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Formulation and Evaluation of Topical Emulgels

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Abstract: *The present study aimed to develop and evaluate Econazole emulgel formulations for enhanced topical delivery, combining the advantages of emulsions and gels to improve patient compliance and therapeutic efficacy. Nine formulations (F1–F9) were prepared using Econazole as the antifungal agent, Carbopol 934 as the gelling agent, and suitable emulsifiers and co-solvents. Preliminary characterization confirmed the purity and physicochemical suitability of Econazole, showing it as a white to off-white crystalline powder with a melting point of 142°C–146°C, slightly soluble in water but freely soluble in ethanol and methanol. The emulgels were prepared by incorporating an optimized oil-in-water emulsion into a Carbopol gel base neutralized with triethanolamine. Evaluation of the formulations revealed uniform yellowish white appearance, good homogeneity, absence of grittiness, pH compatible with skin, viscosities ranging from 4236 to 8536 cps, and satisfactory spreadability. Drug content analysis confirmed uniform distribution, while in vitro drug release studies demonstrated sustained release up to 240 minutes, with F5 exhibiting the most favorable profile. Stability studies over 30 days indicated no significant changes in physical and chemical properties, confirming formulation robustness. These findings support the potential of Econazole emulgel as a promising approach for effective topical antifungal therapy.*

Keywords: Econazole; Emulgel; Carbopol 934; Topical delivery; Antifungal; In vitro release; Stability

I. INTRODUCTION

Fungal infections of the skin, also known as dermatophytoses or superficial mycoses, represent a significant proportion of dermatological diseases worldwide, affecting millions of individuals annually. These infections are primarily caused by dermatophytes, yeasts, and filamentous fungi that invade keratinized tissues such as the stratum corneum, hair, and nails, leading to conditions characterized by erythema, itching, scaling, and discomfort. In recent years, the prevalence of superficial fungal infections has increased, partly due to climatic factors, widespread use of immunosuppressive agents, and lifestyle practices that favor fungal proliferation. Effective management of these infections is therefore essential to prevent chronicity, recurrence, and secondary bacterial complications.[1,2]

Econazole nitrate, an imidazole derivative, is a broad-spectrum antifungal agent widely employed in the treatment of cutaneous mycoses. It exerts its fungistatic and fungicidal action by inhibiting ergosterol synthesis in fungal cell membranes, leading to increased membrane permeability and ultimately cell death. Despite its established efficacy, conventional topical formulations of Econazole, such as creams and ointments, often suffer from limitations including poor patient compliance due to greasiness, reduced drug residence time on the skin, and variable release profiles that may compromise therapeutic outcomes.[3,4]

In this context, the exploration of novel topical delivery systems is of considerable interest. Among them, emulgels, which synergistically combine the properties of emulsions and gels, have emerged as promising platforms for dermatological therapy. Emulgels integrate an oil-in-water emulsion within a gel matrix, thereby enhancing the solubilization of lipophilic drugs like Econazole while improving spreadability, patient acceptability, and controlled drug release. The presence of a gel phase imparts desirable rheological characteristics such as non-greasiness and ease of application, while the emulsion facilitates efficient penetration of the active ingredient through the stratum corneum.

Carbopol 934, a widely used synthetic high-molecular-weight crosslinked polymer of acrylic acid, serves as an effective gelling agent in such systems, providing viscosity and facilitating sustained release. Surfactants like Span 20 (sorbitan monolaurate) and Tween 20 (polyoxyethylene sorbitan monolaurate) play crucial roles in stabilizing the oil

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and aqueous phases, respectively, ensuring the formation of a stable and uniform emulsion. Additionally, incorporation of penetration enhancers such as propylene glycol further promotes drug permeation through the skin, optimizing therapeutic efficacy.[5,6]

The present study was therefore designed with the objective of developing and systematically evaluating Econazole emulgel formulations to address the limitations of conventional topical systems and to enhance antifungal efficacy. A series of formulations (F1–F9) were prepared by varying concentrations of gelling agents and surfactants to investigate their impact on critical quality attributes such as physical appearance, pH, viscosity, spreadability, drug content uniformity, and in vitro drug release. Stability studies were also conducted to assess the formulations' robustness over time. By integrating the benefits of emulsions and gels, this research aims to establish a scientifically rational and patient-friendly approach for the topical delivery of Econazole, potentially contributing to improved management of superficial fungal infections.[7,8]

II. MATERIALS AND METHODS

The formulation of the Econazole emulgel utilized carefully selected materials each serving a defined role: Econazole acted as the antifungal active pharmaceutical ingredient (API) providing therapeutic efficacy, while Carbopol 934 functioned as the gelling agent imparting viscosity and spreadability. Liquid paraffin served as the emollient and oil phase, Span 20 and Tween 20 acted as non-ionic emulsifiers stabilizing the oil and aqueous phases respectively, and propylene glycol enhanced drug penetration and hydration. Triethanolamine (TEA) was employed to neutralize Carbopol and adjust the pH for skin compatibility, with purified water as the solvent base. Preliminary characterization of pure Econazole showed it as a white to off-white crystalline powder with no significant odor, melting between 142°C and 146°C, confirming its purity and stable crystalline nature. Solubility studies revealed Econazole's slight solubility in water but high solubility in ethanol, methanol, acetone, and chloroform, guiding solvent choices for formulation. UV spectroscopic analysis established a maximum absorption at 265 nm, used to construct a linear calibration curve (2–20 µg/mL), validating Beer-Lambert's law for quantitative estimation. FTIR spectroscopy confirmed characteristic functional groups, showing aromatic C–H stretching around 3000–3100 cm^{-1} and N–H stretching near 3300–3400 cm^{-1}, consistent with Econazole's molecular structure, supporting its identification and suitability for further formulation.[9,10]

Formulation of Emulgel

Econazole emulgels were prepared by a standard emulsification and gelation technique, combining an oil phase (liquid paraffin, Span 20, and Econazole) and an aqueous phase (Tween 20, propylene glycol, and purified water), each heated to 70–75°C and then mixed with continuous stirring to form a stable emulsion. Separately, a gel base was made by dispersing Carbopol 934 in purified water and neutralizing with triethanolamine to form a clear gel. The prepared emulsion was then gradually incorporated into the gel base with gentle stirring to yield a uniform emulgel. Formulations F1–F9 were developed by varying concentrations of gelling agents and surfactants to study their impact on the formulation's physical characteristics and drug release.[11,12]

Table 1: Composition of Econazole Emulgel Formulations

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Econazole	1	1	1	1	1	1	1	1	1
Carbopol 934	0.5	0.5	0.5	1.0	1.0	1.0	1.5	1.5	1.5
Liquid Paraffin	3	5	7	3	5	7	3	5	7
Span 20	2	2.5	5	2	2.5	5	2	2.5	5
Tween 20	2	2.5	5	2	2.5	5	2	2.5	5
Propylene Glycol	5	5.5	10	5	5.5	10	5	5.5	10
Triethanolamine (TEA)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

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Evaluation of Econazole Emulgel:

The prepared Econazole emulgel formulations (F1–F9) were evaluated for key parameters to ensure their quality, efficacy, and patient acceptability. Physically, all formulations appeared yellowish white with uniform color and texture; F2 and F5 showed excellent homogeneity and extrudability, while all were grit-free. The pH ranged within skin-compatible limits, measured by dispersing samples in distilled water and recording values with a calibrated digital pH meter. Viscosity, determined using a Brookfield Viscometer, varied from 4236 to 8536 cps, reflecting differences in gel structure. Drug content analysis by UV spectrophotometry at 265 nm confirmed uniform Econazole distribution across formulations. Spreadability testing using glass slides and fixed weights demonstrated good to excellent spread characteristics, essential for ease of application. In vitro drug release studies conducted with the USP type II dissolution apparatus in PBS (pH 7.4) at 37 ± 0.5°C revealed cumulative release profiles over 240 minutes, showing that formulations like F5 achieved faster release while higher viscosity formulations slowed release. Stability studies on F5 and F6 over 30 days at room temperature indicated minimal changes in pH, viscosity, spreadability, drug content, and cumulative release, confirming formulation stability under standard conditions.[13,14]

III. RESULT AND DISCUSSION

Table 2: Physical appearance of pure Econazole

Parameter	Observation
Appearance	White to off-white crystalline powder
Odor	Odorless or faint characteristic odor
Melting Point	142°C – 146°C

Table 3: Solubility of Econazole

Solvent	Solubility of
Water	Slightly soluble
Ethanol (95%)	Freely soluble
Methanol	Freely soluble
Acetone	Soluble
Chloroform	Soluble

Table 4: Physical characterization of Econazole emulgel

Formulation Code	Colour	Homogeneity	Extrudability
F1	Yellowish white	** (Good)	** (Good)
F2	Yellowish white	*** (Excellent)	*** (Excellent)
F3	Yellowish white	** (Good)	** (Good)
F4	Yellowish white	** (Good)	** (Good)
F5	Yellowish white	*** (Excellent)	*** (Excellent)
F6	Yellowish white	** (Good)	** (Good)
F7	Yellowish white	** (Good)	** (Good)
F8	Yellowish white	** (Good)	** (Good)
F9	Yellowish white	** (Good)	** (Good)

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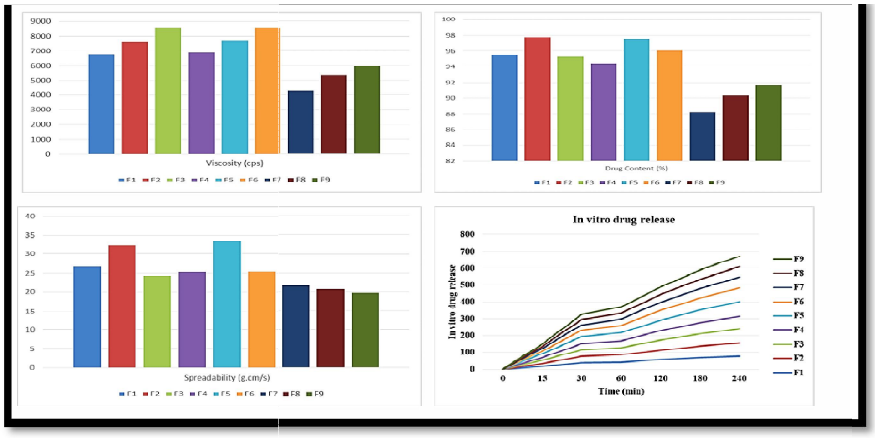

Fig 1: Evaluation of Econazole emulgel

IV. CONCLUSION

The study successfully formulated and evaluated Econazole emulgel systems by integrating an oil-in-water emulsion into a Carbopol gel base, yielding formulations with desirable physicochemical properties for topical application. The optimized formulation (F5) demonstrated excellent homogeneity, spreadability, and a sustained drug release profile, while maintaining stability over 30 days under standard storage conditions. These results highlight the potential of Econazole emulgel as an effective and patient-friendly topical antifungal delivery system, meriting further clinical investigations.

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