed compatibility between drugs and excipients with no interaction. UV spectroscopy further established reliable analytical methods for drug estimation.

The prepared emulgel formulations exhibited desirable physical characteristics, including creamy white appearance, excellent homogeneity, and absence of phase separation, indicating a stable and uniform system. The pH of optimized batches remained within the acceptable ocular range, ensuring safety for ophthalmic use. Rheological studies revealed pseudoplastic behavior, which is advantageous for ease of application and prolonged retention at the site.

Stability studies demonstrated that the formulation remained unchanged in terms of appearance, pH, viscosity, and drug content over one month, confirming its stability. The antimicrobial study showed that the emulgel exhibited a larger zone of inhibition compared to the standard drug, indicating enhanced antibacterial efficacy. Additionally, the absence of redness, itching, and inflammation in the skin irritation test confirmed its safety profile. The swelling index results indicated good hydration and gel strength, which contribute to sustained drug release and improved performance of the formulation.

Results

Preformulation Studies

Parameter	**Drug**	**Observation**	**Interpretation**
Solubility Study	Dexamethasone	Insoluble in water, soluble in ethanol & castor oil	Selected for oil phase
	Tobramycin	Soluble in water, slightly soluble in ethanol	Selected for aqueous phase
	—	—	Confirms suitability for O/W emulgel
Melting Point	Tobramycin	173–176°C (~174°C)	Matches standard → Pure drug
	Dexamethasone	262–268°C (~265°C)	Matches standard → Pure drug
FTIR Analysis	Both drugs	O–H, C=O, N–H peaks observed	No interaction with excipients
UV Spectroscopy	Both drugs	Linear calibration curve	Suitable for quantitative analysis

2. Evaluation of Emulgel Formulations

Physical Properties

Parameter	**Observation**	**Interpretation**
Color	Creamy white	Acceptable appearance
Homogeneity	Good to excellent	Uniform formulation

Parameter	Observation	Interpretation
Phase Separation	Absent	Stable system

pH Determination

Batch	pH
Range	6.25 – 7.80
Optimized (F3/F4)	6.3 – 6.5

Interpretation: Within acceptable ocular pH range → Safe for eye application

Viscosity (Rheology)

Observation	Interpretation
Decreases with shear rate	Pseudoplastic behavior
Shear-thinning	Easy application & good retention

Stability Study (1 Month)

Parameter	Initial	After 1 Month	Result
Appearance	No change	No change	Stable
pH	6.60	6.62	Stable
Drug Content	~99%	~99%	Stable
Viscosity	No change	No change	Stable

3. Antimicrobial Activity

Sample	Zone of Inhibition
Emulgel	24 mm
Standard (Ofloxacin)	14 mm

Interpretation: Emulgel shows **superior antibacterial activity**

4. Skin Irritation Test

Parameter	Observation
Redness	Absent
Itching	Absent
Inflammation	Absent

Interpretation: Formulation is **safe and non-irritant**

5. Swelling Index

Formulation	Swelling Index
F1	20%
F2	30%
F3	10%

Interpretation: Indicates **good hydration capacity and gel strength**

Discussion

Many drugs are hydrophobic in nature and exhibit poor water solubility, making their formulation into effective dosage forms a significant challenge. This limitation often leads to reduced bioavailability and compromised stability of the drug. To address these issues, the emulgel system was selected in the present study as a novel and effective approach. Emulgel is a combination of emulsion and gel, which allows the incorporation

of both hydrophilic and hydrophobic drugs within a single formulation. This dual system enhances drug solubilization and improves therapeutic efficacy. The gel base provides a suitable consistency, while the emulsion facilitates drug delivery. Compared to conventional dosage forms, emulgel offers superior spreadability, ensuring uniform application over the affected area. It also possesses a non-greasy nature, making it more acceptable to patients. The formulation exhibits good stability and an extended shelf life under suitable conditions. Additionally, emulgels have a pleasant appearance, which enhances patient acceptability. They are easy to apply and remove, further improving convenience. Overall, emulgel represents a promising and patient-friendly drug delivery system.

Conclusion

The ophthalmic emulgel formulation of Tobramycin and Dexamethasone was successfully developed and evaluated, demonstrating satisfactory physicochemical and pharmaceutical characteristics. The formulation exhibited good stability, uniformity, and homogeneity, along with a suitable pH compatible with ocular tissues. It showed appropriate viscosity, ensuring ease of application and prolonged retention in the eye. Drug content was found to be uniform, indicating effective formulation techniques. Additionally, the emulgel displayed significant antibacterial activity, confirming its therapeutic potential. The developed system offers prolonged drug release, enhancing drug availability at the site of action. Increased residence time in the ocular cavity further improves treatment efficacy. Overall, the emulgel formulation enhances patient compliance and represents a promising approach for ocular drug delivery.

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