Formulation and Evaluation of a Topical Lotion Containing Clobetasol Propionate, Miconazole Nitrate, Ofloxacin & Zinc Sulphate for the Treatment of Polymicrobial Skin Infections

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Abstract:

Skin is the largest organ of the human body and serves as the first line of defense against environmental insults including microbial invasion. However, due to various factors such as trauma, immunosuppression, poor hygiene, humidity, or systemic disease, the integrity of the skin barrier can be compromised—leading to localized or widespread infections. Among the wide spectrum of dermatological disorders, infections caused by bacterial and fungal pathogens are especially prevalent and difficult to treat when they occur concurrently.

Polymicrobial skin infections typically involve a combination of Gram-positive and Gram-negative bacteria such as Staphylococcus aureus or Pseudomonas aeruginosa, along with fungal species like Candida or dermatophytes (Trichophyton, Epidermophyton). These infections can be complicated by inflammation, secondary colonization, and delayed healing. Traditional monotherapy with either an antibiotic or an antifungal agent is often insufficient in such cases, as it may only target part of the infection. Moreover, inappropriate or incomplete treatment can lead to antimicrobial resistance, recurrence, or chronic skin damage.

Topical drug delivery systems (TDDS) offer an effective and safer alternative by delivering active pharmaceutical ingredients (APIs) directly to the site of infection. This localized approach reduces systemic absorption, minimizes side effects, and allows higher local drug concentrations. Furthermore, TDDS formulations such as lotions, creams, and gels enhance patient compliance due to ease of use, reduced dosing frequency, and improved skin acceptability.

Among the topical dosage forms, lotions are particularly suitable for large surface areas, hairy regions, and acute inflammatory conditions due to their ease of application and fast absorption. When such lotions are formulated with a synergistic combination of an anti-inflammatory

corticosteroid (Clobetasol Propionate), a broad-spectrum antibacterial agent (Ofloxacin), an antifungal drug (Miconazole Nitrate), and a wound-healing agent (Zinc Sulphate), they offer a comprehensive approach to treating complex dermatoses. These four agents target multiple pathological mechanisms — inflammation, infection, and impaired healing — within a single formulation.

This research focuses on developing and evaluating a multi-drug topical lotion that addresses the unmet clinical need for a single, stable, and effective formulation capable of treating bacterial-fungal co-infections with associated inflammation. Such innovation supports the dermatological goal of effective, fast-acting, and well-tolerated skin therapy, particularly in cases where monotherapy fails or polypharmacy is not desirable.

Aim of the Study

The primary aim of this study is to develop and evaluate a pharmaceutically stable and therapeutically effective topical lotion formulation comprising four active pharmaceutical ingredients: Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, and Zinc Sulphate. These agents were specifically selected due to their complementary pharmacological profiles, which collectively address the key pathological features of polymicrobial dermatoses — namely inflammation, bacterial infection, fungal colonization, and impaired skin healing.

Additionally, the aim extends to performing comprehensive preformulation studies, rational excipient selection, emulsification process optimization, and post-formulation evaluation. These efforts are directed toward developing a clinically viable product capable of treating complex skin infections where monotherapy proves insufficient. The ultimate goal is to provide an evidence-based, multi-targeted topical solution that can enhance patient compliance and therapeutic outcomes in dermatological practice.

Keywords: *Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, Zinc Sulphate, topical lotion, polymicrobial skin infections, stability studies.*

1. **Introduction:** Skin infections are among the most common disorders encountered in dermatological practice. Often, these infections are polymicrobial and involve a combination of bacterial, fungal, and inflammatory components. Monotherapies are frequently inadequate in such cases. The use of combination topical formulations improves therapeutic outcomes, enhances patient compliance, and minimizes the need for systemic interventions. This research focuses on the formulation and evaluation of a novel topical lotion containing Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, and Zinc Sulphate.

2. Materials and Methods:

2.1 Materials:

The formulation utilized four active pharmaceutical ingredients (APIs): Clobetasol Propionate (super-potent topical corticosteroid), Miconazole Nitrate (broad-spectrum imidazole antifungal), Ofloxacin (fluoroquinolone antibacterial agent), and Zinc Sulphate (healing and anti-inflammatory agent). All APIs used were of pharmacopeial grade and procured from certified vendors.

Pharmaceutical-grade excipients were used for lotion base development, including:

- Emollients and Solubilizers: Propylene glycol, Iso-propyl myristate
- Emulsifiers and Stabilizers: Cetomacrogol 1000, Cetostearyl alcohol, Glycerol monostearate, Tween 80, Emulsifying wax
- Preservatives: Benzyl alcohol, Chlorocresol
- Humectants and Consistency Agents: Glycerine, Simethicone
- Aqueous Phase: Purified Water

All chemicals and reagents used were analytical or HPLC grade, and water was freshly distilled for all experiments.

2.2 Preformulation Studies:

Preformulation studies represent a crucial phase in the rational design and development of pharmaceutical formulations. The objective is to gather comprehensive information on the physicochemical characteristics of the active pharmaceutical ingredients (APIs) and their interaction with proposed excipients. This data forms the foundation for selecting suitable formulation strategies and ensuring compatibility, stability, and optimal therapeutic efficacy of the final product.

2.2.1 Organoleptic Evaluation

Organoleptic analysis of each active ingredient was carried out to assess basic physical characteristics such as color, odor, taste (where applicable), appearance, and texture. These properties are important for identification purposes and also influence the aesthetic acceptability of the final dosage form. Clobetasol Propionate appeared as a white to off-white powder, Miconazole Nitrate was an odorless crystalline powder, Ofloxacin exhibited slight yellowish color, and Zinc Sulphate was white and crystalline in nature.

2.2.2 Solubility Analysis

Solubility testing was conducted to determine the solubility behavior of each API in various solvents such as water, ethanol, methanol, acetone, and propylene glycol. The purpose was to identify appropriate solvents or co-solvents that would allow for efficient incorporation of each drug into the formulation. Clobetasol Propionate showed poor aqueous solubility but dissolved in organic solvents like acetone and ethanol. Miconazole Nitrate exhibited limited solubility in water and was solubilized using propylene glycol. Ofloxacin showed better aqueous solubility than the other APIs, while Zinc Sulphate was highly water-soluble, which facilitated its incorporation into the aqueous phase of the emulsion.

2.2.3 Melting Point Determination

Melting point determination was performed for each API using a digital melting point apparatus. This provided insight into the thermal stability and purity of the drug substances. Consistency in melting point readings with reference standards helped confirm the identity and absence of major impurities.

2.2.4 High-Performance Liquid Chromatography (HPLC)

HPLC analysis played a pivotal role in quantifying drug content and confirming assay values of the APIs in the final formulation. Individual calibration curves were constructed for Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, and Zinc Sulphate using their respective standard solutions. The HPLC method was validated for parameters such as accuracy, precision, linearity, and specificity. It was later used to assess the drug content in the formulated lotion and monitor its stability during the study.

2.3 Formulation Development:

Six batches (F1–F6) were prepared by oil-in-water emulsification. F1 was optimized based on pH, appearance, viscosity, spreadability, and drug content.

To develop an optimized topical lotion with desired stability and therapeutic efficiency, a total of six formulations (F1–F6) were prepared using varying concentrations of emulsifying agents, solvents, thickeners, and humectants. The objective of these trials was to identify the best excipient combination that would yield a physically and chemically stable product with favorable spreadability, aesthetic appeal, and drug content uniformity.

An oil-in-water (O/W) emulsification technique was selected for formulation development, considering its ability to produce a non-greasy, easily washable, and cosmetically elegant lotion

suitable for broad dermatological use. O/W emulsions also allow for efficient topical drug delivery by enabling rapid absorption through the stratum corneum while maintaining product stability during storage.

Each formulation was evaluated based on physical appearance, viscosity, homogeneity, pH, and drug content. Among these, the formulation coded as F1 demonstrated optimal characteristics and was selected for further evaluation and stability studies.

2.3.1 Optimized Formulation (F1):

- Clobetasol Propionate: 0.14 g
- Ofloxacin: 0.56 g
- Miconazole Nitrate: 11 g
- Zinc Sulphate Monohydrate: 16 g
- Propylene Glycol: 100 g
- Cetomacrogol 1000: 5 g
- Cetostearyl Alcohol: 15 g
- Iso-propyl Myristate: 8 g
- Glycerol Mono Stearate: 6 g
- Simethicone: 5 g
- Glycerine: 6 g
- Benzyl Alcohol: 2 g
- Tween-80: 12 g
- Emulsifying wax: 15 g
- Purified Water: q.s. to 1000 g

2.4 Manufacturing Procedure:

The preparation of the lotion was carried out under controlled laboratory conditions, following a systematic five-step process:

2.4.1 Oil Phase Preparation

The oil phase consisted of lipophilic excipients such as cetostearyl alcohol, glycerol monostearate, iso-propyl myristate (IPM), and emulsifying wax. These components were weighed accurately and transferred to a beaker. The mixture was heated on a water bath to a temperature of 60–70°C, ensuring complete melting and homogeneity. This phase served as the continuous phase for the lipid-soluble components and helped impart emollient and viscosity-enhancing properties to the lotion.

2.4.2 Aqueous Phase Preparation

Simultaneously, the water phase was prepared by dissolving water-soluble components including zinc sulphate monohydrate, glycerine, propylene glycol, Tween-80, and simethicone in purified water. The temperature of the aqueous phase was maintained in the same range (60–70°C) to ensure uniform mixing with the oil phase during emulsification. APIs that exhibited good solubility in water or aqueous co-solvents (like zinc sulphate and Ofloxacin) were incorporated into this phase. The aqueous phase was stirred gently to avoid foam formation and ensure uniform dispersion of ingredients.

2.4.3 Drug Incorporation

Drug substances were incorporated into respective phases based on their solubility profiles established during preformulation.

- Clobetasol Propionate, due to its poor aqueous solubility, was dissolved in propylene glycol and added to the oil phase.
- Miconazole Nitrate, being partially soluble in glycols, was also added to the oil-soluble section.
- Ofloxacin, moderately water-soluble, was introduced into the aqueous phase.
- Zinc Sulphate, highly water-soluble, was directly dissolved into the water phase..

2.4.4 Emulsification and Homogenization

Once both oil and aqueous phases were prepared at equivalent temperatures, the aqueous phase was slowly added to the oil phase under continuous stirring using a mechanical stirrer. Emulsification was carried out under vacuum to prevent air entrapment. The mixture was then passed through a high-speed homogenizer for a fixed time to achieve a uniform, smooth, and stable emulsion with ideal droplet size distribution.

Homogenization played a key role in enhancing the consistency, physical stability, and appearance of the lotion.

2.4.5 Cooling, Perfuming, and Filling

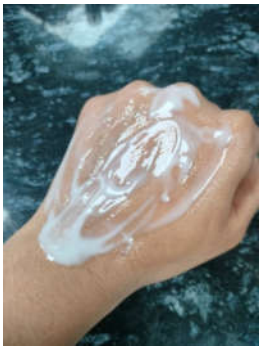
After emulsification, the bulk lotion was allowed to cool gradually to room temperature (25 ± 2°C) under gentle stirring to maintain uniformity. During the cooling phase, perfume (rose white) was added to improve the sensory appeal of the formulation. Cooling also facilitated the setting of the emulsion and solidification of the lipid components for optimal texture.

2.5 Evaluation of Optimized Formulation (F1)

The final selected batch, Formulation F1, underwent a comprehensive evaluation to confirm its pharmaceutical quality, physicochemical stability, and suitability for topical application. These evaluations were performed as per standard guidelines to ensure uniformity, aesthetic appeal, therapeutic consistency, and patient acceptability. All tests were conducted in triplicate, and average values were recorded.

2.5.1 Appearance

Visual examination is a preliminary but essential quality control step in evaluating semisolid formulations. The optimized lotion was inspected for color, phase uniformity, homogeneity, grittiness, and signs of phase separation. F1 exhibited a white, smooth, and viscous consistency with no phase separation, crystal growth, or particulate matter, indicating proper emulsification and physical stability.



Picture:

Appearance check directly on the hands

2.5.2 pH Measurement

The pH of topical formulations must fall within the physiological skin range (3.5–7.0) to prevent irritation or disruption of the acid mantle. The pH of F1 was measured using a digital pH meter calibrated with standard buffer solutions (pH 4.0 and 7.0). The recorded pH was 4.02, which is well within the acceptable range for dermal compatibility. This slightly acidic pH is favorable for maintaining skin health while supporting antimicrobial action.

2.5.3 Viscosity and Spreadability

Viscosity plays a crucial role in determining the lotion's stability, flow behavior, and spreadability. The viscosity of F1 was observed to be suitable for smooth and effortless application, offering an ideal balance between flow and thickness. Manual testing showed excellent spreadability with minimal residue or tackiness. The formulation was easy to apply on both dry and moist skin surfaces and maintained consistency during prolonged storage.

2.5.4 Density

Density measurement helps confirm uniform dispersion and proper emulsification of the formulation components. The density of F1 was measured using a calibrated pycnometer at room temperature and was found to be 0.99 g/mL, indicating appropriate formulation compactness and stability. This parameter supports product consistency and ease of handling during packaging and application.

2.5.5 Drug Content and Assay

Quantitative analysis of the active ingredients was performed using a validated High-Performance Liquid Chromatography (HPLC) method to ensure dose accuracy and content uniformity across the batch. Each API was analyzed against standard calibration curves, and the following concentrations were obtained in the final lotion:

- Clobetasol Propionate: 0.0251% w/v (within target range 0.0225–0.0275%)
- Miconazole Nitrate: 1.97% w/v (target range 1.8–2.2%)
- Ofloxacin: 0.0997% w/v (target range 0.09–0.11%)
- Zinc Sulphate: 2.98% w/v (target range 2.7–3.3%)

All evaluation parameters were found to be within acceptable pharmacopeial limits, confirming the formulation's robustness, therapeutic viability, and patient compliance potential.

2.6 Stability Studies

Stability testing is a critical component in pharmaceutical product development. It determines how the quality of a formulation varies with time under the influence of environmental factors such as temperature, humidity, and light. Stability studies help to establish the shelf-life, optimal storage conditions, and labeling requirements of the formulation. For the present study, Formulation F1, which was previously optimized based on its physicochemical characteristics, was subjected to accelerated stability studies as per ICH Q1A (R2) guidelines.

2.6.1 Stability Protocol

Accelerated stability testing was conducted to simulate long-term storage effects within a reduced timeframe. The optimized formulation (F1) was stored in tightly sealed high-density polyethylene (HDPE) containers and placed in a controlled environmental chamber maintained at:

- Temperature: 40°C ± 2°C & 30°C ± 2°C
- Relative Humidity (RH): 75% ± 5%

The stability study was conducted over a period of nine months, and evaluations were carried out at three time points:

- Initial (0 month)
- Mid-term (6 months)
- Final (9 months)

2.6.2 Parameters Evaluated

The following parameters were analyzed at each interval to assess any physical or chemical changes:

- Physical Appearance:

The lotion was visually inspected for any changes in color, consistency, phase separation, or presence of precipitates. Throughout the study, the formulation retained its white color, uniform texture, and smooth consistency. There was no indication of emulsion breakdown, clumping, or sedimentation, indicating strong physical stability.

- pH Evaluation:

The pH of the formulation was measured using a calibrated digital pH meter to monitor any deviation that could affect product performance or skin compatibility. The pH values remained consistent, showing only minimal variation from the initial pH of 4.02, which remained within the acceptable dermatological range (3.5–7.0). This stability in pH indicates negligible chemical degradation or microbial growth.

Picture: pH Testing

- Density:

Density was assessed using a pycnometer to ensure the formulation retained its homogeneity and mass-to-volume ratio. No significant changes were observed in the density throughout the study, suggesting consistent formulation viscosity and absence of phase migration or evaporation.

Picture: Density through pycnometer

- Assay of Active Ingredients (HPLC):

Quantitative assay for all four active pharmaceutical ingredients — Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, and Zinc Sulphate — was conducted using a validated HPLC method. All actives maintained 95–105% of their initial label claim, satisfying pharmacopeial acceptance criteria. There was no observed degradation or decline in drug potency, confirming the chemical stability of the formulation.

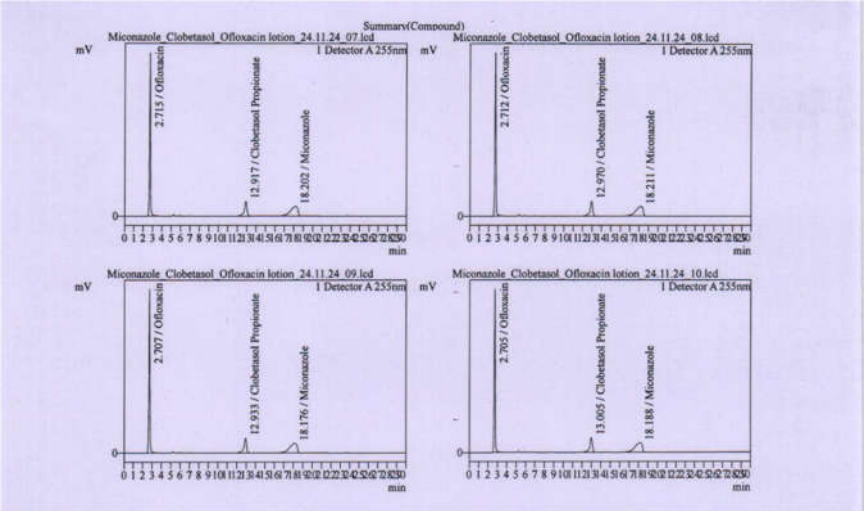


Fig: Clobetasol Propionate & Miconazole HPLC Data

2.6.3 Conclusion of Stability Study

Based on the results of the accelerated stability evaluation, Formulation F1 demonstrated excellent physical and chemical stability over a nine-month accelerated period, which correlates with a minimum of two years real-time shelf life. The consistent results across appearance, pH, density, and assay confirm that the product is suitable for long-term storage under normal pharmaceutical conditions.

This stability profile strengthens the potential for the lotion's commercial scalability and regulatory acceptance as a reliable, multi-targeted topical formulation for polymicrobial skin infections.

3. Results

The evaluation of the optimized formulation (F1) was carried out to ensure it met all predefined pharmaceutical specifications. The following table summarizes the results of key parameters assessed during the initial formulation phase:

3.1 Initial Evaluation of F1 Formulation:

Parameter	**Specification**	**F1 Result (Initial)**
Description	White viscous lotion	Complies (White, smooth, viscous lotion with no phase separation)
pH	3.0 – 7.0	4.02
Density (g/mL)	0.85 – 1.0	0.99

Parameter	Specification	F1 Result (Initial)
Clobetasol Propionate	0.0225% – 0.0275% w/v	0.0251% w/v
Miconazole Nitrate	1.8% – 2.2% w/v	1.97% w/v
Ofloxacin	0.09% – 0.11% w/v	0.0997% w/v
Zinc Sulphate	2.7% – 3.3% w/v	2.98% w/v

All the results were well within the specified limits. The formulation was aesthetically acceptable, physically stable, and showed uniform dispersion of the active ingredients.

3.2 Stability Results (at 40°C ± 2°C, 75% RH ± 5% & 30°C ± 2°C, 75% RH ± 5%):

After a period of **9 months** under accelerated conditions, the F1 formulation was re-evaluated for stability. The findings were as follows:

- **Appearance**: No change observed. The lotion retained its white color and viscous texture with no signs of phase separation or degradation.
- **pH**: Slight increase to **4.23**, still well within acceptable dermatological pH range.
- **Density**: Slightly decreased to **0.97 g/mL**, but still within acceptable limits, indicating consistency in formulation viscosity.
- **API Content (Assay)**: Drug content for all four active ingredients remained within **95–105%** of the initial label claim, indicating excellent chemical stability with no significant degradation.

Station	Description	Identification	pH	Weight per ml at 25°C	Assay-Miconazole Nitrate	Assay-Ofloxacin	Assay-Clobetasol Propionate	Assay-Zinc Sulphate
Limit	White to off white viscous lotion filled in HDPE bottle	Should be complies as per assay	3.0 to 7.0	0.85 to 1.0 g/ml	1.8 to 2.2 %w/v (90.0% to 110.0%)	0.09 to 0.11 %w/v (90.0% to 110.0%)	0.0225 to 0.0275 %w/v (90.0% to 110.0%)	2.7 to 3.3 %w/v (90.0% to 110.0%)
Initial	Complies	Complies	4.021	0.99g/ml	1.97%w/v (98.50%)	0.0997%w/v (99.70%)	0.0251%w/v (100.40%)	2.98%w/v (99.33%)
3M (02.08.24)	Complies	Complies	3.982	0.98g/ml	1.93%w/v (96.50%)	0.0981%w/v (98.10%)	0.0243%w/v (97.20%)	2.89%w/v (96.33%)
6M (11.11.24)	Complies	Complies	4.287	0.96g/ml	1.89%w/v (94.5%)	0.0971%w/v (97.10%)	0.0241%w/v (96.40%)	2.87%w/v (95.67%)

Picture: Stability Raw data at 40°C ± 2°C, 75% RH

Station	Description	Identification	pH	Weight per ml at 20°C	Assay-Miconazole Nitrate	Assay-Ofloxacin	Assay-Clobetasol Propionate	Assay-Zinc Sulphate
Limit	White to off white viscous lotion filled in HDPE bottle	Should be complies as per assay	3.0 to 7.0	0.85 to 1.0 g/ml	1.8 to 2.2 %w/v (90.0% to 110.0%)	0.09 to 0.11 %w/v (90.0% to 110.0%)	0.0225 to 0.0275 %w/v (90.0% to 110.0%)	2.7 to 3.3 %w/v (90.0% to 110.0%)
Initial	Complies	Complies	4.021	0.99g/ml	1.97%w/v (98.50%)	0.0997%w/v (99.70%)	0.0251%w/v (100.40%)	2.98%w/v (99.33%)
3M (02.08.24)	Complies	Complies	3.982	0.98g/ml	1.96%w/v (98.0%)	0.0992%w/v (99.20%)	0.0248%w/v (99.20%)	2.92%w/v (97.3%)
6M (11.11.24)	Complies	Complies	4.231	0.97g/ml	1.92%w/v (96.00%)	0.0980%w/v (98.00%)	0.0242%w/v (96.80%)	2.92%w/v (97.3%)
9M (10.02.25)	Complies	Complies	4.068	0.98g/ml	1.91%w/v (95.5%)	0.0976%w/v (97.60%)	0.0240%w/v (96.00%)	2.91%w/v (97.0%)
12M								
18M								
24M								
Remarks: Stability study complies up to 6M LT as per stability protocol No.: STTB/EXT/001/24-00								

Picture: Stability Raw data at 30°C ± 2°C, 75% RH

The optimized formulation (Batch F1) successfully met all predefined quality parameters at the time of preparation and continued to comply after 9 months of accelerated stability testing.

The results confirm that the lotion retains its physical integrity, therapeutic effectiveness, and chemical stability over time. These findings establish the formulation as suitable for long-term storage and position it as a strong candidate for further clinical evaluation and commercial development in the treatment of polymicrobial skin infections.

4. Discussion

The successful development of a multi-drug topical lotion combining Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, and Zinc Sulphate represents a comprehensive approach to the treatment of polymicrobial skin infections — a condition where single-drug therapy is often insufficient due to the coexistence of bacterial and fungal pathogens and associated inflammation.

The formulation journey began with systematic preformulation studies, which provided crucial insights into the solubility behavior, compatibility, and stability of the selected active pharmaceutical ingredients (APIs). By understanding the physicochemical properties of each drug, appropriate solvents and excipients were selected to enhance their stability and ensure uniform distribution within the lotion matrix. This foundational step ensured that the final product would be both pharmaceutically robust and therapeutically effective.

Among the six trial batches developed, Formulation F1 emerged as the optimized variant, exhibiting superior performance in terms of appearance, homogeneity, spreadability, viscosity, pH, and drug content. The lotion's smooth texture and consistent color were maintained

throughout testing, with no phase separation or degradation, indicating an excellent emulsification process and compatibility between ingredients.

One of the most noteworthy findings of this study was the stability of the formulation under accelerated conditions (40°C ± 2°C, 75% RH ± 5%). Over a period of 9 months, all evaluated parameters — including pH, density, and drug assay — remained within pharmacopeial limits. These results support the long-term shelf-life of the formulation, which is essential for commercial viability and regulatory approval.

Beyond physical and chemical stability, the therapeutic synergy of the combined drugs plays a pivotal role in the formulation's potential impact.

- Clobetasol Propionate, a potent corticosteroid, helps in reducing inflammation, itching, and redness associated with dermatitis and infections.
- Miconazole Nitrate provides broad-spectrum antifungal action, especially against dermatophytes and Candida species.
- Ofloxacin targets a wide range of Gram-positive and Gram-negative bacteria, making it effective in bacterial superinfections.
- Zinc Sulphate, often underutilized in dermatological formulations, contributes not only through its anti-inflammatory and wound healing effects but may also enhance the antimicrobial activity of the other agents due to its epithelial-restorative properties.

The formulation design as a non-greasy lotion is another critical feature that enhances patient compliance, especially for application on large or hairy areas of the skin where creams or ointments may be inconvenient. Its cosmetically elegant texture, easy spreadability, and quick absorption make it highly favorable for long-term and repeated use in outpatient dermatology settings.

Taken together, these results confirm that this multi-drug topical lotion addresses the core challenges of treating complex, polymicrobial skin infections. It not only combines efficacy and safety but also aligns with modern formulation aesthetics and compliance expectations.

Thus, the study successfully demonstrates the formulation's clinical relevance, commercial feasibility, and potential to fill a therapeutic gap in dermatological care — especially where combination therapy is warranted in a single, patient-friendly dosage form

5. Conclusion

The present study culminates in the successful formulation and comprehensive evaluation of a topical polytherapy lotion containing Clobetasol Propionate, Miconazole Nitrate, Ofloxacin, and Zinc Sulphate, designed to address the growing clinical challenge of polymicrobial skin infections. Through meticulous preformulation analysis, rational excipient selection, and optimized emulsification techniques, the finalized batch (F1) demonstrated exceptional pharmaceutical performance.

The formulation met and maintained all critical quality attributes — including physical stability, pH compatibility, viscosity, homogeneity, and drug content — not only at the point of manufacture but also over extended accelerated stability testing in accordance with ICH Q1A (R2) guidelines. These findings confirm both formulation integrity and shelf-life assurance, meeting key regulatory and industrial benchmarks.

What sets this formulation apart is its multi-targeted therapeutic profile — combining potent anti-inflammatory, antifungal, antibacterial, and skin-repairing agents in a cosmetically elegant, non-greasy, and patient-friendly lotion base. This approach offers a significant advance over monotherapies or systemic treatments, particularly in cases involving recurrent, co-infected, or treatment-resistant dermatoses.

Clinically, this formulation holds great promise as a topical-first solution that can minimize systemic exposure, reduce polypharmacy, and enhance patient adherence — all critical to achieving superior therapeutic outcomes in dermatological care.

In conclusion, this work not only introduces a novel, synergistically active topical dosage form but also lays a foundation for future clinical trials and commercial translation. It addresses a real-world medical need with scientific rigor and innovation, making a meaningful contribution to the evolving landscape of advanced topical drug delivery systems in the pharmaceutical sciences.

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