



ISSN: 2231-3656

International Journal of Pharmacy and Industrial Research (IJPIR)

IJPIR | Vol. 16 | Issue 4 | Oct-Dec-2026

www.ijpir.com

DOI: <https://doi.org/10.61096/ijpir.v16.iss4.2026.989-1005>

Formulation and Evaluation of Miconazole Nitrate Nanoemulsion in Coconut Oil Base

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11.10.2026
Published by:
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Abstract: Fungal skin infections are common conditions that often require effective topical antifungal therapy. This study aimed to develop a miconazole nitrate nanoemulsion using coconut oil to improve drug solubility, stability, and skin penetration. Nanoemulsions were prepared by high shear homogenization and evaluated for physicochemical properties, stability, and drug release. Among all formulations, F3 showed the best performance with nanosized droplets, high drug content, excellent stability, and 99.65% drug release within 24 hours. The optimized oil-in-water nanoemulsion demonstrated controlled drug release and may serve as a promising topical delivery system for the effective treatment of fungal infections.

Keywords: Fungal skin infections, Nanoemulsions, coconut oil base

INTRODUCTION

Fungal skin infections are among the most common dermatological disorders affecting millions of people worldwide. These infections are mainly caused by dermatophytes, yeasts, and molds, leading to symptoms such as itching, redness, scaling, irritation, and inflammation of the skin.^{1,3} Although topical antifungal agents are widely used for treatment, conventional formulations often show limited therapeutic effectiveness due to poor drug solubility, inadequate skin penetration, and reduced retention at the site of infection.^{1,4} Miconazole nitrate, a broad-spectrum imidazole antifungal agent, is commonly prescribed for the management of superficial fungal infections; however, its low aqueous solubility restricts its clinical performance.⁷ Recent advances in nanotechnology have provided promising approaches to improve topical drug delivery systems.⁵

Among these, nanoemulsions have gained considerable attention because of their nanosized droplets, improved stability, enhanced drug solubilization, and better skin permeation properties.^{5,6} Nanoemulsions are fine oil-in-water or water-in-oil dispersions stabilized by suitable surfactants and are capable of increasing drug bioavailability and controlled release. Coconut oil was selected as the oil phase in the present study because of its excellent solubilizing capacity, biocompatibility, skin-friendly nature, and additional antimicrobial properties.^{1,4}

The present study was therefore designed to formulate and evaluate a miconazole nitrate nanoemulsion using coconut oil for enhanced topical delivery. The developed nanoemulsion system is expected to improve drug solubility, stability, skin penetration, and antifungal effectiveness, thereby providing a promising approach for the treatment of fungal skin infections.

MATERIALS AND METHODS

Materials

All materials used in the present study were of analytical reagent (AR) or pharmaceutical grade and procured from reliable sources. KEN Laboratories supplied miconazole nitrate as the therapeutic antifungal agent. Coconut oil was obtained from Poongar Traditional Mart and used as the oil phase. Tween 80, sorbitol, methanol, methyl paraben, and propyl paraben were procured from MIDC Industry and used as surfactant, co-surfactant, solubilizing agent, and preservatives, respectively. Distilled water used as the aqueous phase was obtained from Astra Chemicals.

Methodology

Formula

Sl.no	Ingredients	F1	F2	F3	F4	F5
1	Miconazole nitrate %	1%	1%	1%	1%	1%
2	Coconut oil %	10	10	10	12	15
3	Tween 80 %	10	15	20	22	20
4	Sorbitol %	5	6	5	8	8
5	Methanol %	5	5	5	5	5
6	Methyl paraben (g)	0.05	0.05	0.1	0.1	0.1
7	Propyl paraben (g)	0.05	0.05	0.1	0.1	0.1
8	Distilled water (ml)	100	100	100	100	100

Preparation of Nanoemulsion

Procedure

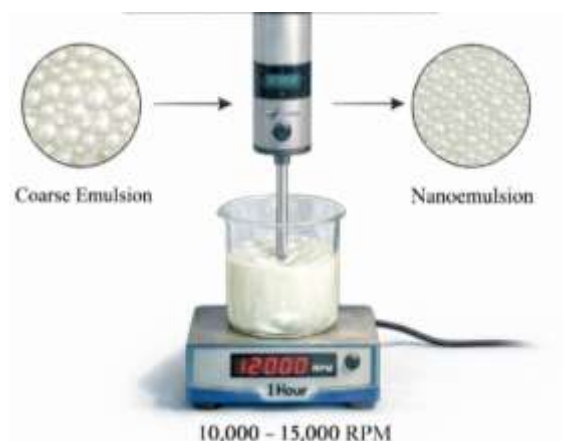
a) Preparation of Pre-emulsion

Miconazole nitrate was dissolved in methanol and mixed with coconut oil. Tween 80 was added to form the oil phase. The aqueous phase was prepared separately using distilled water, sorbitol, methyl paraben, and propyl paraben. Preservatives were dissolved with slight heating, cooled, and sorbitol was added. The aqueous phase was then added dropwise to the oil phase under magnetic stirring at 700–1000 rpm for 1 hour to obtain a coarse emulsion.¹⁵



b) High-Shear Homogenization

The coarse emulsion was transferred to a high-shear homogenizer and processed at 10,000–15,000 rpm for 1 hour. Intense shear forces reduced droplet size from micrometre to nanometre range, producing a stable nanoemulsion. Parameters were optimized to prevent phase separation and ensure uniform droplet distribution.¹⁶



c) Final Nanoemulsion

After homogenization, the nanoemulsion was allowed to stand at room temperature to remove entrapped air and stabilize droplets. The final product appeared translucent to milky, confirming nanosized droplets, and was stored in airtight, light-resistant containers for further evaluation and stability studies.¹⁵



Preformulation Studies of Miconazole Nitrate

Physical Characteristics

Miconazole nitrate is a white or almost white, odorless crystalline powder that is stable under normal conditions. It is practically insoluble in water but soluble in organic solvents such as methanol and ethanol, indicating lipophilic nature. It has a melting point of 170–185°C, exists in fine crystalline form suitable for topical formulations, is non-hygroscopic, and shows slight acidity due to the nitrate group.¹²

Solubility Studies of Miconazole Nitrate

Miconazole nitrate is freely soluble in N,N-dimethylformamide, sparingly soluble in methanol, slightly soluble in ethanol, acetone, and acetic acid, and very slightly soluble in water and diethyl ether.¹²

Calibration Curve of Miconazole Nitrate

A calibration curve was prepared in methanol using concentrations of 12.5–200 µg/ml (five dilutions). Absorbance was measured at 272 nm using methanol as blank. All measurements were performed in triplicate, and the mean values were used to plot concentration versus absorbance followed by linear regression analysis.¹³

Fourier Transform Infrared (FTIR) Spectroscopic Analysis

a) FTIR Analysis of Miconazole Nitrate

FTIR analysis of miconazole nitrate (Sample ID: MIZ) was carried out using an FTIR spectrophotometer in % transmittance mode with Happ–Genzel apodization, 2 cm⁻¹ resolution, and 45 scans. The sample was prepared as KBr pellet or thin film, and scanned after recording background spectrum.¹⁵

b) FTIR Analysis of Methyl Paraben

FTIR analysis of methyl paraben (Sample ID: MPB) was performed under the same conditions using suitable sample preparation and background correction.¹⁵

c) FTIR Analysis of Propyl Paraben

FTIR analysis of propyl paraben (Sample ID: PPB) was conducted under similar conditions to identify functional groups and confirm purity and structural integrity.¹⁴

d) FTIR Analysis of Drug and Excipients

FTIR spectra of individual excipients were recorded separately to identify characteristic functional groups and evaluate drug–excipient compatibility. Spectra were recorded in the range of 4000–400 cm⁻¹.¹⁶

List of equipments used

Sl.No	Equipments	Source
1	Magnetic stirrer	Reminotars
2	High shear homogenizer	Wahal engineers
3	Electronic balance	Reminotars
4	FT-IR Spectrophotometer	Bomen FTIR MB II
3	UV-Spectrophotometer	UV-2001 Techcomp
4	pH meter	Elico Ltd
5	Particle size analyser	MALVEM zeta sizer lab V230
6	Centrifuge	Remi Elektrotechnik Ltd
7	Franz diffusion cell	Labline instruments DCA1495

Characterization of Developed Nanoemulsion

Organoleptic Character

The nanoemulsion was visually examined for colour, odour, clarity, and phase separation. It appeared translucent to milky, uniform, homogeneous, and free from creaming, sedimentation, or grittiness, with a mild non-irritant odour, indicating good stability and acceptability.¹⁷

Dye Test

The dye test was performed using methylene blue to identify the nanoemulsion type. Uniform dispersion of dye indicated an oil-in-water (O/W) nanoemulsion, while poor dispersion suggested water-in-oil (W/O) type.¹⁸

pH

The pH was measured using a calibrated digital pH meter at room temperature after standardization with pH 4.0 and 7.0 buffers to confirm suitability for topical application.¹⁷

Centrifugation

About 5 mL of nanoemulsion was centrifuged at 3000 rpm for 30 min and observed for phase separation, creaming, or sedimentation. Absence of changes indicated good physical stability.¹⁷

Particle Size Analysis

Particle size was determined by Dynamic Light Scattering using a particle size analyser after suitable dilution with distilled water. Average droplet size was calculated using software.¹⁹

Zeta Potential

Zeta potential was measured using an electrophoretic light scattering analyzer after dilution of sample. Readings were taken in triplicate and mean value recorded to assess stability.²¹

Drug Content Determination

Drug content was estimated using UV-visible spectrophotometry. Nanoemulsion equivalent to 10 mg drug was extracted with methanol, filtered, diluted, and absorbance measured at 272 nm using methanol as blank.¹⁸

In Vitro Drug Release Study

Drug release was studied using Franz diffusion cell with PBS pH 7.4 as receptor medium, stirred at 600 rpm and maintained at $35 \pm 0.5^\circ\text{C}$. Samples were withdrawn at intervals and analyzed at 272 nm.^{19, 20}

In Vitro Drug Kinetics Study

Release data were fitted into zero-order, first-order, Higuchi, and Korsmeyer-Peppas models to determine the mechanism of drug release from the nanoemulsion.²¹

Stability Study

The optimized nanoemulsion formulation was subjected to stability studies by storing samples in airtight containers at room temperature and accelerated conditions for a specified period. Samples were periodically evaluated for appearance, phase separation, pH, particle size, and drug content. No significant changes indicated good formulation.

RESULT

PREFORMULATION STUDIES OF MICONAZOLE NITRATE

Organoleptic Characteristics

The organoleptic characteristics of MCZ were evaluated, including its general appearance, colour, odour, and taste. MCZ was observed to be a white crystalline powder with a slightly bitter taste and no characteristic odour.

Table 1: Organoleptic characters

S.No	Test	Specification	Observation
1.	Colour	White	White
2.	Odour	Odourless	Odourless
3.	Nature	Amorphous	Amorphous

Solubility

The solubility of miconazole nitrate was found to be different in various solvents, as given below

Table 2: Solubility study

S.no	Solvent system	Specification as per IP	Result
1.	Methanol	Sparingly soluble	Sparingly soluble
2.	Propylene glycol	Soluble	Soluble
3.	Water	Very slightly soluble	Very slightly soluble

Identification of the drug through UV Spectroscopy

Standard calibration curve of miconazole nitrate as a pure drug

The absorption spectrum of pure Miconazole nitrate was recorded in methanol over the wavelength range 200–400 nm.

Table 3: Standard calibration curve of miconazole nitrate

S.no	Concentration of Miconazole nitrate (mcg/ml)	Absorbance
1.	5	0
2.	10	0.057
3.	15	0.116
4.	20	0.161
5.	25	0.215
6.	30	0.259
7.	35	0.354

UV shows that miconazole nitrate gives maximum absorbance at 272nm and is shown in a linear standard calibration, as shown in figure no.5.1

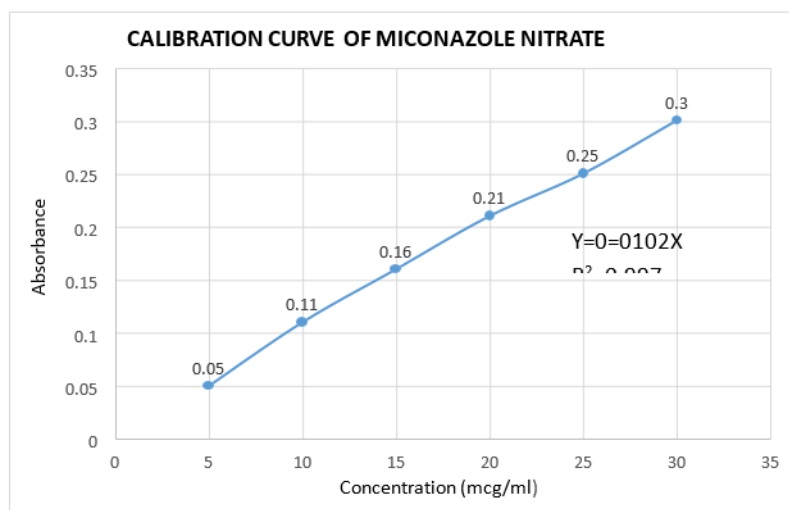


Fig 1: Standard calibration curve of miconazole nitrate in methanol

Infrared Spectroscopy of Miconazole Nitrate

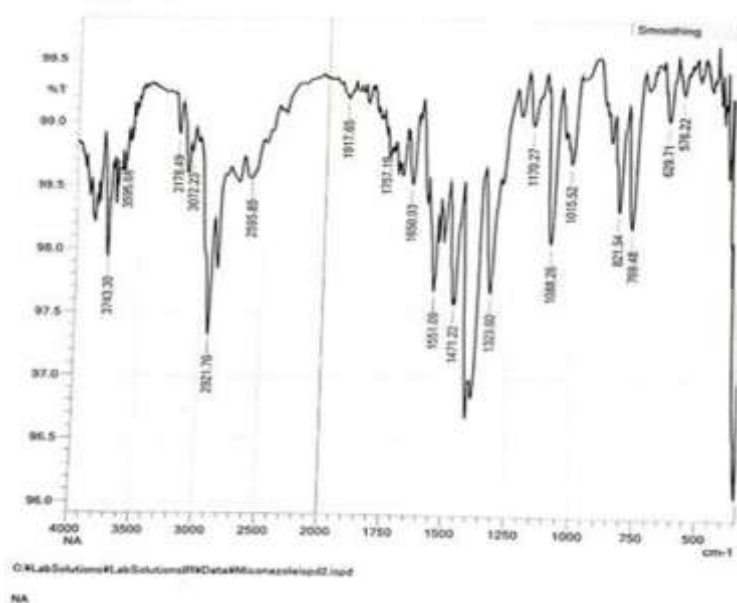


Fig 2: FTIR of miconazole nitrate

Table 4: FTIR of Miconazole Nitrate

FUNCTIONAL GROUP	REPORTED VALUE (cm ⁻¹)	OBSERVED VALUE (cm ⁻¹)
C-cl	785-540	684.75
C=C	1600-1475	1529.6
C-O	1300-1000	1207.48
C-N	1350-1000	1206

Infrared Spectroscopy of Propyl Paraben

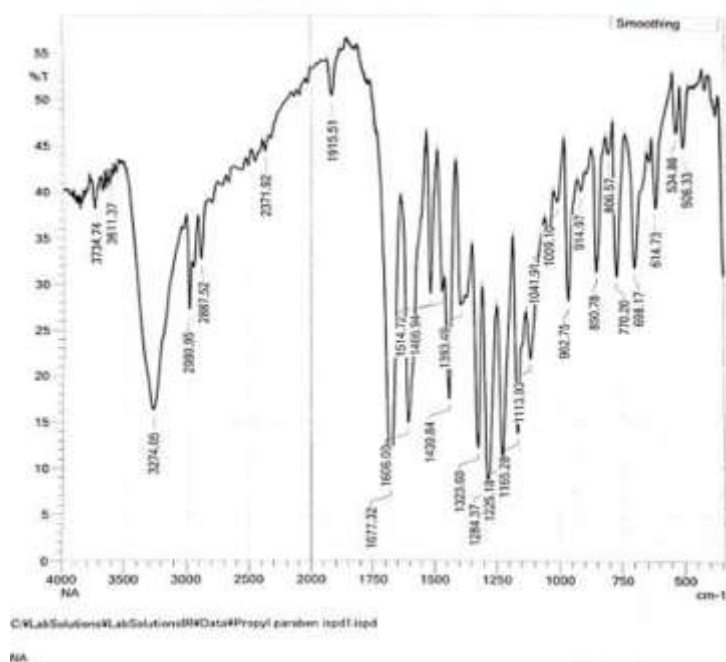


Fig 3: FTIR of Propyl Paraben in Miconazole Nitrate

Table 5: FTIR of Propyl Paraben

FUNCTIONAL GROUP	REPORTED VALUE (cm ⁻¹)	OBSERVED VALUE (cm ⁻¹)
O-H	3300-3400 cm ⁻¹	3356 cm ⁻¹
C=O	1700 cm ⁻¹	1529.6 cm ⁻¹
C=C	1600 cm ⁻¹	1207.48 cm ⁻¹
C-O	1200-1300 cm ⁻¹	1206 cm ⁻¹

Infrared Spectroscopy of Methyl Paraben

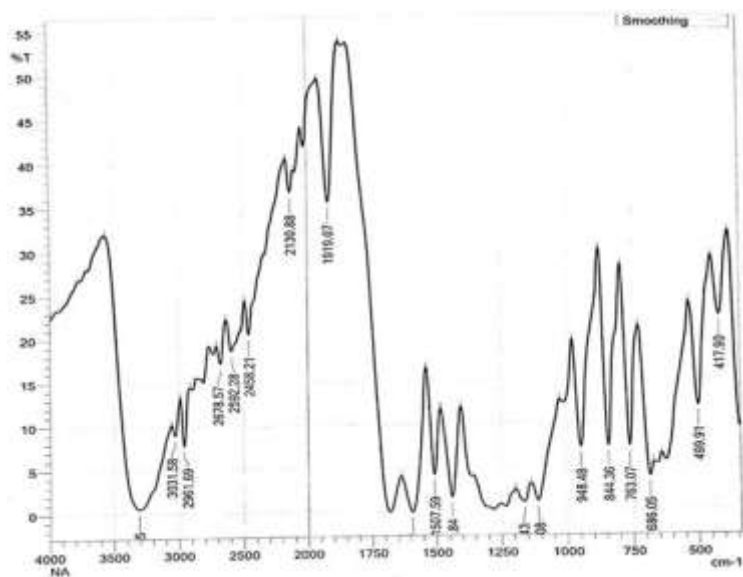
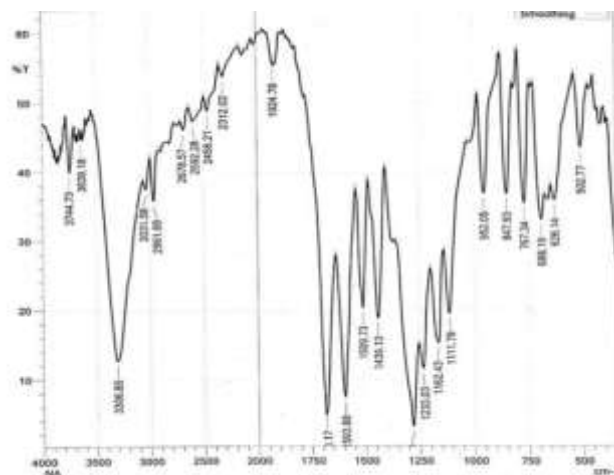


Fig 4: FTIR of Methyl Paraben**Table 6 FTIR of Methyl Paraben**

FUNCTIONAL GROUP	REPORTED VALUE (cm ⁻¹)	OBSERVED VALUE (cm ⁻¹)
O-H	3300 cm ⁻¹	3356 cm ⁻¹
C=O	1700 cm ⁻¹	1529.6 cm ⁻¹
C=C	1600 cm ⁻¹	1207.48 cm ⁻¹
C-O	1200-1300 cm ⁻¹	1206 cm ⁻¹

Drug and Excipients Compatibility Study

**Fig 5k** Mixture DA**Table 7: FTIR of Drug and Excipients compatibility study**

Sl.No	Item	Value
1	Sample name	Mixture DA
2	Sample ID	DA
3	Intensity Mode	%Transmittance
4	Apodization	Happ-Genzel
5	No.of scans	45
6	Resolution	2cm ⁻¹

EVALUATION**Physical Examination**

Appears as a milky white emulsion. It is odorless and free from visible impurities when examined under normal lighting conditions. The result table no.5.8 shows that F3's physical examination showed excellent homogeneity and consistency

Table 8: Physical Examination of Nanoemulsion

S.NO	Formulation Code	Appearance	Phase Separation	Homogeneity	Consistency
1.	F1	Milky White	Yes	Not good	Not good
2.	F2	Milky White	None	Good	Good
3.	F3	Milky White	None	Excellent	Excellent
4.	F4	Milky White	None	Good	Good

5.	F5	Milky White	None	Good	Good
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Fig 6: Appearance of Nanoemulsion Formulation

Dye Test

Methylene blue uniformly stains the entire sample blue. This indicates water is the external phase (o/w). The prepared miconazole nitrate nanoemulsion containing coconut oil was confirmed to be an oil-in-water (o/w) nanoemulsion.



Fig 7: Dye test of nanoemulsion

pH

All formulations had pH values ranging from 7.85 to 6.5, which are considered suitable for avoiding skin irritation upon application. The result table no.9 shows that the pH of formulation 3 was 6.5, indicating the stability of the formulation.

Table 9: Nanoemulsion ph

SL.NO	Formulation code	pH(mv)
1	F1	7.25
2	F2	7.05
3	F3	6.5
4	F4	6.97

5 F5 6.8

All formulations had pH values ranging from 7.85 to 6.5, which are considered suitable for avoiding skin irritation upon application. The result table no.5.9 shows that the pH of formulation 3 was 6.5, indicating the stability of the formulation.

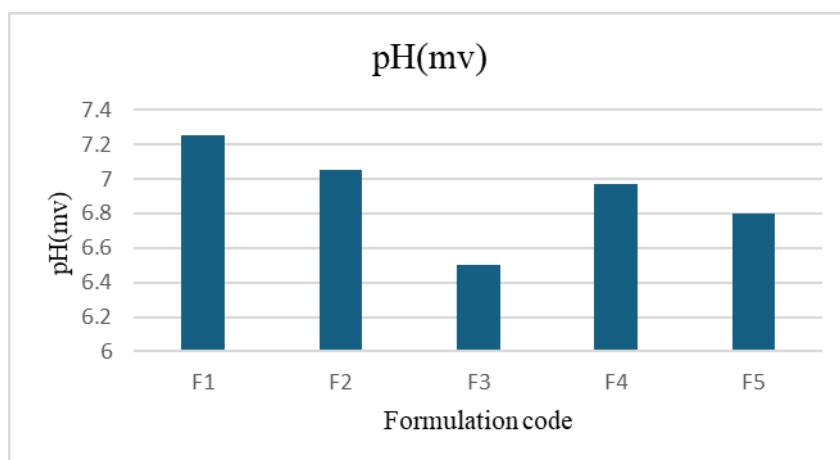


Fig 8: pH of nanoemulsion formulation

Centrifugal Stability

During centrifugation (commonly at 3000–5000 rpm for 15–30 minutes), formulations containing Miconazole nitrate are examined for phase separation, creaming, cracking, or sedimentation. A stable formulation shows no visible separation after centrifugation. The result table no.10 demonstrates that a centrifugation study of the F3 formulation showed stability of the formulation.

Table 10: Centrifugation stability of nanoemulsion

S.NO	Formulation code	Centrifugation study
1	F1	Phase separation
2	F2	No phase separation
3	F3	No phase separation
4	F4	No phase separation
5	F5	No phase separation

Particle Size

Particle size analysis of Miconazole Nitrate is crucial because it directly affects the drug's dissolution rate, solubility, and bioavailability. Smaller particle sizes increase surface area, enhancing dissolution and improving antifungal efficacy in topical formulations such as creams, gels, and ointments. The result table no.11 shows that the formulation 3 particle size was 86.4nm.

Table 11: Particle size of nanoemulsion formulation

S.NO	Formulation code	Particle size (nm)
1	F1	150
2	F2	92
3	F3	86.4

4	F4	93
5	F5	100

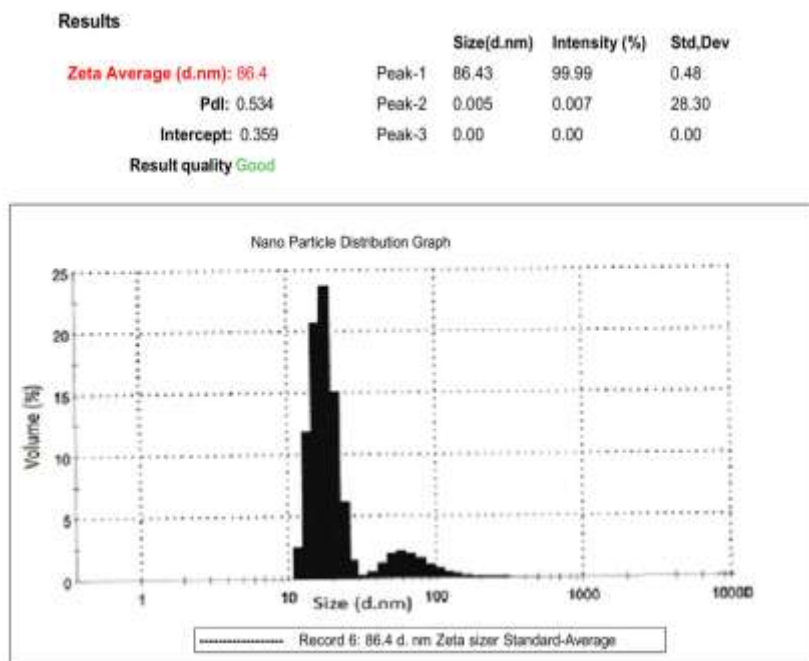


Fig 9: Particle size of nanoemulsion (f3)

Zeta Potential

The result table no.12 shows that the Formulation F3 zeta potential was determined to be -47.6 mV. The negative zeta potential means that the nanoemulsion droplets have no charge, and that the system is stable since there is no flocculation.

Table 12: Zeta potential of nanoemulsion formulation

SL.NO	Formulation code	Zeta potential ($\pm$ mv)
1	F1	-86
2	F2	-52.6
3	F3	-47.6
4	F4	-53
5	F5	-55

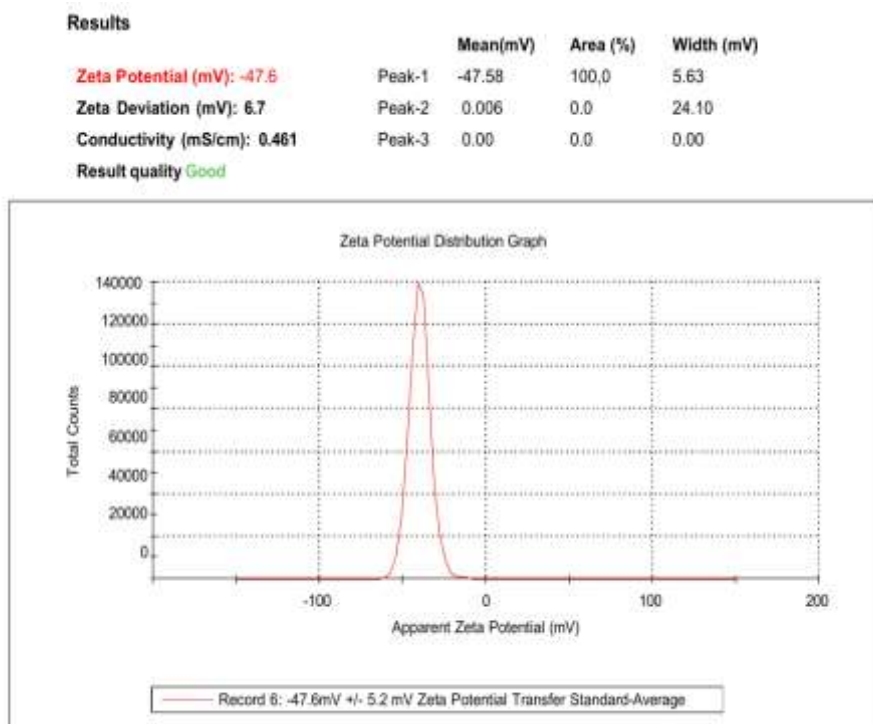


Fig 10: zeta potential of nanoemulsion formulation (f3)

Drug Content %**Table 13: Nanoemulsion Formulation**

S.NO	FORMULATION CODE	Drug content (%)
1	F1	77.05%
2	F2	90.15%
3	F3	95.15%
4	F4	92.25%
5	F5	91%

The drug content of the nanoemulsion was determined by spectrophotometry at 272 nm, with a range of 77.05%-95.15%. The result table no. 13 shows that the highest drug content was found with formulation F3

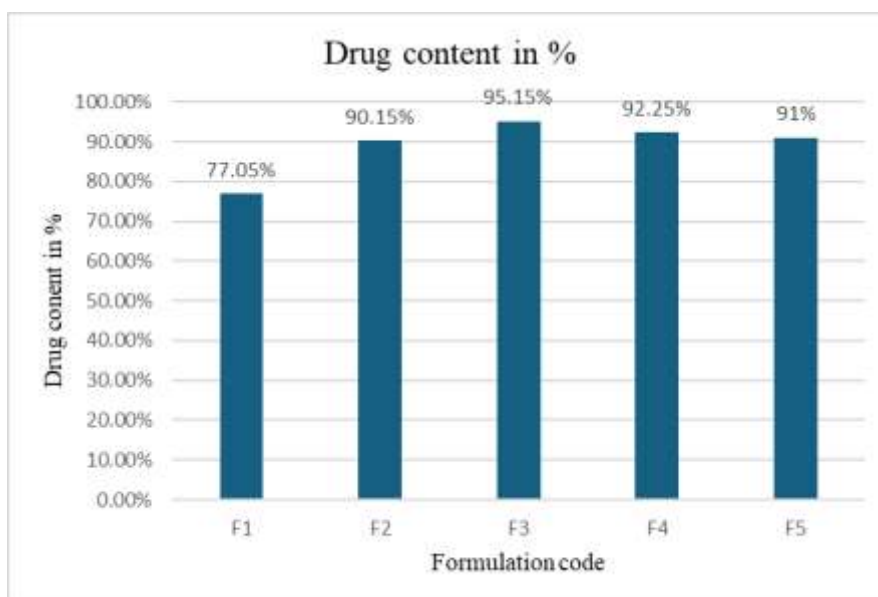
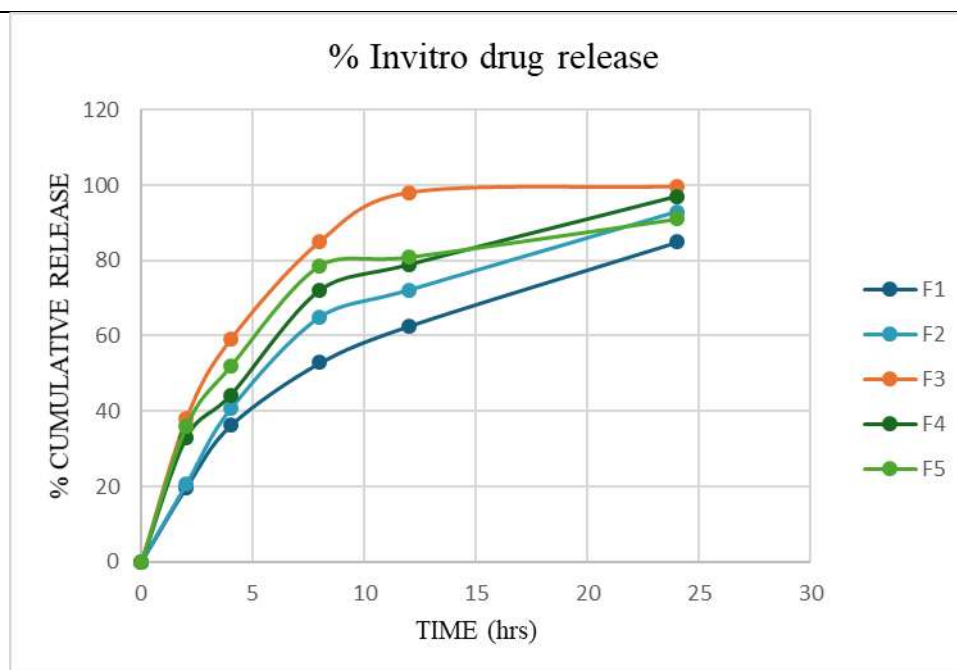


Fig 11: Drug content in % of nanoemulsion formulation**In Vitro Release Kinetic Studies****Table 14: In Vitro Drug Release in Percentage**

S.NO	TIME (hrs)	SQRT	PERCENTAGE CUMMULATIVE DRUG RELEASE (%)				
			F1	F2	F3	F4	F5
1	0	0	0	0	0	0	0
2	2	1.414	19.7	20.6	37.98	32.90	35.87
3	4	2.000	36.23	40.67	59.13	44.32	51.98
4	8	2.828	52.88	65.05	85.12	72.12	78.65
5	12	4.000	62.65	72.21	98.05	78.89	80.87
6	24	4.899	85	93	99.65	97	90.98

**Fig 12:** % invitro drug release

Results of in vitro drug release from different formulations are tabulated in table no.14 and graphically shown in figure no.12. The prepared formulation F3 shows a better release profile as compared to other preparations F1, F2, F4, and F5.

In Vitro Drug Kinetic Studies

The in-vitro drug release data were fitted into various kinetic models to elucidate the release behavior of Miconazole nitrate from the nanoemulsion formulations. The models applied included Zero-order kinetics, Higuchi's model (Table 5.15), Korsmeyer–Peppas model (Table 5.16), and First order (Table 5.17).

Table 15: In vitro drug release and Higuchi's data

Sl.No	Formulation code	Time (h)	Sqrt	Cumulative % release
1		0	0	0
2		2	1.414	37.98
3	F3	4	2.000	59.13
4		8	2.828	85.12
5		16	4.000	98.05

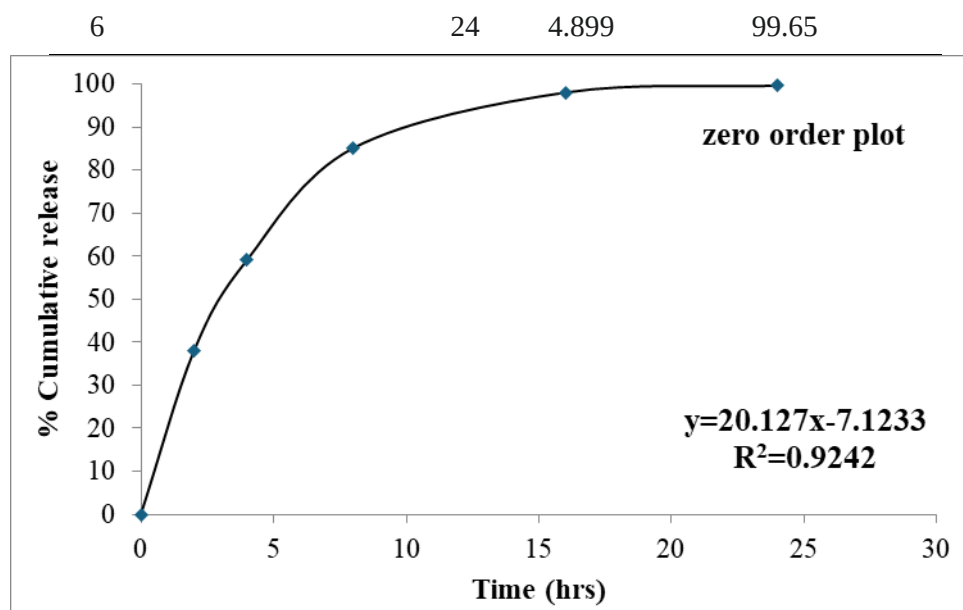


Fig 13: Zero-order cumulative percentage release

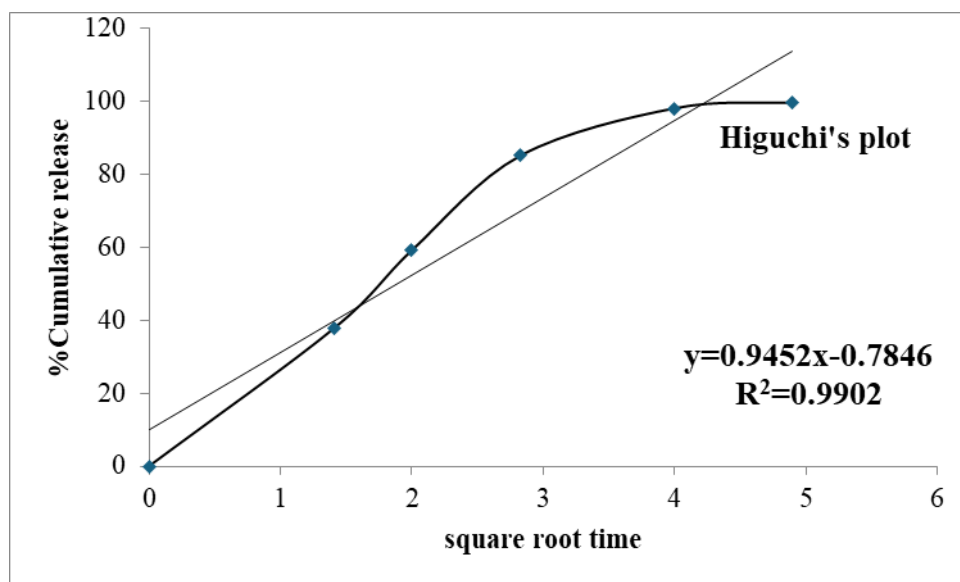


Fig 14: Higuchi's plot

Table 16: Korsmeyer Peppas's data

S.No	Formulation code	Log time	Log cumulative % release
1	F3	0.301	1.580
2		0.602	1.772
3		0.903	1.930
4		1.204	1.991
5		1.380	1.998

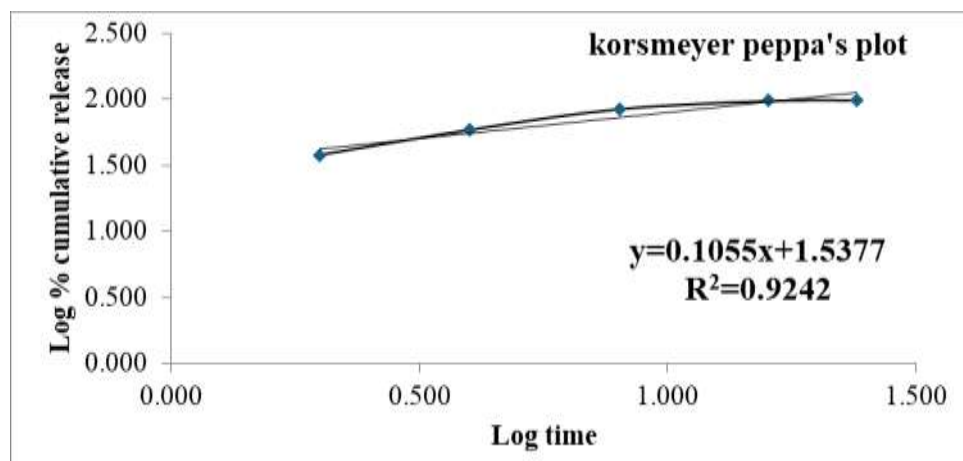


Fig 15: Korsmeyer Peppa's plot

Table 17: First-order data

Sl.NO	Time (hrs)	% of drug remaining
1	0	0
2	2	62.02
3	4	40.87
4	8	14.88
5	16	1.95
6	24	0.35

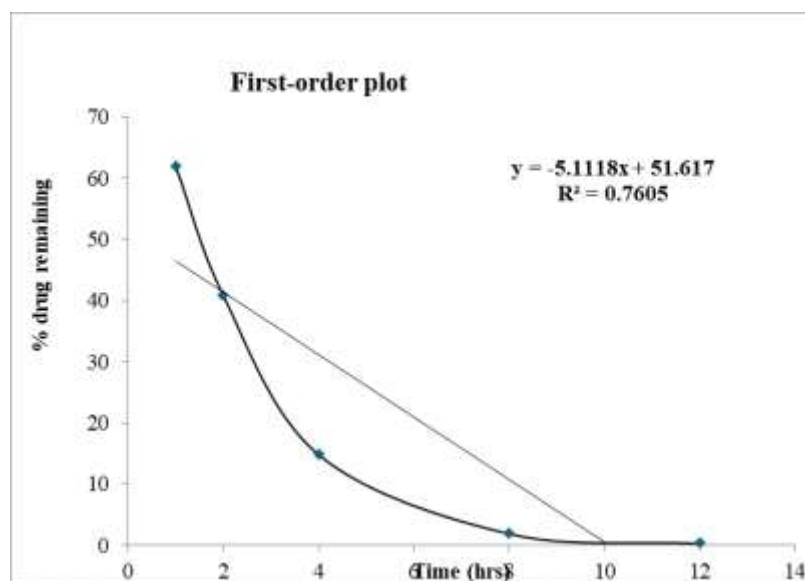


Fig 16: First-order plot

The correlation coefficient (r) values obtained from the Higuchi model were used to determine the release kinetics, while the diffusion exponent (n) from the Peppas model was used to interpret the mechanism of drug release.

Table 18: Diffusion characteristics of nanoemulsion formulation (f3)

Formulation code	Correlation coefficient values (r)		Diffusion exponent value (n)
	Zero Order	Higuchi's Model	
Nanoemulsion formulation (F3)	0.845	0.961	0.391

The correlation coefficient values (r) from Higuchi's model 0.961 indicate the kinetics of zero-order drug release, and diffusion exponent values (n) from Peppas's model 0.391 (Table 18) indicate the Fickian release mechanism of Miconazole nitrate from nanoemulsion.

DISCUSSION

Miconazole Nitrate, a BCS Class II drug, faces limited efficacy in traditional creams due to poor solubility and skin penetration. To solve this, researchers developed an oil-in-water (o/w) nano emulsion that encapsulates the drug in nanosized droplets. This nanotechnology approach bypasses the skin's natural barrier, delivering the antifungal agent directly to the infection site more effectively. The formulation uses coconut oil for its biocompatibility and inherent antimicrobial properties. Stability is achieved using Tween 80 as a surfactant and Sorbitol as a co-surfactant to lower interfacial tension. High-shear homogenization at 15,000 rpm produced an optimized droplet size of 86.4 nm, while a zeta potential of -47.6 mV ensures strong particle repulsion to prevent clumping. With a pH of 6.5, the formulation is non-irritating and matches the natural acidity of human skin. Dye tests confirmed its o/w structure, showing uniform distribution of water-soluble methylene blue throughout the continuous phase. Centrifugation tests further proved the emulsion's physical integrity, as the mixture showed no phase separation under high-stress conditions. The optimized F3 nano emulsion achieved a 95.15% drug content and a nearly complete 99.65% release over 24 hours. Release kinetics followed the Higuchi and Peppas models, indicating a steady process of Fickian diffusion. This controlled delivery ensures sustained therapeutic concentrations, making this coconut oil-based system a superior carrier for topical antifungal therapy

CONCLUSION

The study concludes that the development of a Miconazole Nitrate nano emulsion using coconut oil is a highly effective strategy for enhancing the topical delivery and therapeutic performance of this BCS Class II antifungal drug. By achieving an optimized droplet size of 86.4 nm through high-shear homogenization, the formulation F3 ensures superior skin penetration and a large surface area for drug action. The use of coconut oil not only provides a stable lipophilic base but also offers inherent antimicrobial benefits, while the high negative zeta potential of -47.6 mV guarantees long-term physical stability. With a skin-compatible pH of 6.5 and a controlled, near-complete drug release of 99.65% over 24 hours following the Higuchi diffusion model, this nano emulsion serves as an advanced, safe, and efficient alternative to conventional treatments for fungal skin infections.

ACKNOWLEDGEMENT

The author would like to thank the faculty of pharmacy and dean for the support and providing the research work.

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