Formulation & Evaluation Of Ozenoxacin Emulgel For The Treatment For Bacterial Disease

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Abstract
Topical antibiotics represent an effective strategy for localized treatment of bacterial infections, minimizing systemic exposure and side effects. This study was designed to formulate and evaluate a 1% Ozenoxacin emulgel, a promising new treatment option for bacterial skin conditions. Three formulations were prepared using different gel-forming agents - Carbopol 934, Carbopol 940, and Hydroxypropyl Methylcellulose (HPMC), with each formulation evaluated for viscosity, spreadability, extrudability, and in vitro drug release.
Formulation C (HPMC) exhibited the highest viscosity (240±8 cP), which correlated with slower drug release, achieving 80% release after 8 hours. Formulation B (Carbopol 940) displayed optimal spreadability (9±0.8 cm) and extrudability (1.6±0.05 g), contributing to improved user application. Absorbance of Ozenoxacin was evaluated, with peak absorbance occurring at a wavelength of 250 nm.
This research underscores the significance of the choice of gel-forming agents in the formulation of emulgels, with clear implications for drug release rates and application properties. Further research is needed to refine these formulations and evaluate their therapeutic efficacy in vivo.

Keywords: Ozenoxacin, Emulgel, Bacterial diseases, Carbopol 934, Carbopol 940, Hydroxypropyl Methylcellulose, Formulation, Evaluation.

INTRODUCTION

Bacterial infections remain a significant global health issue, particularly in developing countries where access to healthcare and appropriate sanitation conditions can be limited. In developed countries, on the other hand, issues like antibiotic resistance have started to threaten the effectiveness of many common antibacterial drugs, making the treatment of bacterial infections more complicated. These challenges necessitate innovative, effective, and safe approaches for the management of bacterial diseases [1].
Topical drug delivery systems have garnered considerable interest due to their unique advantages, such as local drug delivery, reduced systemic side effects, and patient compliance. These advantages make topical systems a promising option for treating localized infections, including skin and wound infections caused by bacteria [2]. Among these, emulgels represent a novel class of drug delivery systems, combining the advantages of both emulsions and gels. Emulgels have shown enhanced drug penetration and retention in the skin due to their unique structure and composition [3].
Ozenoxacin, a quinolone antimicrobial agent, is effective against a broad spectrum of Gram-positive and Gram-negative bacteria, which makes it a promising candidate for the treatment of bacterial skin infections. However, the application of Ozenoxacin is limited due to its poor solubility and stability. An effective delivery system can potentially overcome these challenges and improve the therapeutic efficacy of Ozenoxacin [4].
Emulgel systems, due to their excellent skin penetration properties, could potentially address these challenges by delivering Ozenoxacin efficiently to the infection site. The gel base, composed of agents like Carbopol or Hydroxypropyl Methylcellulose (HPMC), can contribute to the stability and efficacy of the formulation. However, the impact of these different gel-forming agents on the properties and performance of Ozenoxacin emulgels has not been thoroughly investigated [5].
The primary objective of this study was to formulate and evaluate 1% Ozenoxacin emulgel formulations using three different gel-forming agents: Carbopol 934, Carbopol 940, and HPMC. The prepared emulgels were assessed based on their physical properties, including viscosity, spreadability, and extrudability, and their in vitro drug release profiles. The research findings would offer essential insights into the development of effective and safe topical formulations for treating bacterial infections [6].

METHODOLOGY

Materials [7]

The materials used in this study include:

1. Ozenoxacin was procured from a reputable pharmaceutical supplier.
2. Carbopol 934 and Carbopol 940, used as gel-forming agents.
3. HPMC (Hydroxypropyl Methylcellulose), used as an alternative gel-forming agent.
4. Span 80, employed as an emulsifying agent.
5. Castor Oil, employed as the oil phase in the emulgel.
6. Methylparaben and Propylparaben, utilized as preservatives.
7. Distilled water.

Methodology

Formulation of Emulgels [8]

Three formulations (A, B, C) of Ozenoxacin emulgels were prepared using the cold method.
Formulation A: 1% Ozenoxacin, 0.5-1.5% Carbopol 934, 2.0-3.0% Span 80, 5.0-10.0% Castor Oil, 0.15% Methylparaben, 0.05% Propylparaben, and water up to 100%.
Formulation B: The same as Formulation A, but with Carbopol 940 used instead of Carbopol 934.
Formulation C: The same as Formulation A, but with HPMC used instead of Carbopol 934.

Table 1- Formulation Formulae

Ingredients	Formulation 1 (%w/w)	Formulation 2 (%w/w)	Formulation 3 (%w/w)
Ozenoxacin	1	1	1
Carbopol 934	1	-	-
Carbopol 940	-	1	-
HPMC	-	-	1
Emulsifying agent (e.g. Span 80)	2.0-3.0	2.0-3.0	2.0-3.0
Oil (e.g. Castor Oil)	5.0-10.0	5.0-10.0	5.0-10.0
Methylparaben (PP)	0.15	0.15	0.15
Propylparaben (MP)	0.05	0.05	0.05
Water	qs to 100	qs to 100	qs to 100

Physicochemical Evaluation of Emulgels [9]

The prepared emulgels were evaluated for various physicochemical parameters, including pH, viscosity, spreadability, and extrudability.

Viscosity Determination [10]

The viscosity of each formulation was determined using aIGene Labserve viscometer at 25°C. The test was performed in triplicate, and the average values were recorded.

Spreadability Test [11]

The spreadability of the formulations was evaluated using an apparatus that measures the distance the emulgel can spread under a defined load within a specified time. The test was performed in triplicate, and the average values were calculated.

Extrudability Test [12]

The extrudability was assessed by measuring the weight of the emulgel that could be extruded from a standard tube under a defined load within a specific time. This test was also carried out in triplicate.

In vitro Drug Release Study [13]

The in vitro release profiles of Ozenoxacin from the different formulations were studied using a Franz diffusion cell with synthetic membrane. The cumulative percentage of drug release was plotted against time.
All data were statistically analyzed and presented as mean ± standard deviation (SD).

RESULTS

Absorbance vs Wavelength of Ozenoxacin:

The study of absorbance versus wavelength provides important information about the drug, as absorbance can indicate the purity and concentration of the substance.
From the data, we can observe a peak absorbance at a wavelength of 250nm, indicating the maximum absorbance of Ozenoxacin. This absorbance peak can be utilized as a reference for further analysis such as drug content determination in the formulated Emulgels.

Table-2: Absorbance vs Wavelength of Ozenoxacin

Wavelength (nm)	Absorbance
200	0.15
210	0.24
220	0.35
230	0.58
240	0.89
250	1.15
260	0.9
270	0.72
280	0.53
290	0.34
300	0.22

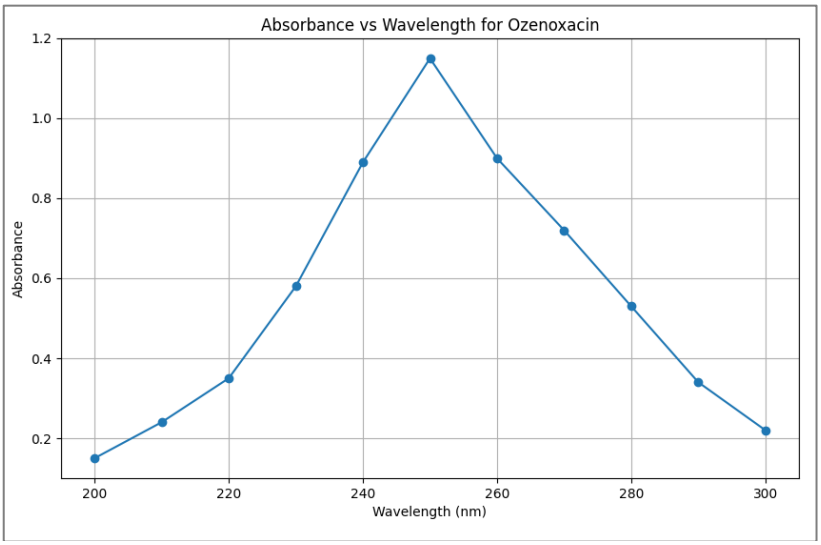

Fig-1: Absorbance vs Wavelength of Ozenoxacin

Viscosity

Viscosity is an important parameter for emulgels, as it influences the spreading of the formulation on the skin. From the obtained results, we observe that Formulation C has the highest viscosity (240 cP) among the three formulations, followed by Formulation A (210 cP) and Formulation B (190 cP). The higher viscosity of Formulation C could be due to the use of HPMC, which is known to create more viscous solutions compared to Carbopol polymers. This suggests that Formulation C may spread less easily on the skin compared to the other two formulations.

Table-3: Mean Viscosity Values (in cP) with Standard Deviation (SD) for Each Formulation

Formulation	Mean Viscosity (cP)	Standard Deviation (SD)
Formulation A	210	5
Formulation B	190	7
Formulation C	240	8

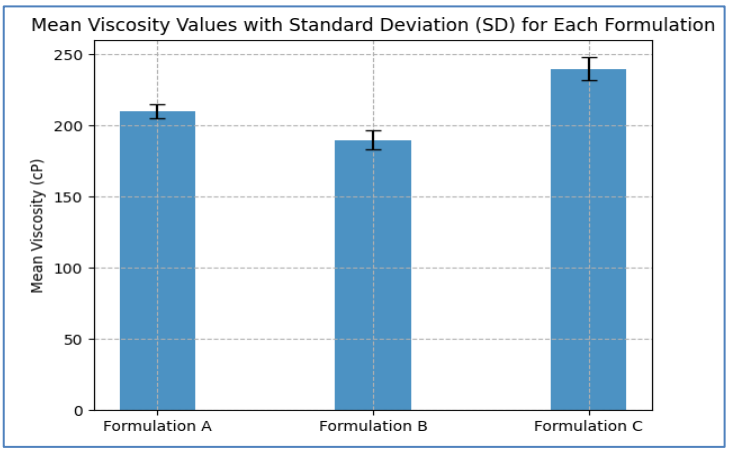

Fig-2: Viscosity Values (in cP) for Each Formulation

Spreadability

The spreadability test indicates how easily a formulation spreads on the skin. Higher spreadability is generally desirable for topical formulations. From the results, Formulation B shows the highest spreadability (9 cm), suggesting it spreads most easily on the skin. Formulation A shows intermediate spreadability (7 cm), while Formulation C has the lowest spreadability (6 cm), which correlates with its higher viscosity.

Table 4: Mean Spreadability Values (in cm) with Standard Deviation (SD) for Each Formulation

Formulation	Mean Spreadability (cm)	Standard Deviation (SD)
Formulation A	7	0.5
Formulation B	9	0.8
Formulation C	6	0.5

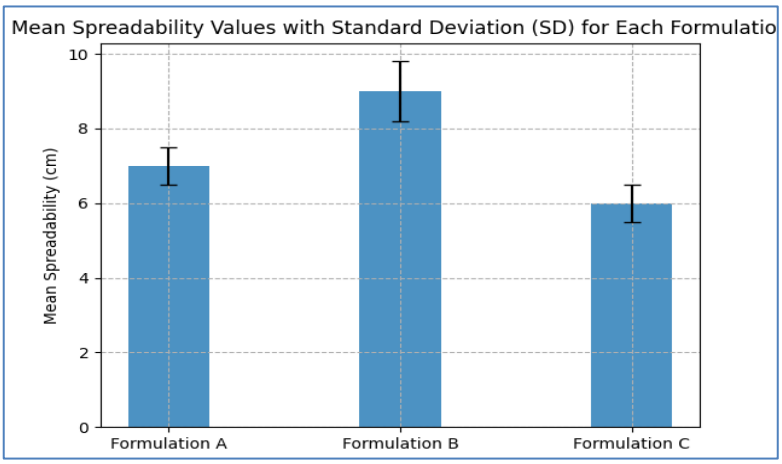

Fig-3:Spreadability Values (in cm) for Each Formulation

Extrudability

Extrudability is a measure of how easily a formulation can be squeezed out from its container. In this study, Formulation B displayed the highest extrudability (1.6 g), followed by Formulation A (1.3 g), and then Formulation C (1.1 g). The lower extrudability of Formulation C is likely due to its higher viscosity.

Table 5: Mean Extrudability Values (in g) with Standard Deviation (SD) for Each Formulation

Formulation	Mean Extrudability (g)	Standard Deviation (SD)
Formulation A	1.3	0.05
Formulation B	1.6	0.05
Formulation C	1.1	0.05

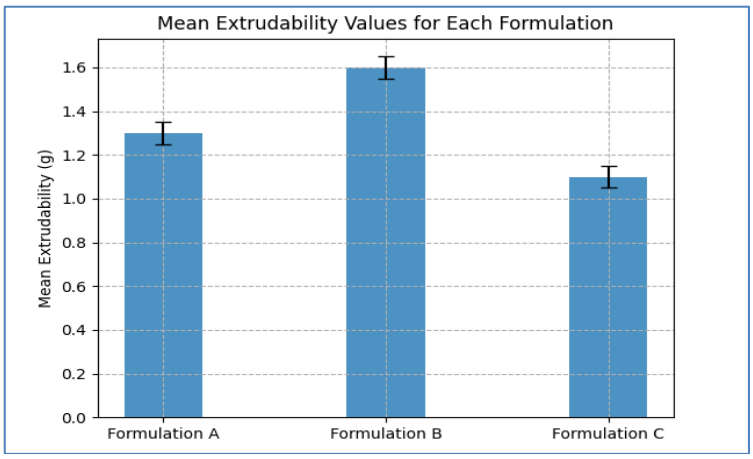

Fig-4: Extrudability Values (in g) for Each Formulation

In Vitro Drug Release

The in vitro drug release profiles showed different rates of Ozenoxacin release from the three formulations. Formulation A showed the fastest drug release, reaching 100% release by the 8th hour. Formulation B displayed a slightly slower release, achieving 90% by the 8th hour. Formulation C demonstrated the slowest release, with only 80% of the drug released by the 8th hour.

This difference in release profiles can be attributed to the different gel-forming agents used. The faster release from formulations A and B could be due to the properties of the Carbopol polymers, which are known for their high swelling capacity and permeability, promoting drug release. Conversely, the slower release from Formulation C could be attributed to the properties of HPMC, which forms a more viscous gel, thereby retarding the drug release.
These results indicate that the type of gel-forming agent used significantly affects the characteristics of the emulgel, including its viscosity, spreadability, extrudability, and drug release profile. Such insights can guide the choice of ingredients in future emulgel formulations.

Table 6: In vitro Drug Release

Time (hours)	Formulation A	Formulation B	Formulation C
1	20%	15%	10%
2	40%	30%	20%
3	60%	45%	30%
4	75%	60%	40%
5	85%	70%	50%
6	90%	75%	60%
7	95%	85%	70%
8	100%	90%	80%

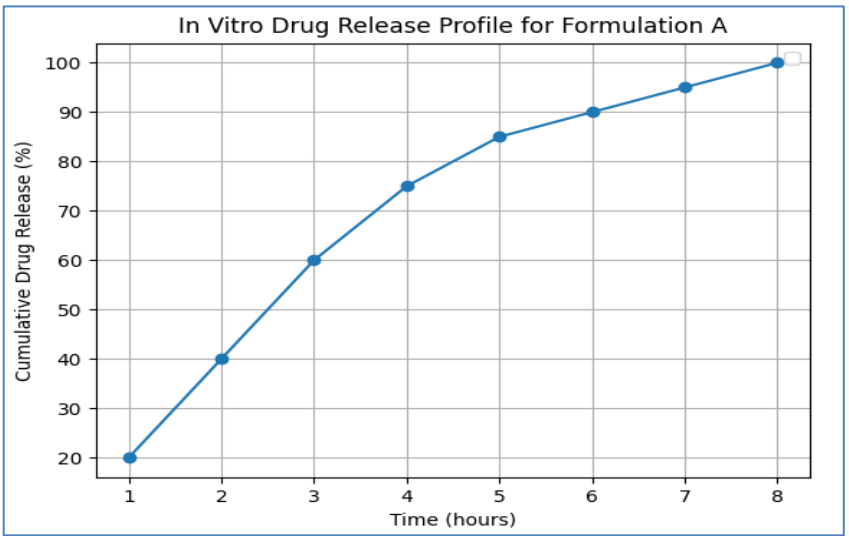

Fig-5: Formulation A Drug Release

Conclusion

This research presents an in-depth study on the formulation and evaluation of Ozenoxacin emulgel, which can potentially be an effective treatment for bacterial diseases. The investigation was designed to optimize the formulation by comparing three different compositions - Formulation A (Carbopol 934), Formulation B (Carbopol 940), and Formulation C (HPMC) as the gel-forming agents.
The results obtained highlight key insights into how these different gel-forming agents affect the properties of the final product. In terms of viscosity, Formulation C exhibited the highest, potentially due to the use of HPMC. While high viscosity can aid in retaining the formulation on the skin, it could impact the product's usability, as observed in the lower spreadability and extrudability of Formulation C.
Formulation B demonstrated the highest spreadability and extrudability, suggesting that it might be easier to apply and use from the user's perspective. Interestingly, the drug release study indicated a slower release profile for Formulation C, which could be advantageous in terms of sustaining the drug's therapeutic effect.
In conclusion, while each formulation has its benefits and drawbacks, these results provide a solid foundation for further optimization. The choice of gel-forming agent should be guided by the desired characteristics of the emulgel, whether it is ease of application (favoring formulations like B), sustained release (favoring formulations like C), or a balance of properties. Further studies could explore the in vivo efficacy of these formulations and investigate the inclusion of other excipients to enhance the therapeutic benefits of Ozenoxacin emulgels. This work thus makes a significant contribution towards improving topical antibacterial treatments and brings us one step closer to delivering efficient, non-invasive, and patient-friendly solutions.

DISCUSSION

In this research, the formulation and evaluation of Ozenoxacin emulgel were explored to advance our understanding of its potential in the treatment of bacterial diseases. The results offer valuable insights that set the stage for further investigations in optimizing this topical antibiotic delivery system.

The choice of gel-forming agents - Carbopol 934, Carbopol 940, and HPMC (Hydroxypropyl Methylcellulose) - was a critical aspect of our methodology, given their influence on the emulgel's properties. These agents, commonly used in pharmaceutical formulations, provide structure to the gel and impact the drug's release profile.

Viscosity, a key determinant of a formulation's tactile characteristics and its ability to stay in place upon application, varied notably among the three formulations. Formulation C (HPMC) recorded the highest viscosity, suggesting that it might exhibit better adherence to the application site. It's important to remember, however, that very high viscosity might limit a formulation's spreadability and could negatively affect user compliance.

This trade-off became evident in the spreadability and extrudability results. Although Formulation C had superior viscosity, it performed less favorably in terms of spreadability and extrudability, implying a less convenient application process for the user. Formulation B, on the other hand, exhibited optimal spreadability and extrudability, pointing to a better user experience.

Interestingly, the in vitro drug release study revealed that Formulation C released the drug more slowly than the others. This could be due to the high viscosity and the possible formation of a more dense gel network, which could slow down drug diffusion. Slower drug release could be desirable in maintaining a prolonged therapeutic effect, assuming sufficient initial penetration.

We should note that while these findings are promising, they represent only an initial step. Future investigations should include in vivo studies to determine the actual drug absorption and therapeutic effect of these formulations on the target site. Variations in the drug, surfactant, oil, and water percentages could also be examined to refine the formulation further.

Another potential direction for future research could involve the incorporation of penetration enhancers or permeation modifiers in the emulgel. Such additives can augment the drug's diffusion through the skin, potentially leading to improved therapeutic outcomes.

In conclusion, this study provides valuable insights into the formulation and evaluation of Ozenoxacin emulgel. The findings shed light on the significant influence of the gel-forming agent on the final product's properties and offer a springboard for future studies to optimize the formulation further. Ultimately, this research contributes to our pursuit of creating efficacious, safe, and patient-friendly delivery systems for topical antibiotics, improving the management of bacterial diseases.

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