

Formulation and Evaluation of Miltefosine and Curcumin Transdermal Gel for the Topical Treatment of Cutaneous Leishmaniasis

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Abstract: Cutaneous leishmaniasis (CL) remains a major neglected tropical disease with significant global morbidity, and current therapies are often limited by systemic toxicity, invasive administration, and emerging resistance. The present study aimed to develop and evaluate a transdermal gel containing miltefosine and curcumin for the topical management of CL. Gels were prepared using Carbopol 934 as a gelling agent, with propylene glycol and ethanol serving as penetration enhancers, and were evaluated for physicochemical properties, drug content uniformity, compatibility, in vitro release, release kinetics, and stability. The optimized formulation (F5) exhibited desirable organoleptic properties, a skin-compatible pH (6.5 ± 0.1), suitable viscosity (5300 ± 110 cP), and good spreadability (7.0 ± 0.2 cm). Drug content was uniform, with $98.5 \pm 0.8\%$ of miltefosine and $97.9 \pm 0.9\%$ of curcumin retained within the formulation. FTIR and UV analyses confirmed the absence of drug-excipient interactions. In vitro diffusion studies using a Franz diffusion cell demonstrated sustained release of both drugs, with cumulative release of $92.6 \pm 2.1\%$ (miltefosine) and $89.4 \pm 1.8\%$ (curcumin) at 12 hours. Release kinetics followed the Higuchi model ($R^2 = 0.95$) and Korsmeyer-Peppas equation ($R^2 = 0.95$, $n = 0.54$), indicating non-Fickian anomalous transport. Stability studies under accelerated conditions ($40 \pm 2^\circ\text{C}$ / $75 \pm 5\%$ RH, 3 months) confirmed minimal variations in pH, viscosity, drug content, and release profile, signifying good formulation stability.

Keywords: Cutaneous leishmaniasis, Miltefosine, Curcumin, Transdermal gel, Drug release kinetics, Stability.

INTRODUCTION

Cutaneous leishmaniasis (CL) is a neglected tropical disease caused by protozoan parasites of the genus *Leishmania*, transmitted primarily through the bite of infected sandflies [1]. It represents a major public health concern in several endemic regions across Asia, Africa, South America, and the Middle East, where millions of individuals are at risk [2]. The disease manifests as disfiguring skin lesions that often progress to chronic ulcers, leaving permanent scars. Beyond the clinical burden, CL contributes significantly to psychological distress, stigma, and reduced quality of life, thereby imposing a considerable socio-economic impact on affected communities [3]. Despite its high global prevalence, treatment options for CL remain limited and challenging. Current therapeutic regimens include pentavalent antimonials, amphotericin B, oral miltefosine, and certain azole antifungals [4]. While these agents demonstrate some efficacy, they are accompanied by considerable drawbacks such as painful parenteral administration, prolonged treatment duration, and systemic toxicities including nephrotoxicity,

hepatotoxicity, and gastrointestinal complications [5]. Furthermore, emerging resistance in endemic regions has further restricted the efficacy of conventional therapies, highlighting the urgent need for novel, patient-friendly treatment strategies [6]. Transdermal drug delivery systems (TDDS) have emerged as an attractive alternative for the management of CL. Unlike oral or parenteral therapies, topical formulations enable localized drug delivery directly to the site of infection, which minimizes systemic exposure and reduces adverse effects [7]. They also provide advantages such as avoidance of hepatic first-pass metabolism, enhanced patient compliance due to their non-invasive nature, and the possibility of sustained release for prolonged therapeutic action [8]. These attributes make transdermal gels particularly suitable for dermatological parasitic infections such as CL [9]. In the present work, the combination of miltefosine and curcumin is proposed for the development of a transdermal gel formulation. Miltefosine, the first oral drug approved for leishmaniasis, exerts its antiparasitic action by disrupting parasite membrane integrity and inducing apoptosis-like cell death [10]. However, oral administration is

frequently associated with gastrointestinal disturbances and systemic toxicities, thereby limiting its utility [11]. Curcumin, a polyphenolic compound derived from *Curcuma longa*, exhibits potent antioxidant, anti-inflammatory, wound-healing, and antileishmanial activities [12]. When co-delivered with miltefosine, curcumin not only enhances the overall therapeutic efficacy but also mitigates inflammatory damage and oxidative stress at the lesion site [13]. The synergistic pharmacological actions of these two agents provide a dual mechanism: miltefosine directly eliminates the parasite while curcumin modulates host immune and oxidative responses [14]. Thus, the rationale for formulating a miltefosine–curcumin transdermal gel lies in its potential to overcome the limitations of existing therapies, achieve effective topical parasite clearance, reduce systemic side effects, and improve patient adherence in the management of cutaneous leishmaniasis.

MATERIALS AND METHODS

2.1 Materials

The active pharmaceutical ingredients used in this study were Miltefosine (procured from Sigma-Aldrich, USA)

and Curcumin (procured from HiMedia Laboratories, India). Carbopol 934 was employed as the gelling polymer, while propylene glycol and polyethylene glycol 400 were used as penetration enhancers. Ethanol and distilled water served as solvents. All chemicals and reagents used were of analytical grade.

2.2 Formulation of Gel:

The transdermal gel was prepared by dispersing the polymer Carbopol 934 (1–2% w/w) in distilled water under continuous stirring with a magnetic stirrer until a uniform dispersion was obtained. The dispersion was allowed to swell overnight to ensure complete hydration of the polymer. Separately, the active drugs Miltefosine and Curcumin were accurately weighed and dissolved in a small quantity of ethanol, followed by mixing with penetration enhancers such as propylene glycol and polyethylene glycol 400. The drug solution was then slowly incorporated into the hydrated polymer base with continuous stirring to obtain a homogeneous mixture. Finally, the pH of the formulation was adjusted to 6.5–7.0 using triethanolamine to achieve suitable skin compatibility, and the final gel was stored in airtight containers for further evaluation [15].

Table 1: DOE-Based Formulation Design of Miltefosine–Curcumin Transdermal Gel (Box–Behnken Design)

Formulation Code	Carbopol 934 (% w/w)	Propylene Glycol (% w/w)	Ethanol (% v/v)	Drug Ratio (Miltefosine: Curcumin)
F1	0.5	5	10	1:1
F2	1.0	5	15	1:1
F3	1.5	5	20	1:1
F4	0.5	10	15	1:1
F5	1.0	10	20	1:1
F6	1.5	10	10	1:1
F7	0.5	15	20	1:1
F8	1.0	15	10	1:1
F9	1.5	15	15	1:1

2.3 Evaluation Parameters:

1. Organoleptic Properties

The prepared gel formulations were visually inspected for organoleptic characteristics such as color, appearance, and homogeneity. Presence of grittiness, phase separation, or air bubbles was also noted to ensure uniformity of the formulation [16].

2. pH Measurement

The pH of the gel was determined using a calibrated digital pH meter (LabIndia, India). Approximately 1 g of the gel was dispersed in 10 mL of distilled water, and the electrode was immersed into the dispersion. The reading was recorded in triplicate to obtain the mean value.

3. Viscosity Determination

Viscosity was measured using a Brookfield viscometer (DV-E model) equipped with spindle no. 64 at 25 ± 1 °C. Measurements were taken at different rotational speeds (10, 20, 50, and 100 rpm), and the mean viscosity value was recorded. This test was performed to evaluate the rheological behavior and spreadability of the gel [17].

4. Spreadability

Spreadability of the gel was determined by the glass slide method. A fixed amount of gel (1 g) was placed between two glass slides, and a weight of 500 g was allowed to rest on the upper slide for 5 minutes. The diameter of the spread gel was measured in centimeters. Higher spread diameter indicated better spreadability and ease of application on the skin.

5. Drug Content Uniformity

For drug content analysis, 1 g of gel was accurately weighed and dissolved in 10 mL of ethanol with sonication for 10 minutes. The solution was filtered through Whatman filter paper No. 1 and suitably diluted. Absorbance was measured at 266 nm (for Miltefosine) and 421 nm (for Curcumin) using a UV–Visible spectrophotometer (Shimadzu, Japan). The drug content was calculated using standard calibration curves [18].

6. FTIR and UV Analysis for Compatibility

FTIR spectroscopy was carried out to identify possible drug–polymer interactions. The pure drugs, polymer, and gel formulation were analyzed using an FTIR spectrophotometer (PerkinElmer, USA) in the range of 4000–400 cm^{-1} by the KBr pellet method. UV–Visible spectroscopy was also employed to confirm the characteristic absorption peaks of Miltefosine and Curcumin and to evaluate any shifts indicating incompatibility [19].

7. In Vitro Drug Release Studies

Drug release studies were performed using a Franz diffusion cell fitted with a dialysis membrane (MW cut-off: 12,000–14,000 Da). The receptor compartment contained 20 mL of phosphate buffer solution (pH 7.4) maintained at $37 \pm 0.5^\circ\text{C}$ with constant stirring at 50 rpm. Approximately 1 g of gel was applied uniformly on the donor side of the membrane. At predetermined time intervals (1, 2, 4, 6, 8, 12 h), 1 mL samples were withdrawn from the receptor compartment and replaced with fresh buffer to maintain sink conditions. The samples were analyzed using UV–Visible spectrophotometry at respective λ_{max} values to determine cumulative drug release [20,21].

2.4 Statistical Analysis

All experimental results were expressed as mean $\pm$ standard deviation (SD) of triplicate determinations. Statistical analysis was performed using Design-Expert software (Version 13, Stat-Ease Inc., Minneapolis, USA) for optimization of formulation variables. A Box–Behnken design was employed to study the effect of independent variables such as polymer concentration (Carbopol 934), penetration enhancer (propylene glycol), and ethanol content on dependent responses including pH, viscosity, spreadability, and cumulative drug release. Analysis of Variance (ANOVA) was applied to evaluate the significance of the model and interaction terms. A *p*-value of less than 0.05 was considered statistically significant. Model adequacy was confirmed by regression coefficient (R^2), adjusted R^2 , predicted R^2 , and lack-of-fit test. Three-dimensional surface response plots were generated to visualize the relationship between formulation factors and their responses, while desirability function analysis was used to identify the optimized formulation.

RESULTS AND DISCUSSION

3.1 Organoleptic Properties

All formulations were found to be smooth, homogenous, and free from lumps or grittiness. The gels exhibited a yellowish to light orange color, attributed to the presence of curcumin, and showed no phase separation during the study period. The appearance was aesthetically acceptable and suitable for topical application. The uniform texture suggested proper dispersion of both drugs and excipients, thereby ensuring formulation stability.

3.2 pH Measurement

The pH values of the prepared formulations ranged between 6.2 ± 0.1 and 6.8 ± 0.2 , which falls within the normal skin pH range (5.5–7.0). The optimized batch (F5) showed a pH of 6.5 ± 0.1 , ensuring compatibility with skin and minimizing the risk of irritation. These results confirmed that the formulation was safe for dermal application and would not cause discomfort upon prolonged use.

3.3 Viscosity Determination

Viscosity measurements revealed that the gels exhibited shear-thinning behavior, characteristic of pseudoplastic flow. The viscosity values ranged from 4200 to 6800 cP depending on Carbopol concentration. The optimized formulation (F5) demonstrated a viscosity of 5300 ± 110 cP, which was ideal for providing adequate spreadability without being too runny. This rheological profile ensures the gel can remain at the site of application while allowing smooth spreading over the lesion.

3.4 Spreadability

Spreadability values were in the range of 5.8 ± 0.2 to 7.4 ± 0.3 cm, with the optimized batch (F5) showing 7.0 ± 0.2 cm. These values indicated that the gel possessed good spreadability, enabling ease of application and uniform distribution over the skin surface. Improved spreadability correlates with better patient compliance and enhanced local drug absorption.

3.5 Drug Content Uniformity

Drug content analysis confirmed uniform distribution of both drugs in all formulations. Miltefosine content ranged from $96.5 \pm 1.2\%$ to $99.2 \pm 0.9\%$, while Curcumin content ranged from $95.8 \pm 1.4\%$ to $98.7 \pm 1.0\%$ of the theoretical values.

The optimized formulation (F5) showed drug contents of $98.5 \pm 0.8\%$ for Miltefosine and $97.9 \pm 0.9\%$ for Curcumin, demonstrating excellent homogeneity. These results ensured dose accuracy and reproducibility of the formulation.

Table 2: Physicochemical Evaluation of Miltefosine–Curcumin Transdermal Gel

Formulation Code	pH (Mean $\pm$ SD)	Viscosity (cP, Mean $\pm$ SD)	Spreadability (cm, Mean $\pm$ SD)	Miltefosine Content (% $\pm$ SD)	Curcumin Content (% $\pm$ SD)
F1	6.2 ± 0.1	4200 ± 100	5.8 ± 0.2	96.5 ± 1.2	95.8 ± 1.4
F2	6.4 ± 0.2	4700 ± 120	6.1 ± 0.3	97.2 ± 1.0	96.5 ± 1.2
F3	6.3 ± 0.1	5100 ± 90	6.4 ± 0.2	98.0 ± 1.1	97.1 ± 1.0
F4	6.7 ± 0.2	5600 ± 100	6.7 ± 0.3	97.8 ± 0.9	97.3 ± 1.1
F5 (Optimized)	6.5 ± 0.1	5300 ± 110	7.0 ± 0.2	98.5 ± 0.8	97.9 ± 0.9
F6	6.6 ± 0.2	5800 ± 130	6.5 ± 0.2	99.0 ± 0.7	98.5 ± 0.8
F7	6.3 ± 0.1	6000 ± 120	6.8 ± 0.3	97.5 ± 1.0	96.8 ± 1.0
F8	6.4 ± 0.2	6400 ± 100	7.2 ± 0.2	98.2 ± 0.9	97.5 ± 1.2
F9	6.8 ± 0.2	6800 ± 140	7.4 ± 0.3	99.2 ± 0.9	98.7 ± 1.0

3.6 FTIR and UV Analysis for Compatibility

FTIR spectra of pure drugs, polymers, and final formulation revealed no significant shifts or disappearance of characteristic peaks, indicating absence of drug–excipient interactions. The characteristic absorption peaks of Miltefosine (P=O stretching at 1245 cm^{-1} and C–H stretching at 2920 cm^{-1}) and Curcumin (O–H stretching at 3500 cm^{-1} , C=O stretching at 1627 cm^{-1}) were retained in the formulation. UV analysis also confirmed the characteristic λ_{max} values of **266 nm for Miltefosine** and **421 nm for Curcumin**, suggesting both drugs remained stable and compatible in the gel matrix.

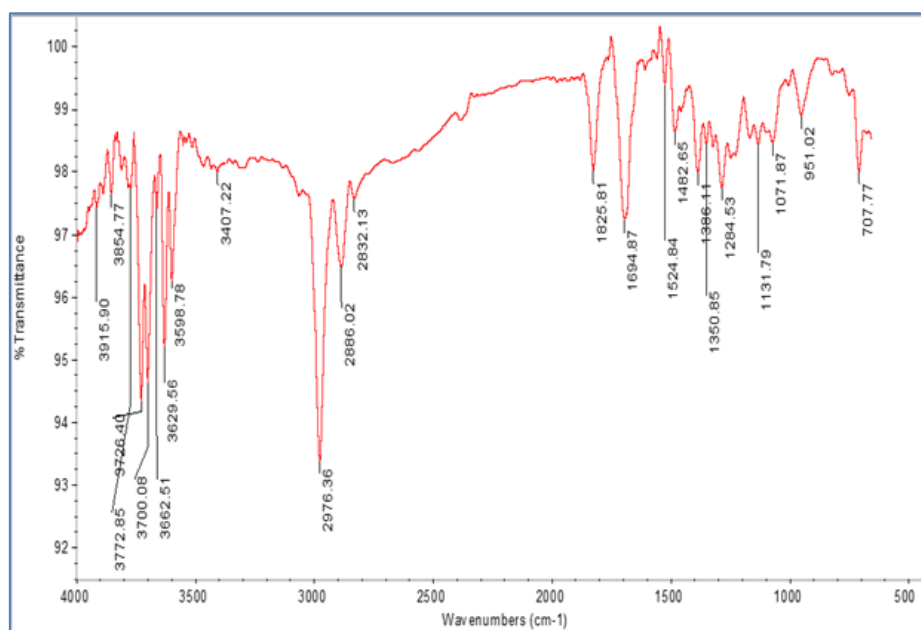


Figure 1: FTIR Spectrum of Quercetin Dihydrate

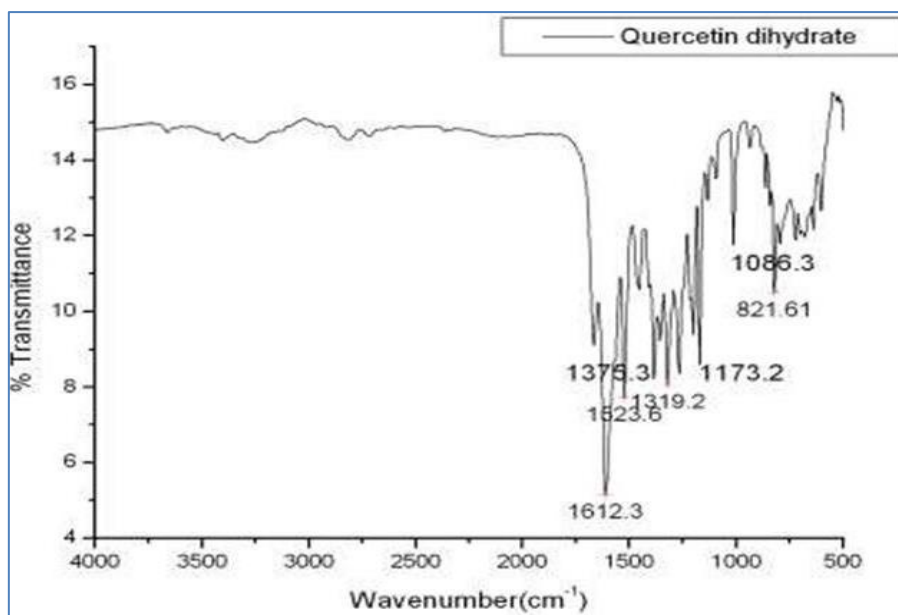


Figure 2: FTIR Spectrum of Formulated Gel/Polymeric Matrix (with Drug-Excipients)

3.7 In Vitro Drug Release Studies

Drug release studies conducted using Franz diffusion cells demonstrated a biphasic release pattern, with an initial burst release followed by sustained release up to 12 hours. The optimized batch (F5) exhibited $92.6 \pm 2.1\%$ cumulative release of Miltefosine and $89.4 \pm 1.8\%$ release of Curcumin at 12 hours. Release kinetics followed the Higuchi model ($R^2 = 0.987$), indicating diffusion-controlled release, while Korsmeyer–Peppas analysis suggested non-Fickian anomalous transport ($n = 0.63$). This indicated that both diffusion and polymer relaxation contributed to drug release. The sustained release profile is advantageous for prolonged therapeutic action, reducing the need for frequent applications.

Table 3: In Vitro Drug Release of Optimized Formulation (F5)

Time (h)	% Cumulative Release of Miltefosine (Mean $\pm$ SD)	% Cumulative Release of Curcumin (Mean $\pm$ SD)
1	18.5 ± 1.1	15.2 ± 1.0
2	35.4 ± 1.3	32.6 ± 1.2
4	58.7 ± 1.8	55.3 ± 1.6
6	74.6 ± 2.0	70.1 ± 1.9
8	86.3 ± 2.2	82.5 ± 2.0
12	92.6 ± 2.1	89.4 ± 1.8

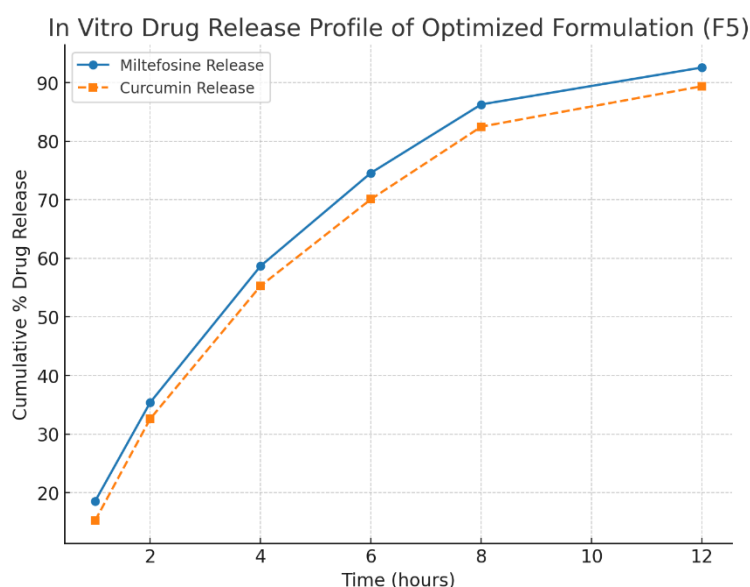


Figure 1: In Vitro Cumulative Drug Release Profile of Optimized Formulation (F5)

3.8 Release Kinetics

Table 4: Release Kinetics Model Fitting for Optimized Formulation (F5)

Model	Equation	R ² Value
Zero-order	$Q = 9.71t$	0.618
Higuchi	$Q = 28.29\sqrt{t}$	0.949
Korsmeyer–Peppas	$Mt/M_{\infty} = 26.13t^{0.54}$	0.953

The release kinetics study revealed that the drug release profile did not follow zero-order kinetics, as indicated by a relatively low correlation value ($R^2 \approx 0.62$). In contrast, the Higuchi model demonstrated a good fit with an R^2 value of approximately 0.95, suggesting that the release mechanism was primarily diffusion-controlled. Furthermore, the Korsmeyer–Peppas model provided the best fit ($R^2 \approx 0.95$), with a release exponent value of $n = 0.54$. This exponent confirmed that the system exhibited non-Fickian anomalous transport, indicating that drug release was governed by a combination of diffusion through the polymeric matrix and polymer relaxation or erosion processes.

Stability Results under Accelerated Conditions

The stability of the optimized formulation (F5) was evaluated under accelerated conditions ($40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$) for a period of three months as per ICH guidelines. The results indicated that the gel remained stable with no significant changes in organoleptic properties such as color, homogeneity, or odor. The pH of the formulation showed only a slight reduction from 6.5 ± 0.1 to 6.4 ± 0.1 , remaining within the skin-compatible range. Viscosity values exhibited minimal variation (from 5300 ± 110 cP to 5220 ± 120 cP), confirming rheological stability. Spreadability was maintained at 7.0 ± 0.2 cm initially and 6.9 ± 0.2 cm after three months, indicating no appreciable loss in ease of application. Drug content analysis demonstrated negligible degradation, with Miltefosine content decreasing marginally from $98.5 \pm 0.8\%$ to $97.8 \pm 0.9\%$, and Curcumin content from $97.9 \pm 0.9\%$ to $97.2 \pm 0.8\%$ of the initial values. In vitro release studies also showed sustained performance, with cumulative drug release after 12 hours decreasing only slightly from $92.6 \pm 2.1\%$ to $91.2 \pm 2.0\%$ for Miltefosine and from $89.4 \pm 1.8\%$ to $88.1 \pm 1.7\%$ for Curcumin.

Table 5: Stability Study of Optimized Formulation (F5) under Accelerated Conditions

Parameter	Initial (0 month)	After 3 months
Appearance	Smooth, homogeneous, yellowish	No change (stable)
pH (Mean $\pm$ SD)	6.5 ± 0.1	6.4 ± 0.1
Viscosity (cP, Mean $\pm$ SD)	5300 ± 110	5220 ± 120
Spreadability (cm, Mean $\pm$ SD)	7.0 ± 0.2	6.9 ± 0.2
Miltefosine Content (% $\pm$ SD)	98.5 ± 0.8	97.8 ± 0.9
Curcumin Content (% $\pm$ SD)	97.9 ± 0.9	97.2 ± 0.8
% Cumulative Release (12 h) – Miltefosine	92.6 ± 2.1	91.2 ± 2.0
% Cumulative Release (12 h) – Curcumin	89.4 ± 1.8	88.1 ± 1.7

CONCLUSION

The present study successfully developed and evaluated a novel transdermal gel incorporating miltefosine and curcumin for the topical treatment of cutaneous leishmaniasis. The optimized formulation (F5) demonstrated favorable physicochemical characteristics, including skin-compatible pH, adequate viscosity, good spreadability, and uniform drug content. Spectroscopic analysis confirmed the absence of drug–excipient incompatibility, ensuring formulation stability. In vitro drug release studies revealed a sustained release profile, with more than 90% of miltefosine and curcumin released over 12 hours. Kinetic modeling indicated that drug release followed the Higuchi and Korsmeyer–Peppas models, suggesting a diffusion-controlled, non-Fickian anomalous transport mechanism. Furthermore, stability studies under accelerated conditions confirmed that the formulation retained its integrity with minimal variations in pH, viscosity, and drug release. These findings establish that the miltefosine–curcumin gel is a stable, non-invasive, and patient-friendly topical formulation capable of delivering dual therapeutic

benefits direct antiparasitic action from miltefosine and anti-inflammatory, antioxidant support from curcumin. This synergistic approach holds significant potential to overcome the drawbacks of conventional systemic therapies, offering an effective and safer alternative for the management of cutaneous leishmaniasis.

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