RESEARCH PAPER

Design Development and Optimization of Econazole Nitrate Anti-Fungal Emulgel by Using Factorial Design Approach

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ABSTRACT

Background: Emulgel-based topical systems offer combined advantages of emulsions and gels, including enhanced drug solubilization, controlled release, improved penetration, and better patient acceptability. The present study aimed to design, develop, and optimize an econazole nitrate emulgel using a factorial design approach for effective topical antifungal delivery.

Methods: Econazole nitrate emulgels were prepared using Isopropyl myristate as a penetration enhancer and Sepineo DERM as a gelling agent. A 3^2 factorial design was employed to evaluate the influence of formulation variables on drug release and viscosity. The formulations were evaluated for physical characteristics, pH, viscosity, spreadability, drug content, and in-vitro drug diffusion. Optimization was carried out using Design-Expert software, and the optimized batch was further evaluated for antifungal activity using the agar diffusion method.

Results: All formulations exhibited acceptable physical appearance, pH in the range of 6.00–6.16, uniform drug content (98.25–101.15%), and suitable rheological properties. In-vitro drug release ranged from 84.78% to 97.54% over eight hours. Statistical analysis revealed that Isopropyl myristate significantly enhanced drug release, while Sepineo DERM had a major influence on viscosity. The optimized formulation showed controlled drug release (98.50%) and exhibited superior antifungal activity with a zone of inhibition of 25 mm, comparable to the standard drug.

Conclusion: The optimized econazole nitrate emulgel demonstrated favorable physicochemical properties, controlled drug release, and effective antifungal activity, indicating its potential as a promising topical delivery system for fungal infections.

Keywords: Econazole nitrate, emulgel, antifungal, factorial design, topical drug delivery, optimization

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INTRODUCTION

Fungal infections constitute one of the most frequently encountered infectious skin disorders and remain a persistent challenge in clinical dermatology. These infections are mainly caused by dermatophytes, yeasts, and filamentous fungi and commonly manifest as tinea infections, candidiasis, and other superficial mycoses. The incidence of fungal infections has increased considerably in recent years due to factors such as hot and humid climatic conditions, poor personal hygiene, prolonged antibiotic therapy, diabetes, and immunosuppression. Although most superficial fungal infections are not life-threatening, they often lead to itching, erythema, inflammation, and secondary infections, thereby affecting patient comfort and quality of life [1].

Topical drug delivery is widely preferred for the treatment of superficial fungal infections as it allows direct application of the drug at the site of infection, resulting in higher local drug concentrations and reduced systemic exposure. Econazole nitrate, an imidazole derivative with broad-spectrum antifungal activity, is extensively used against dermatophytes, Candida species, and other pathogenic fungi. The drug exerts its antifungal action by inhibiting the synthesis of ergosterol, an essential component of the fungal cell membrane, thereby disrupting membrane integrity and leading to cell death. However, oral administration of

econazole is associated with several drawbacks such as poor aqueous solubility, low systemic bioavailability, gastrointestinal irritation, and the risk of hepatic toxicity upon prolonged use. These limitations highlight the advantage of delivering econazole nitrate through topical routes, where localized action with minimal systemic absorption can be achieved [2,3].

Conventional topical formulations including creams, ointments, and lotions often suffer from disadvantages such as greasy texture, poor spreadability, inadequate drug penetration, and limited patient acceptability. Emulgels are formed by incorporating an emulsion into a gel base, thereby combining the beneficial properties of both systems. The presence of an emulsion allows effective incorporation of hydrophobic drugs, while the gel matrix provides a non-greasy, easily spreadable, and aesthetically acceptable formulation. This dual system enhances formulation stability, improves patient compliance, and facilitates controlled drug release.

Emulgels have demonstrated significant potential in enhancing the topical bioavailability of poorly water-soluble drugs. The emulsion component promotes better solubilization of lipophilic drugs such as econazole nitrate, while the gel network prolongs the residence time of the formulation on the skin surface. Additionally, emulgels enhance drug permeation across the stratum corneum by maintaining an optimal concentration gradient, thereby improving therapeutic efficacy and reducing the frequency of application. These advantages make emulgels an ideal carrier system for topical antifungal therapy.

The formulation of emulgels involves multiple variables that can significantly influence product performance, including the concentration of gelling agents, type and ratio of emulsifiers, and oil phase composition [4]. Therefore, a systematic optimization strategy is essential to achieve a formulation with desirable physicochemical properties and enhanced drug release characteristics. Factorial design, a statistical optimization technique, enables the simultaneous evaluation of multiple formulation variables and their interactions with a reduced number of experimental trials, ensuring reproducibility and formulation efficiency.

In view of the limitations associated with oral econazole therapy and the advantages offered by emulgel-based topical delivery, the present investigation aims to design, develop, and optimize an econazole nitrate antifungal emulgel using a factorial design approach, thereby emphasizing the necessity of this study for improving the safety, efficacy, and patient acceptability of antifungal treatment.

MATERIALS AND METHODS

Materials and Instrumentation

Econazole nitrate was obtained as a gift sample from a reputed pharmaceutical manufacturer. Sepineo D.E.R.M, isopropyl myristate, Tween 80, Span 20, propylene glycol, methyl paraben, and triethanolamine were procured from certified laboratory suppliers. All reagents and solvents were of analytical grade, and purified water was used throughout the study. The instruments used included a digital melting point apparatus, Jasco V-550 UV–visible spectrophotometer, Shimadzu IR-Affinity-1 FT-IR spectrophotometer, Brookfield viscometer (Amtech LVDVE), digital pH meter (Labman LMPH-10), Franz diffusion cell, sonicator, magnetic stirrer, and hot air oven.

Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical properties of econazole nitrate and to generate preliminary data required for formulation development. Drug characterization involved assessment of colour, odour, and appearance. A small quantity of the drug was placed on butter paper and observed under daylight to record colour, gently smelled to detect odour, and rubbed between the fingers to evaluate physical appearance and texture.

The melting point of econazole nitrate was determined by the open capillary method as an indicator of purity. The powdered drug was filled into a sealed glass capillary tube, placed in a melting point apparatus, and the temperature at which complete melting occurred was recorded.

Solubility studies were performed in methanol, dimethyl sulfoxide, dimethylformamide, and water. Twenty milligrams of the drug was added to 10 mL of each solvent, sonicated for 10 minutes, and visually examined for undissolved particles.

For UV–visible spectrophotometric analysis, a stock solution of econazole nitrate (1000 µg/mL) was prepared in methanol. Suitable dilutions were made to obtain concentrations ranging from 5 to 25 µg/mL. Absorbance was measured at 220 nm using methanol as blank, and a calibration curve was constructed.

FT-IR spectroscopy was carried out using the KBr pellet method over a range of 400–4000 cm^{-1}. The obtained spectrum was compared with standard reference spectra to confirm the identity of the drug.

Drug–Excipient Compatibility Study

Drug–excipient compatibility studies were conducted to detect possible interactions between econazole

nitrate and selected excipients. The drug and each excipient were mixed in a 1:1 ratio, passed through a sieve, filled into clean glass vials, and stored in a stability chamber maintained at 40 ± 2°C and 75 ± 5% relative humidity. The samples were periodically examined for physical changes such as discoloration, agglomeration, or liquefaction.

Preparation of Econazole Nitrate Emulgel

The oil phase was prepared by dissolving econazole nitrate in isopropyl myristate with gentle heating at 40–45°C, followed by the addition of Span 20 with continuous mixing. The aqueous phase was prepared by dissolving Tween 80 in purified water heated to 60–65°C and adding propylene glycol under stirring. Methyl paraben, previously dissolved in warm propylene glycol, was incorporated into the aqueous phase.

The oil phase was slowly added to the aqueous phase at the same temperature with continuous stirring to obtain a uniform oil-in-water emulsion. Separately, Sepineo D.E.R.M was dispersed in purified water and allowed to hydrate to form a smooth gel base. The prepared emulsion was gradually incorporated into the gel base with gentle mixing. The pH of the formulation was adjusted using triethanolamine, and the final volume was made up with purified water to obtain the emulgel.

Optimization of Formulation

A 3^2 full factorial design was employed to optimize the formulation by studying the influence of isopropyl myristate (X_1) and Sepineo D.E.R.M (X_2) on percentage in-vitro drug release (Y_1) and viscosity (Y_2). Nine experimental formulations were prepared at three levels of each variable. The optimized batch was selected using desirability functions based on an appropriate balance between drug release, viscosity, and physical stability. Table no.1 illustrates the details of the optimization of the formulation.

Independent variables	Name	Unit	Levels		
			Low (-1)	Middle	High (+1)
X1	Isopropyl myristate	%	5	7.5	10
X2	Sepineo D.E.R.M	%	0.5	1	1.5
Responses					
Y1	% In vitro drug release				
Y2	Viscosity				

Table no.1: Optimization of the formulation

Evaluation Parameters

All formulations were visually inspected for colour, odour, appearance, presence of grittiness, phase separation, and air bubbles. The pH of each formulation was determined by dispersing 1 g of emulgel in 10 mL of distilled water, allowing it to stand for 2 hours, and measuring with a calibrated digital pH meter in triplicate.

Viscosity was measured using a Brookfield viscometer with spindle no. 64 at 25 ± 1°C after allowing the sample to stand undisturbed to remove entrapped air.

Spreadability was determined by the slip and drag method. A fixed quantity of gel was placed between two glass slides, and the time required for the upper slide to move a specified distance under a known weight was recorded. Spreadability was calculated using the formula S = ML/T.

For drug content uniformity, gel equivalent to 10 mg of econazole nitrate was extracted with methanol, filtered, and suitably diluted. Absorbance was measured at 220 nm, and drug content was calculated using the calibration curve.

In-vitro drug release studies were performed using a Franz diffusion cell with phosphate buffer (pH 6.8) as receptor medium maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined time intervals, replaced with fresh medium, and analyzed spectrophotometrically to calculate cumulative drug release.

Antifungal Activity

Antifungal activity was evaluated by the disc diffusion method using Candida albicans cultured on Sabouraud dextrose agar. Discs impregnated with the emulgel were placed on inoculated plates and incubated at 28–30°C for 24–48 hours. The diameter of the zone of inhibition was measured and compared with that of a marketed formulation and placebo.

Accelerated Stability Studies

Accelerated stability studies were conducted on the optimized formulation as per ICH guidelines at 40 ± 2°C and 75 ± 5% relative humidity for 30 days. Samples were evaluated for physical appearance, pH, and drug content to assess formulation stability.

RESULTS

Preformulation results demonstrated white, crystalline, odourless econazole nitrate with a melting point of 160–162°C and solubility in methanol, DMSO, and DMF. UV spectrophotometry showed λmax at 220 nm with linearity (R^2 = 0.9917). FT-IR confirmed characteristic functional groups, and compatibility studies revealed no drug–excipient interactions, confirming formulation suitability for topical delivery applications.

The formulated econazole nitrate emulgel batches were subjected to comprehensive physicochemical evaluation to assess their suitability for topical application. All formulations exhibited uniform white

coloration and a mild characteristic odour, indicating formulation homogeneity and absence of degradation or instability. No inter-batch variation in colour or odour was observed. With respect to consistency, most formulations showed smooth and homogeneous appearance, while a few batches exhibited comparatively higher viscosity due to increased polymer concentration. The pH values of all batches ranged between 6.00 ± 0.1 and 6.16 ± 0.1, which lies within the acceptable physiological range for topical preparations and suggests minimal risk of skin irritation. Viscosity measurements revealed a progressive increase with increasing concentration of Sepineo DERM, confirming its dominant role in governing the rheological characteristics of the emulgel system, while Isopropyl myristate exerted a minor reducing effect on viscosity by improving drug solubility and spreadability. Spreadability values ranged from 10.5 ± 0.1 to 14.7 ± 0.2 g·cm/sec and demonstrated an inverse relationship with viscosity, wherein formulations containing higher polymer concentrations exhibited reduced spreading capacity. Drug content analysis by UV-Visible spectrophotometry confirmed uniform distribution of econazole nitrate in all batches, with values ranging from 98.25% to 101.15%, indicating excellent content uniformity and reproducibility of the formulation process. In-vitro diffusion studies demonstrated cumulative drug release in the range of 84.78% to 97.54% over an 8-hour period, with formulations containing lower polymer concentration and higher penetration enhancer levels exhibiting enhanced diffusion profiles. Among all batches, formulation F7 demonstrated the most desirable balance between viscosity, spreadability, drug content, and release characteristics and was therefore selected for further optimization and biological evaluation.

The effect of formulation variables on drug release was systematically investigated using factorial design and response surface methodology. The figure no. 1 depicts the drug release with respect to the time points specified. Fit summary analysis suggested the linear model as the most appropriate for describing the drug release response, with the model exhibiting a highly significant F-value of 195.48 and a p-value less than 0.0001, indicating an excellent fit of the experimental data. The regression analysis revealed that both independent variables significantly influenced drug release, with Isopropyl myristate exerting a positive effect and Sepineo DERM exerting a negative effect on the diffusion of econazole nitrate. The high coefficient of determination (R^2 = 0.9849) along with close agreement between adjusted and predicted R^2 values confirmed the robustness and predictability of the model. The final regression equation demonstrated that an increase in Isopropyl myristate concentration enhanced drug release, whereas an increase in polymer concentration retarded diffusion due to increased matrix viscosity and reduced drug mobility. Response surface and contour plots further illustrated that Isopropyl myristate was the dominant factor controlling drug diffusion. Figure no. 2 demonstrated the finding of colour plot of drug release. Table no. 2 illustrates the details of drug release from the econazole emulgel. These findings clearly establish the critical role of formulation composition in modulating release kinetics and confirm the suitability of the optimized formulation for prolonged antifungal therapy.

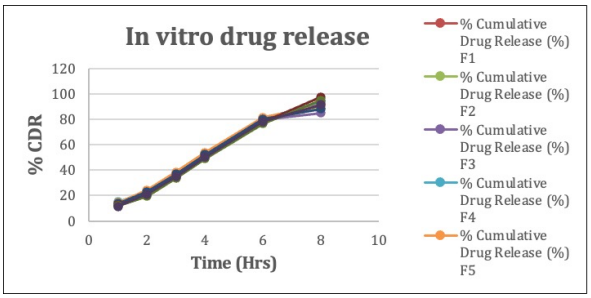

Figure no. 1: % CDR vs Time for drug diffusion

Table no. 2: Drug release with respect to ratio of polymers

Sr no.	A: % Isopropyl myristate	B: % Sepineo DERM	Drug release %
1	7.5	1	90.68
2	7.5	0.5	94.02
3	5	0.5	92.41
4	10	1.5	91.41
5	7.5	1.5	87.99
6	10	1	94.82
7	5	1.5	84.73
8	5	1	88.28
9	10	0.5	97.54

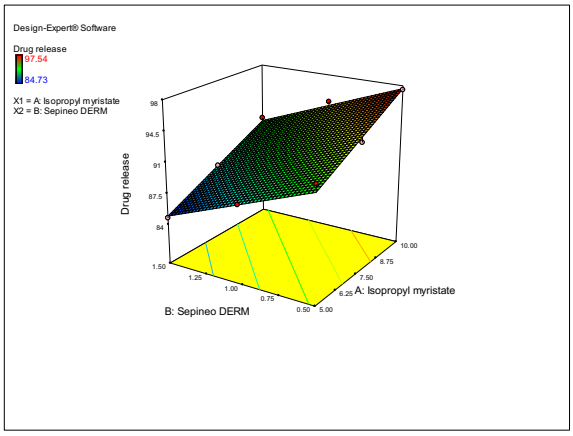

Figure no. 2 : 3D plot for Drug release

The viscosity was another variable studied with the variation of the formula. Table no.3 indicates the details of viscosity. Optimization of viscosity was carried out using a two-factor interaction model, which was selected as the best-fitting model based on fit summary and statistical evaluation. The ANOVA results demonstrated a highly significant model with an F-value of 5773.84 and p-value less than 0.0001, confirming the strong influence of formulation variables on rheological behavior. Both Isopropyl myristate and Sepineo DERM, along with their interaction, were found to significantly affect viscosity. The extremely high R^2 value (0.9997) and Adequate Precision ratio (185.442) indicated excellent model accuracy and signal reliability. Regression analysis revealed that viscosity increased markedly with increasing Sepineo DERM concentration, confirming its primary role as a gelling and thickening agent, while increasing Isopropyl myristate concentration resulted in a reduction in viscosity due to its plasticizing and solubilizing effects. Three-dimensional response surface plots clearly demonstrated the dominant contribution of Sepineo DERM to viscosity modulation . Figure no. 3 illustrates the 3D plot of viscosity. These results highlight the importance of polymer concentration in controlling the consistency, stability, and application characteristics of emulgel formulations.

Table no. 3: Viscosity with respect to ratio of polymers

Sr no.	A: % Isopropyl myristate	B: % Sepineo DERM	Viscosity cP
1	7.5	1	5539
2	7.5	0.5	4252
3	5	0.5	4412
4	10	1.5	6539
5	7.5	1.5	6822
6	10	1	5303
7	5	1.5	7144
8	5	1	5726
9	10	0.5	4145

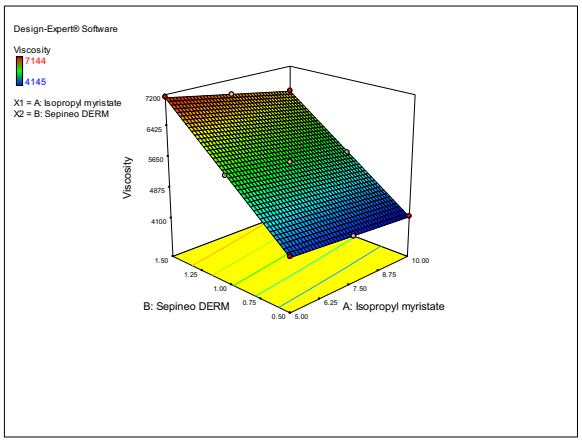

Figure no. 3: 3D plot for viscosity

The optimized batch F7 was further evaluated for antifungal efficacy using the agar diffusion method. The formulation produced a zone of inhibition measuring 25 mm, which was comparable to that produced by the standard antifungal agent Nystatin (24 mm). The comparable inhibitory activity confirms that incorporation of econazole nitrate into the emulgel base did not compromise its antifungal potency and that the optimized formulation effectively delivers the drug to the target site. The enhanced antifungal activity may be attributed to improved drug release, appropriate viscosity, and prolonged residence time at the site of application. Overall, the combined results of physicochemical evaluation, statistical optimization, and biological assessment confirm that the optimized econazole nitrate emulgel formulation possesses suitable physicochemical properties, controlled drug release behavior, and significant antifungal activity, making it a promising topical delivery system for the treatment of fungal infections.

DISCUSSION

The present study demonstrated the successful development and optimization of an econazole nitrate emulgel using a factorial design approach, with a primary focus on drug release, viscosity, and antifungal activity. The formulated emulgels exhibited acceptable physical appearance, skin-compatible pH, uniform drug content, and reproducible rheological behavior, indicating formulation stability and suitability for topical application. Similar physicochemical profiles

have been reported in previously developed antifungal emulgels, confirming the appropriateness of emulgel systems for poorly water-soluble drugs [5-7].

Comparatively, the in vitro drug release profile revealed that formulations containing higher concentrations of Isopropyl myristate showed enhanced drug diffusion, which may be attributed to its penetration-enhancing and lipid-disrupting properties. This observation is consistent with earlier studies where Isopropyl myristate significantly improved transdermal permeation of azole antifungals [8]. Contrastingly, increasing Sepineo DERM concentration resulted in higher viscosity and reduced drug release, likely due to the formation of a denser polymeric network that restricts drug diffusion. Similar inverse relationships between polymer concentration and drug release have been reported in gel-based delivery systems [9].

Factorial design analysis confirmed that both independent variables significantly influenced drug release and viscosity. However, comparatively, Isopropyl myristate had a stronger positive impact on drug release, while Sepineo DERM predominantly governed viscosity. These findings align with previously published factorial optimization studies on topical emulgels, emphasizing the importance of balancing penetration enhancers and gelling agents for optimal performance [14]. The high R^2 values and adequate precision obtained from statistical modeling further validated the robustness and predictability of the developed formulations.

Viscosity studies indicated pseudoplastic flow behavior, which is desirable for topical formulations as it ensures ease of application and better patient compliance. Similar rheological trends have been reported for antifungal emulgels developed using polymeric gelling agents [10]. Spreadability decreased with increasing viscosity, which is expected and has been reported consistently in topical semisolid dosage forms [11].

The antifungal activity of the optimized batch demonstrated a zone of inhibition comparable to that of the standard antifungal agent, confirming effective drug release and retention of antifungal efficacy. Comparatively, the enhanced antifungal performance may be attributed to improved drug penetration and prolonged residence time at the site of infection. Similar results have been reported for econazole and other azole-based emulgel formulations [12-15]. Overall, the results of the present study are in agreement with existing literature and further support the potential of emulgel systems as effective carriers for topical antifungal therapy.

CONCLUSION

In the present study application of response surface methodology enabled systematic investigation of the influence of formulation variables, particularly Isopropyl myristate and Sepineo DERM, on critical quality attributes such as drug release and viscosity. Statistical analysis revealed that Isopropyl myristate significantly enhanced drug diffusion, whereas increasing concentrations of Sepineo DERM markedly increased viscosity and retarded drug release. The optimized formulation (F7) exhibited an ideal balance between rheological properties and sustained drug release, ensuring improved application characteristics and prolonged therapeutic action.

Furthermore, the optimized emulgel demonstrated superior antifungal activity comparable to the standard agent, confirming that incorporation of econazole nitrate into the emulgel matrix did not compromise its pharmacological efficacy. The enhanced release profile and adequate viscosity likely contributed to improved drug availability at the site of infection and prolonged residence time.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this research work.

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