European Journal of Clinical Pharmacy

Print ISSN: 2385-409X **Online ISSN**: 3105-0409

Website: https://farmclin.com/

Original Research Article

Formulation and Evaluation of Terbinafine Hydrochloride Emulgel for Topical Delivery

Article History:

Name of Author:

Rakhi Verma[1], Rashda Qureshi[2], Shrey Parmar[3], Vimla Soni[3], Nootan Shewaram[3], Rimjhim Arora[4]

Affiliation:

[1]*Gurukul Pharmacy College, Kota, Rajasthan, India*

[2]*Maulana Azad University, Jodhpur, Rajasthan, India*

[3]*Maulana Azad Institute of Pharmacy, Jodhpur, Rajasthan, India*

[4]*ICFAI School of Pharmaceutical Sciences, Jaipur, Rajasthan, India*

Corresponding Author:

Rakhi Verma

Email: Rakhi91verma@gmail.com

Received: 21-12-2025

Revised: 25-12-2025

Accepted: 28-12-2025

Published: 30-12-2025

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Noncommercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

Abstract: ***Background***: Background: Terbinafine hydrochloride is a potent antifungal agent widely used for the treatment of dermatophytic infections. Oral therapy is associated with systemic adverse effects and extensive first-pass metabolism, while conventional topical formulations often show limited drug penetration and patient acceptability. Emulgel systems combine the advantages of emulsions and gels and are particularly suitable for the topical delivery of hydrophobic drugs. ***Objective***: The present study aimed to develop and evaluate a topical emulgel formulation of terbinafine hydrochloride with improved physicochemical characteristics, controlled drug release, and good stability. ***Methods***: Terbinafine hydrochloride emulgels were prepared using hydroxypropyl methylcellulose (HPMC LV 50) as a gelling agent and propylene glycol as a penetration enhancer. Nine formulations (F1–F9) were developed by varying polymer and permeation enhancer concentrations. The formulations were evaluated for physical appearance, pH, drug content, viscosity, spreadability, extrudability, in-vitro drug release, release kinetics, stability as per ICH guidelines, and skin irritation potential. ***Results***: All formulations exhibited acceptable pH (5.8–6.4), good homogeneity, and drug content within pharmacopoeial limits. The optimized formulation (F9) showed desirable viscosity, good spreadability and extrudability, and sustained drug release over 12 h following diffusion-controlled kinetics. Stability studies demonstrated no significant changes in physicochemical parameters, and the formulation was found to be non-irritant in skin irritation studies. ***Conclusion***: The developed terbinafine hydrochloride emulgel represents a promising pharmaceutical dosage form for topical antifungal therapy, offering controlled drug release, good stability, and improved patient acceptability.

Keywords: Terbinafine hydrochloride, emulgel, topical drug delivery, HPMC, antifungal.

INTRODUCTION

Topical drug delivery systems are widely employed for the treatment of dermatological disorders due to their ability to deliver drugs directly to the site of action while minimizing systemic exposure. However, the barrier property of the stratum corneum often limits drug permeation, particularly for hydrophobic drugs. Terbinafine hydrochloride, an allylamine antifungal agent, is effective against dermatophytes and Candida species but exhibits poor skin penetration when formulated in conventional creams or gels.

Emulgels are gellified emulsions that combine the penetration and solubilization advantages of emulsions with the elegance, patient acceptability, and rheological properties of gels. They are especially suitable for the topical delivery of poorly water-soluble drugs. The present study focuses on the formulation and evaluation of a terbinafine hydrochloride emulgel using HPMC as a gelling agent and propylene glycol as a penetration enhancer to improve topical drug delivery and therapeutic performance.

MATERIALS AND METHODS

Materials

Terbinafine hydrochloride was obtained as a gift sample. Hydroxypropyl methylcellulose (HPMC LV 50) was used as the gelling agent. Propylene glycol was used as a penetration enhancer. Light liquid

© 2025 European Journal of Clinical Pharmacy; Volume: 7: Issue: 1| All Right Reserved

paraffin, Span 80, Tween 80, methyl paraben, and other excipients were of pharmaceutical grade.

Pre-formulation Studies

Pre-formulation studies included identification of terbinafine hydrochloride by IR spectroscopy, melting point determination, solubility analysis, drug–excipient compatibility studies, and UV spectrophotometric analysis for method development.

2.3 Formulation of Terbinafine Hydrochloride Emulgel

Emulgels were prepared by dispersing HPMC in purified water to form a gel base. An oil-in-water emulsion was prepared using light liquid paraffin as the oil phase with Span 80 and Tween 80 as emulsifying agents. The drug was incorporated into the oil phase, and the emulsion was subsequently mixed with the gel base in a suitable ratio to obtain the emulgel. Nine formulations (F1–F9) were prepared by varying concentrations of HPMC and propylene glyco

Table 1: Preparation of terbinafine hydrochloride emulgel (%w/w)

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Terbinafine hydrochloride	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Light Liquid paraffin	5	5	5	5	5	5	5	5	5
Span 80	1	1	1	1	1	1	1	1	1
Tween 80	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Methyl-paraben	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
HPMC LV 50	5	7.5	10	5	7.5	10	5	7.5	10
Propylene glycol	5	5	5	7.5	7.5	7.5	10	10	10
Water (qs)	30	30	30	30	30	30	30	30	30

Evaluation of Emulgel Formulations

The prepared emulgel formulations (F1–F9) were evaluated for various physicochemical, mechanical, and performance parameters as described below.

Physical Appearance and Homogeneity

All emulgel formulations were visually inspected for color, clarity, phase separation, and homogeneity. A small quantity of emulgel was pressed between the thumb and index finger to assess texture and presence of any coarse particles.1

Determination of pH

The pH of emulgel formulations was measured using a calibrated digital pH meter. One gram of emulgel was dispersed in 10 mL of distilled water and allowed to equilibrate for 2 h at room temperature. The pH measurement was performed in triplicate and the mean value ± standard deviation was recorded.2

Drug Content Determination

Accurately weighed emulgel equivalent to 100 mg was dissolved in 10 mL of methanol with continuous stirring. The solution was filtered through Whatman filter paper (No. 42), suitably diluted, and analyzed spectrophotometrically at 282 nm against methanol as blank. Drug content was calculated using the previously constructed calibration curve.3

Viscosity Measurement

Viscosity of emulgel formulations was determined using a Brookfield viscometer fitted with spindle no. 96. Samples were allowed to equilibrate at room temperature for 30 min prior to measurement. Viscosity was recorded at different rotational speeds (10, 20, 30, 40, and 50 rpm), and mean viscosity values were calculated.4-5

Spreadability Study

Spreadability was determined using the slip-and-drag method. An excess quantity of emulgel was placed between two glass slides of known dimensions. A weight was applied to the upper slide for uniform spreading, and the time taken by the upper slide to move a specified distance was recorded. Spreadability was calculated using the formula:6-7

$S = m \times l / t$

where m is the applied weight, l is the length moved by the slide, and t is the time taken.

Extrudability Study

Extrudability was evaluated by filling the emulgel in a collapsible aluminum tube. The force required to extrude a defined quantity of emulgel in a fixed time was noted and expressed as grams per second. Higher extrudability indicated better applicability.8-9

In-vitro Drug Release Study

In-vitro drug release studies were carried out using a modified Franz diffusion cell with an effective diffusion area of known diameter. Cellophane membrane previously soaked in phosphate buffer was mounted between the donor and receptor compartments. Emulgel equivalent to a fixed dose of terbinafine hydrochloride was placed in the donor compartment, while the receptor compartment was filled with phosphate buffer pH 7.4 containing methanol to maintain sink conditions. The system

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

was maintained at 37 ± 0.5 °C with continuous stirring. Aliquots were withdrawn at predetermined intervals, replaced with fresh medium, and analyzed spectrophotometrically at 282 nm.10-11

Release Kinetics

Drug release data were fitted to various kinetic models including zero-order, first-order, Higuchi, and Korsmeyer–Peppas models to elucidate the mechanism of drug release from the emulgel formulations.12-13

Stability Studies

Accelerated stability studies were conducted on the optimized formulation as per ICH Q1 guidelines. The formulation was stored at 40 ± 2 °C / 75 ± 5% RH for a period of three months. Samples were evaluated at predetermined intervals for physical appearance, pH, drug content, and in-vitro drug release.14-17

Skin Irritation Study

Skin irritation potential of the optimized emulgel formulation was evaluated using albino rabbits. The formulation was applied to a shaved area of skin and observed for signs of erythema or edema at specified time intervals. The study confirmed the non-irritant nature of the formulation.18-19.

Results and Discussion:

Physical Appearance and Homogeneity

All the formulated emulgels (F1–F9) were found to be white, smooth, and homogeneous with no visible phase separation or grittiness. The absence of lumps and coarse particles indicated uniform dispersion of drug and excipients. Good homogeneity is essential for dose uniformity and patient acceptability in topical formulations.

Table 2: Physical examination

Formulation	Color	Homogeneity	Texture
F1	white	Homogeneous	Smooth
F2	white	Homogeneous	Smooth
F3	white	Homogeneous	Smooth
F4	white	Homogeneous	Smooth
F5	white	Homogeneous	Smooth
F6	white	Less homogeneous	Smooth
F7	white	Homogeneous	Smooth
F8	white	Homogeneous	Smooth
F9	white	Homogeneous	Smooth

pH of Emulgel Formulations

The pH of all formulations ranged between 5.8 and 6.4, which is considered suitable for topical application and compatible with the normal pH of human skin. No significant variation in pH was observed during storage, indicating formulation stability.

Table 3: pH of prepared terbinafine hydrochloride emulgel

Formulation code	pH				
	1	**2**	**3**	**Average**	**S.D.**
F1	6.2	6.4	6.3	6.3	0.1
F2	5.9	5.9	6.1	5.9	0.11
F3	6.1	6	5.9	6	0.1
F4	5.8	5.9	5.8	5.8	0.05
F5	6.4	6.1	6.2	6.2	0.15
F6	5.6	5.9	6.2	5.9	0.3
F7	5.8	5.9	5.8	5.8	0.05
F8	5.9	6	6	5.9	0.05
F9	6.1	6.2	6.1	6.1	0.05

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

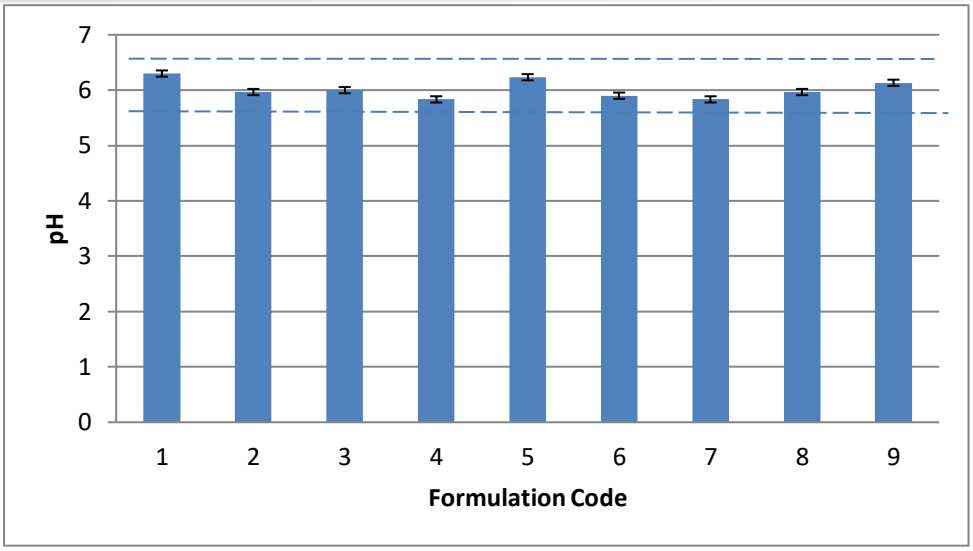

Figure 1: pH of prepared terbinafine hydrochloride emulgel formulation

Drug Content Uniformity

Drug content of the prepared emulgels was found to be in the range of 98.2% to 101.4%, indicating uniform distribution of terbinafine hydrochloride throughout the formulation. This confirms the suitability of the formulation method employed.

Table 4: Drug content of prepared terbinafine hydrochloride emulgel

Formulation code	Drug Content* (%)				
	1	2	3	Average	S.D.
F1	88.4	89.6	86.87	88.29	1.36
F2	90.45	91.85	90.6	90.96	0.76
F3	97.56	100.45	99.73	99.24	1.50
F4	100.78	99.87	102.67	101.10	1.42
F5	107.45	109.56	108.82	108.61	1.07
F6	107.96	106.79	106.45	107.06	0.79
F7	108.61	109.71	108.62	108.98	0.63
F8	110.02	109.91	109.78	109.903	0.12
F9	110.71	110.37	111.49	110.857	0.57

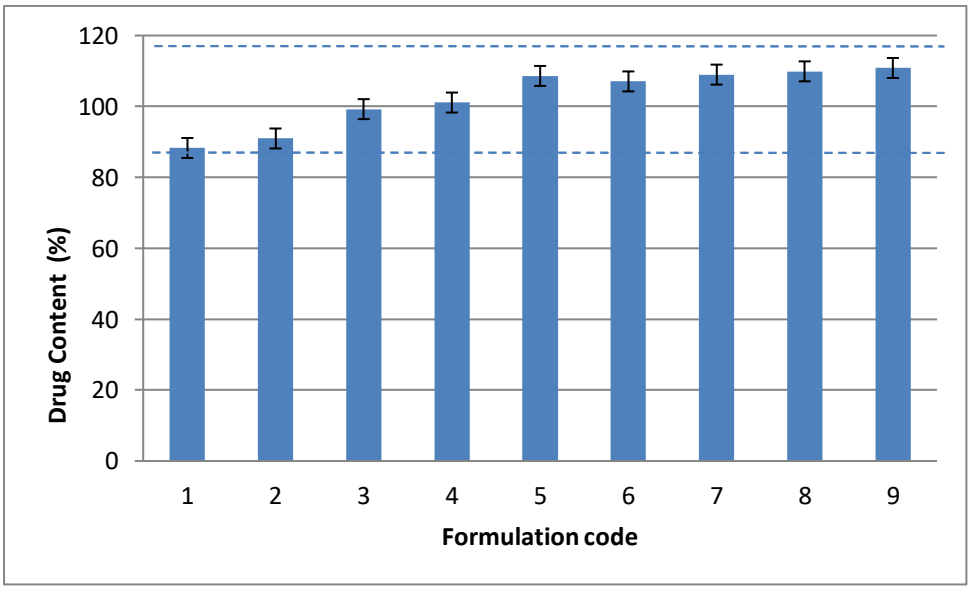

Figure 2: Drug content determination of prepared terbinafine hydrochloride emulgel formulation

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

Viscosity Studies

Viscosity increased with increasing concentration of HPMC. Formulations with lower polymer concentration showed lower viscosity and higher spreadability, while higher polymer concentration resulted in thicker gels. Optimized viscosity is crucial to ensure easy application without runoff from the site of application.

Table 5: Viscosity of prepared terbinafine hydrochloride emulgel

rpm	Viscosity (cPs)*								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
10	16716 ±63	19961 ±75	29019 ±51	17058 ±85	20087 ±22	30002 ±60	19852 ±31	21666 ±37	33757 ±43
20	15427 ±64	18737 ±83	26874 ±97	15952 ±86	19828 ±65	25894 ±69	18720 ±82	20186 ±32	31253 ±57
30	14930 ±68	17791 ±58	24831 ±77	13839 ±16	17522 ±28	25832 ±65	16973 ±101	20264 ±41	30257 ±41
40	12875 ± 21	15953 ±49	21631 ±55	11779 ±65	14706 ±50	21735 ±57	14759 ±41	19928 ±51	27955 ±27
50	9581 ± 63	10763 ±53	18665 ±64	8578 ±76	11815 ±70	19101 ±52	13273 ±15	18470 ±68	25758 ±24

* Data indicates mean± S.D. of triplicate determinations

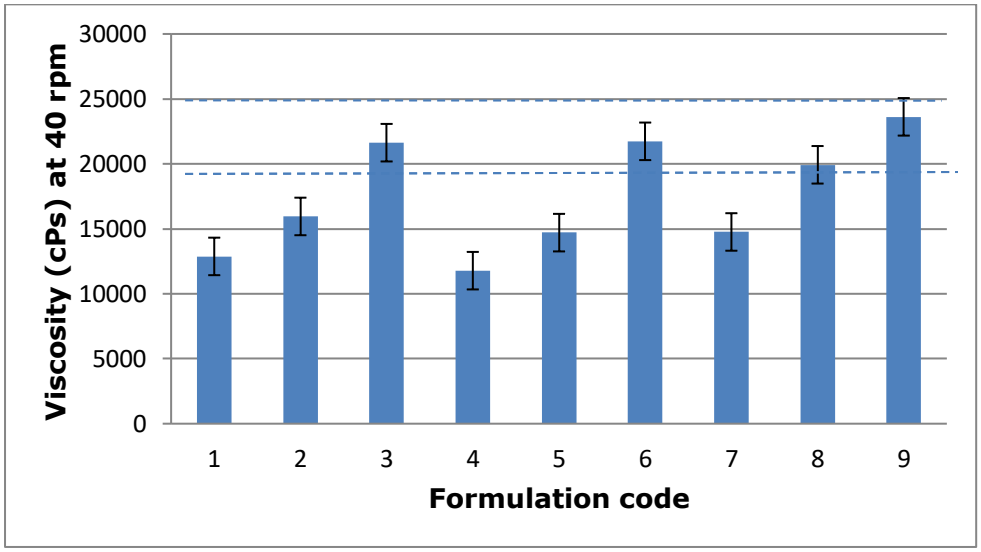

Figure 3: Viscosity of prepared Terbinafine Emulgel

Spreadability and Extrudability

Spreadability values decreased with increasing viscosity, indicating an inverse relationship between viscosity and spreadability. Formulation F9 showed optimum spreadability and extrudability, ensuring ease of application and uniform spreading on the skin surface.

Table 6: Extrudability of terbinafine emulgel

Sr. no.	Formulation code	Extrudability (%)*
1	**F1**	2.98 ±0.16
2	**F2**	1.89 ±0.21
3	**F3**	1.48 ±0.11
4	**F4**	2.37 ±0.29
5	**F5**	1.71 ±0.12
6	**F6**	1.61 ±0.06
7	**F7**	2.51 ±0.07
8	**F8**	1.79 ±0.05

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

9	**F9**	1.62 ±0.07

* Data represents mean ± SD, n=3

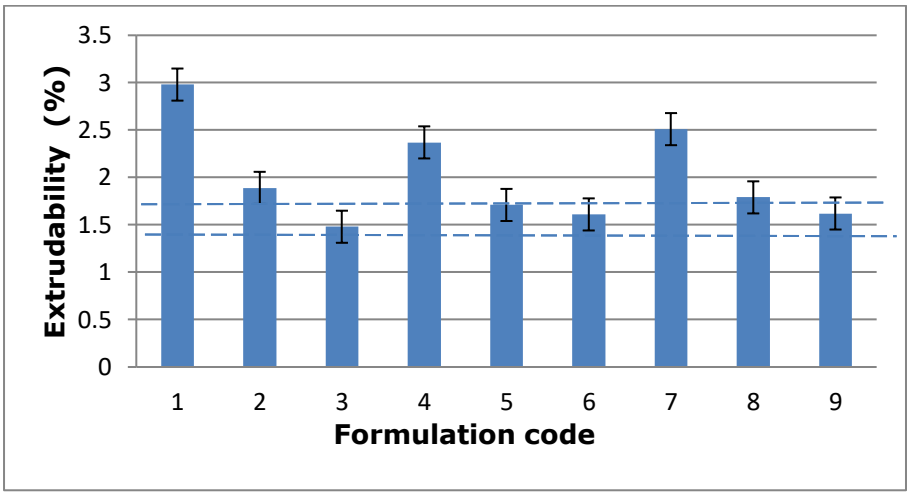

Figure 4: Extrudability of prepared Terbinafine Emulgel

Table 7: Spreadability of terbinafine emulgel

Sr. no.	Formulation	Spreadability (gm.cm/sec)*
1	F1	66.13 ± 0.56
2	F2	42.45 ± 0.98
3	F3	36.62 ± 0.99
4	F4	63.75 ± 0. 54
5	F5	39.96 ± 0.64
6	F6	35.57 ± 0.43
7	F7	45.89 ±0.82
8	F8	42.72 ±0.73
9	F9	40.47 ±0.59

* Data represents mean ± SD, n=3

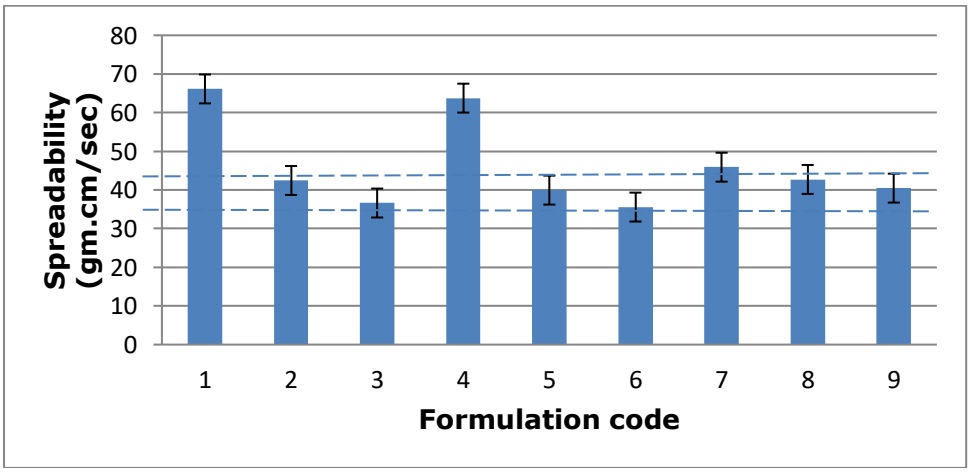

Figure 5: Spreadability of prepared Terbinafine Emulgel

In-vitro Drug Release Studies

In-vitro drug release studies demonstrated that all formulations exhibited sustained release behavior. The optimized formulation F9 showed maximum cumulative drug release over 12 h compared to other formulations. Increased polymer concentration retarded drug release due to formation of a dense gel matrix.

Table 8: *In-vitro* release of terbinafine from emulgel formulation

Time (Min)	% Cumulative drug release*									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**TP**

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

0	0	0	0	0	0	0	0	0	0	0
30	11.46 ±0.01	10.66 ±0.01	7.20±0 .02	11.84± 0.04	9.52±0 .02	1.08±0 .01	19.22± 0.01	10.35± 0.02	6.71±0 .01	4.16
60	18.52 ±0.01	19.24± 0.02	11.13± 0.01	16.30± 0.01	16.01± 0.04	5.74±0 .01	31.88± 0.01	18.19± 0.01	11.31± 0.01	8.33
90	27.89 ±0.03	24.74± 0.03	15.67± 0.01	31.92± 0.01	23.92± 0.01	10.06± 0.01	33.46± 0.06	19.88± 0.02	15.15± 0.02	12.49
120	38.76 ±0.01	30.04± 0.02	19.11± 0.02	36.83± 0.03	34.68± 0.03	10.96± 0.03	43.80± 0.02	24.76± 0.01	20.02± 0.02	16.66
240	62.03 ±0.01	44.31 ±0.04	23.02± 0.03	60.03± 0.01	53.82± 0.05	25.58± 0.02	72.64± 0.03	41.87± 0.01	35.77± 0.01	33.33
360	81.29 ±0.03	73.4 ±0.02	38.19± 0.07	77.22± 0.02	70.47± 0.02	40.16± 0.01	76.23± 0.04	70.70± 0.02	55.76± 0.01	50
f_2	33.70	42.80	58.08	35.09	40.89	61.02	24.54	47.37	72.01	

*Data represent mean ± S.D. (n=3)

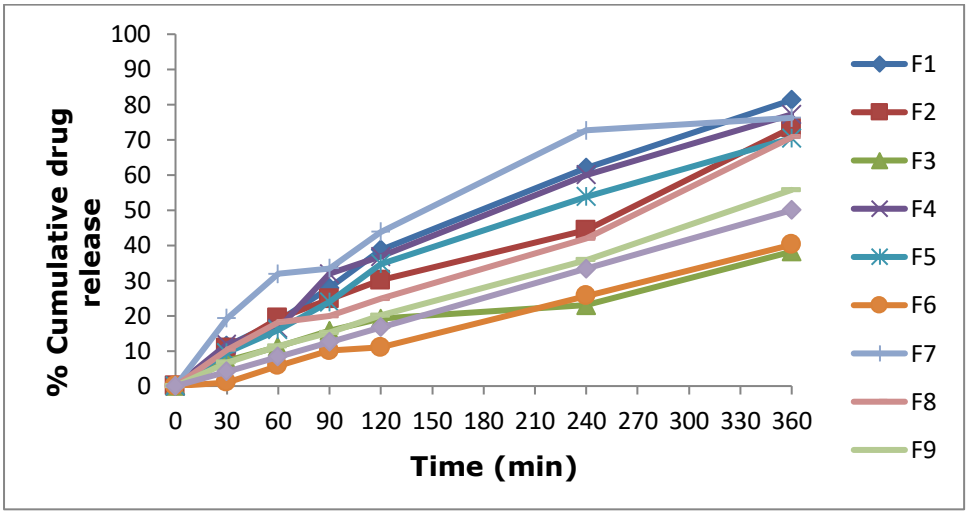

Fig 6: *In-vitro* release of terbinafine from the prepared emulgel formulations

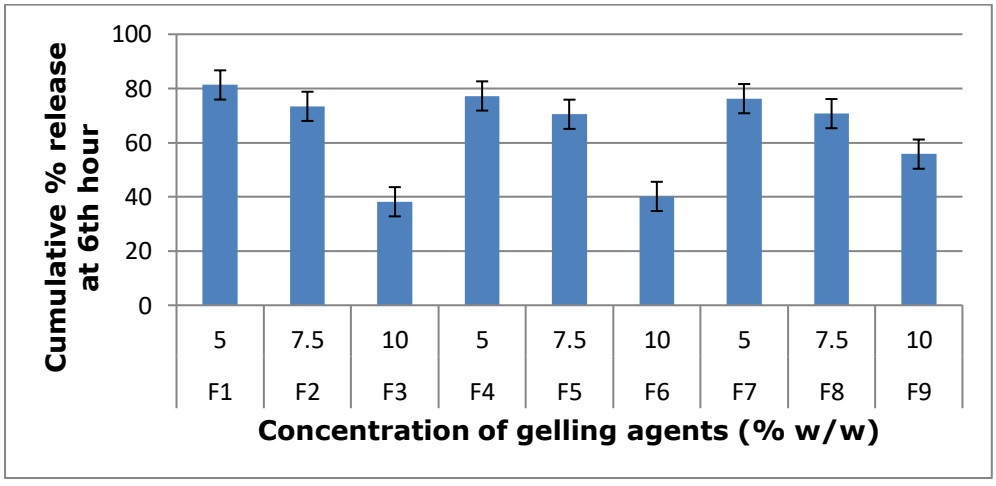

Fig 7: In-vitro release of terbinafine from the prepared emulgel (in 360 min)

Release Kinetics

Release kinetics analysis revealed that the drug release from the optimized formulation followed Higuchi diffusion kinetics, indicating diffusion-controlled release from the emulgel matrix. The Korsmeyer–Peppas model further confirmed non-Fickian diffusion behavior.

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

Table 9: Model fitting for release kinetics of prepared terbinafine emulgel

Batch	Release models							Best fit model
	Zero order	First order	Higuchi model	Hixon-crowell	Korsmeyer Peppas			
	r	r	r	r	r	K	n	
F1	0.992	0.927	0.997	**0.999**	0.996	0.003	0.809	Hixon-crowell
F2	0.991	0.948	0.978	0.978	**0.993**	0.004	0.732	Peppas
F3	0.976	0.931	0.971	0.975	**0.985**	0.004	0.63	Peppas
F4	0.985	0.914	0.995	**0.997**	0.985	0.003	0.788	Hixon
F5	0.989	0.92	**0.997**	0.997	0.994	0.002	0.824	Higuchi
F6	**0.998**	0.864	0.986	0.996	0.974	0.002	1.361	Zero
F7	0.847	0.789	0.895	0.881	**0.917**	0.017	0.545	Peppas
F8	**0.991**	0.973	0.968	0.976	0.986	0.004	0.733	Zero
F9	**0.999**	0.962	0.984	0.994	0.997	0.001	0.846	Zero

Stability Studies

The optimized formulation F9 showed no significant changes in physical appearance, pH, drug content, or in-vitro drug release profile during accelerated stability studies. These results indicate that the formulation is stable under stressed storage conditions.

Skin Irritation Study

No signs of erythema or edema were observed during the skin irritation study, confirming that the formulation is non-irritant and safe for topical application.

Figure 8: Skin irritation study images showing absence of irritation.

CONCLUSION

A stable and effective topical emulgel of terbinafine hydrochloride was successfully developed using HPMC and propylene glycol. The optimized formulation exhibited desirable physicochemical properties, sustained drug release, good stability, and skin compatibility. The emulgel system thus offers a promising pharmaceutical approach for the topical management of fungal infections.

REFERENCES

1. Panwar AS, Upadhyay N, Bairagi M. Emulgel: A review. Asian J Pharm Life Sci. 2011;1(3):333–343.
2. Williams AC, Barry BW. Terpenes and the lipid–protein partitioning theory of skin penetration enhancement. Pharm Res. 1991;8(1):17–24.
3. Shokri J, Javadzadeh Y, Hamishekar H. Effects of various penetration enhancers on percutaneous absorption of piroxicam from emulgels. Res Pharm Sci. 2012;7:225–234.

© 2025 European Journal of Clinical Pharmacy; All Right Reserved

4. Dadwal M. Emulgel: A novel approach to topical drug delivery. Int J Pharm Biol Sci. 2013;4(1):847–856.
5. Jacobsen F, Fisahn C, Sorkin M, et al. Efficacy of topically delivered linezolid against wound infection by Pseudomonas aeruginosa and methicillin-resistant Staphylococcus aureus. Antimicrob Agents Chemother. 2011;55(5):2325–2334.
6. Ashara KC, Paun JS, Soniwala MM. Micro-emulsion based emulgel: A novel topical drug delivery system. Asian Pac J Trop Dis. 2014;4(Suppl 1):S27–S32.
7. Upadhyaya S, Chauhan BS, Kothiyal P. Emulgel: A novel approach for topical delivery of hydrophobic drugs. Int J Universal Pharm Bio Sci. 2014;3:176–189.
8. Joshi B, Singh G, Rana AC. Emulgel: A comprehensive review on recent advances in topical drug delivery system. Int Res J Pharm. 2013;4:66–70.
9. Nabarawi MA, Rahman DA, Halim SA. Pharmaceutical studies on fluconazole topical emulgel. Indian Streams Res J. 2014;4(1):45–48.
10. Terbinafine hydrochloride. Wikipedia. Available from: https://en.wikipedia.org/wiki/Terbinafine_hydrochloride (accessed 10 Oct 2016).
11. Guleri TK, Kaur LP. Formulation and evaluation of topical gel of aceclofenac. J Drug Deliv Ther. 2013;3(6):51–53.
12. Ganeshpurkar A, Vishya P, Jain S. Delivery of amphotericin B via emulgel system for treatment of Candida albicans-induced dermal mycosis in rats. Indian J Dermatol. 2014;59(2):98–103.
13. Patil SS, Sharma RP, Adnaik RS, Mohite SK. Novel cosmeceutical herbal emulgel for skin care. World J Pharm Pharm Sci. 2014;3(4):801–811.
14. Vats S, Saxena C, Easwari TS, Shukla VK. Emulsion-based gel technique: A novel approach for enhancing topical delivery of hydrophobic drugs. Int J Pharm Res Scholars. 2014;3(2):649–660.
15. Khullar R, Kumar D, Seth N, Saini S. Formulation and evaluation of mefenamic acid emulgel for topical delivery. Saudi Pharm J. 2012;20:63–67.
16. Anbhule RM, Chemate SJ. Formulation and evaluation of terbinafine hydrochloride film-forming emulgel. Int J Drug Res Technol. 2016;6(3):164–174.
17. Tiwari S, Mistry P, Patel V. Solid lipid nanoparticles based on co-processed lipids for topical delivery of terbinafine hydrochloride. J Pharm Drug Dev. 2014;2(4):1–8.
18. Prasad AK, Narayanan N, Rajalakshmi G. Preparation and evaluation of solid dispersion of terbinafine hydrochloride. Int J Pharm Sci Rev Res. 2010;3:130–134.
19. Sen M, Uzun C, Güven O. Controlled release of terbinafine hydrochloride from pH-sensitive poly(acrylamide-maleic acid) hydrogels. Int J Pharm. 2000;203:149–157.

 © 2025 European Journal of Clinical Pharmacy; All Right Reserved