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Original Article

Formulation and optimization of clotrimazole nail lacquer as transungual drug delivery system

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Received: 12 October 2025; **Revised:** 19 January 2026; **Accepted:** 20 January 2026

ABSTRACT

Clotrimazole nail lacquer was created using this research, which also included the incorporation of two different kinds of polymers. (Eudragit RL 100 and ethyl cellulose) in various concentrations, as well as castor oil as a plasticizer, salicylic acid as a keratolytic agent, and N-acetylcysteine as a penetration enhancer. The objective was to optimize the selection of polymers and their concentrations to enhance release efficacy based on in vitro permeability experiments, while also ensuring favorable film characteristics, such as flexibility, gloss, adhesive qualities, drying time, non-volatile content, viscosity, and water resistance. Formulation F3 was selected as the superior formula considering several parameters, including excellent flow and gloss, ideal drying time and viscosity, adhesiveness, and penetration tests. Formula After 24 hours, F3, the drug penetration rate, was 78.4%. Based on the outcomes of the earlier tests, the formulated medicated nail lacquers are cost-effective and exhibit superior patient compliance.

Keywords: Clotrimazole, Nail lacquer, Penetration enhancer, Drug delivery

Introduction

Nail lacquer compositions are called transungual medication delivery in the pharmaceutical industry. When you say "transungual," the words "trans" and "unguis" denote "nails" respectively. One way to treat nail diseases is via a transungual drug delivery system, which is a way to introduce the medicine into the keratinized nail plate. The transungual drug administration method is thought to be very effective for treating nail diseases since it sticks better and works in a specific area, with little systemic side effects [1]. Nail diseases aren't necessarily fatal, but they can be extremely painful, make normal activities difficult, and have significant emotional, psychological, and physical effects, reducing people's quality of life [2]. Beyond their obvious practical and aesthetic uses, human nails have the potential to serve as a novel route for the administration of medications, especially for treating nail problems like psoriasis, onychomycosis, and paronychia [3]. Common methods for treating these nail disorders include oral medication. The site of action experiences a decrease in the potency of a medicine when it is taken orally or systemically [4-13]. To circumvent this pharmaceutical loss, the topical route of administration is employed. effectiveness level [3]. Topical drug delivery has several advantages over oral drug delivery, featuring a lower chance of systemic side effects, less invasiveness, better patient

Access this article online	
Website: www.japer.in	**E-ISSN:** 2249-3379

How to cite this article: Nief RA, Fadhel AY, Mahmood GH, Saeed AMH, Hamzah ML, Tarkan FW, et al. Formulation and optimization of clotrimazole nail lacquer as transungual drug delivery system. J Adv Pharm Educ Res. 2026;16(1):73-9. https://doi.org/10.51847/6aCU1pFl8L

compliance, localized action (activity at the site of the problem), and perhaps lower treatment costs [14, 15]. Common dermatological products such as ointments, lotions, powders, gels, and salves are not appropriate for transungual application. The drug is not released uniformly since these formulations are readily washed or rubbed out after use [16]. After the solvent in nail lacquer evaporates, the layer it forms on the nail or skin is thin and transparent. When nail lacquer is applied directly to the nail, it changes the composition of the film that forms. This is because the volatile components of the formulation are lost as the film forms on the nail surface. Then, these formulations penetrate the nail by breaking the disulphide bond, causing new pores to form. The treatment of nail diseases will be improved if the medicine is able to penetrate the nail plate effectively [17, 18].

Clotrimazole, a synthetic imidazole derivative, is well-known due to its antifungal properties. Because of its broad effects, it can be used to treat a variety of ailments and conditions [19]. Based on in vitro permeability tests, the goal was to maximize the choice of polymers and their concentrations to improve release efficacy while guaranteeing advantageous film properties.

Materials and Methods

Clotrimazole

It is a widely used antifungal agent, primarily employed in the treatment of various fungal infections [19].

Eudragit RL100

This is a type of acrylic polymer used in pharmaceutical formulations, particularly in controlled-release drug delivery systems. It is known for its permeability, which allows for the controlled release of the active ingredient. It also helps improve the stability and bioavailability of the drug [20].

Ethyl cellulose

A cellulose derivative commonly used as a binder, coating agent, and film-forming agent in pharmaceutical and cosmetic formulations. Ethyl cellulose can enhance the texture and stability of topical products, ensuring a smooth application and controlled release of the active ingredients.

Salicylic acid

Known for its keratolytic and anti-inflammatory properties, salicylic acid is commonly used in the treatment of acne, warts, and psoriasis. In topical formulations, it helps to exfoliate the skin, unclog pores, and reduce the buildup of dead skin cells.

Castor oil

This vegetable oil is widely used in pharmaceutical and cosmetic formulations as an emollient, to improve skin hydration, and to facilitate the absorption of active ingredients. Its moisturizing properties make it useful in various topical applications.

Ethanol

A commonly used solvent in pharmaceutical formulations. It helps dissolve active ingredients, enhances skin penetration, and has antimicrobial properties, making it useful in topical antimicrobial formulations.

N-acetylcysteine

In the making of nail lacquer, it serves as an enhancer of penetration. These three objectives are mainly helped by the addition of N-acetyl cysteine in this formulation [21].

1) It helps the medicine go deeper into the nail bed, from the nail plate.

2) The analgesic effects are there.

3) N-acetylcysteine can reduce inflammation.

Method of preparation

Nail lacquers containing clotrimazole were made utilizing a straightforward procedure including a magnetic stirrer. **Table 1** shows the results of the formulation trials [F1-F6]. A magnetic stirrer was used at 185 rpm and 60°C to dissolve clotrimazole in the specified volume of ethanol. The polymer (either Eudragit or ethyl cellulose) was added in ethanol and mixed in a magnetic stirrer at 950 rpm and 200°C, then after dissolving, we mixed it at 250 rpm and 60°C. The dissolved medication was mixed with the polymeric solution. Finally, a magnetic stirrer was used to mix in the plasticizer (castor oil-CA), keratolytic agent (salicylic acid), and penetration enhancer (N-acetylcysteine-NAC). The completed nail polish was contained in a glass bottle with a tiny opening, a plastic screw lid, and the necessary labelling [22].

Table 1 shows that five formulas were prepared. All were subjected to *in-vitro* Characterization and evaluation [23-30].

Table 1. Ingredients Used in the Formulation of Nail Lacquer (*All the ingredients in the table represent %w/v)

NM Code	Clotrimazole	E-RL 100	Ethyl cellulose	Salicylic acid	CA oil	NAC	Ethanol up to (ml)
F1	1	8	-	1	10	1	50
F2	1	12	-	1	10	1	50
F3	1	16	-	1	10	1	50
F4	1	-	8	1	10	1	50
F5	1	-	12	1	10	1	50
F6	1	-	16	1	10	1	50

Formulation optimizationm

The formulation of clotrimazole nail lacquer was created by considering multiple concentrations [8–16% w/v] and polymers [Eudragit RL100 & Ethyl cellulose].

Evaluation

Drying time

Using a brush, the prepared nail polish was evenly applied to a petri dish. A stopwatch was used to record how long it took for a dry to touch film to form. When there was no sample stuck to the finger upon touching (non stickiness), the film was deemed sufficiently dry [22].

Smoothness to flow

The sample was spread out on a glass plate after being poured into it from a height of 1.5 inches. designed to rise vertically, and the flow's smoothness was visually assessed [22, 31].

Glossiness

Visual inspection was used to assess the prepared formulation's glossiness [22].

Non-volatile content

Initially, the weight of the petri dish (M1) was recorded, followed by the addition of 1 gram (M) of each sample, which was then evenly distributed inside the petri dishes. One of the things that was recorded was the weight of each Petri dish that contained a sample. It was maintained in the hot air oven for a duration of 2.5 hours at a temperature of 100 ± 2 degrees Celsius. The Petri dish was allowed to cool for one hour before being weighed once more (M2) after the cooling period had passed. The percentage of non-volatile content was computed by assessing the weight differential as depicted by the following equation [22, 32].

$$\% \text{ Non} - \text{volatile content} = \text{M2} - \text{M1}/\text{M} \times 100 \quad (1)$$

Water resistance evaluation

It is conducted to assess the formulation's resistance to water. In order to carry out the test, the required quantity of nail lacquer was applied to a glass plate in a uniform manner, and the plate was then left to dry. In order to determine the weight of the sample that contained glass, it was first placed in a beaker that was filled with pure water. A second round of weighing was performed after the plate had been dried with filter paper for a period of twenty-four hours. The difference in weight between the beginning and the end of the experiment was used to evaluate water resistance, and the results were presented as a percentage reduction in weight [32].

Viscosity analysis and determination

A Digital Viscometer (NDJ-5S) was used to measure the viscosity of the produced clotrimazole nail lacquer at room temperature and with a spindle operating at 30 revolutions per minute [22].

In-vitro film adhesion test

A uniform film was applied to a glass plate using a lacquer brush and allowed to dry for 24 hours at room temperature. The film was sectioned into uniform portions of 1 mm by utilizing a scalpel (0.37 mm blade thickness) in both parallel and perpendicular orientations. Subsequently, pressure-sensitive adhesive cellophane tape was applied to the film, and a finger was utilized to smooth the surface, leaving a section of tape unattached. After a few minutes, at a 60° angle, the film was physically extracted by gripping the free end of the unadhered tape. The total number of squares of the film that attached to the tape was quantified, and the percentage peel-off was calculated using the formula below [22].

% Peel off =Initial squares of film − Final squares of film/ Initial squares of film × 100

In-vitro transungual permeation study

Hooves procured from sheep, free of any attached tissue, were submerged in distilled water for 24 hours. The Franz diffusion cell was utilized to conduct in vitro transungual permeation, with the hoof membrane (about 1 mm in thickness) carefully positioned onto the cell. A clotrimazole lacquer equivalent to 200 mg was uniformly applied to the membrane's surface. A mixture of phosphate buffer with a pH of 7.4 was injected into the receptor compartment. On top of the cell assembly was where it was brought into position. At a temperature of 37 degrees Celsius, the assembly was stirred constantly for a period of twenty-four hours. Extraction of ten millilitres of the sample was performed at time intervals of one, three, five, seven, ten, thirteen, sixteen, twenty, and twenty-four hours, with fresh medium being added to ensure that the volume remained constant. An ultraviolet spectrophotometer set to 261 nm was utilized in order to analyze the samples [22].

Results and Discussion

Drying time

The ideal drying time was six minutes [33]. The drying time for formulas (F1-F6), as shown in **Table 2**, is between 55 and 180 seconds. It was shown that the drying time goes up when the polymer concentration goes up.

Smoothness to flow

Formulas F1-F3 had good flow qualities because they used Eudragit RL 100 as a polymer. This made the nail lacquer the right amount of viscous. On the other hand, formulas F4-F6

made the nail lacquer too viscous since they used ethyl cellulose as a polymer. **Table 2** shows the findings of the flow property.

Glossiness

Formulas F1-F3 have a medium amount of gloss because they utilize E-RL 100. Formulas F4-F6, on the other hand, have a considerable amount of gloss because they use ethyl cellulose as a polymer. **Table 2** shows the findings for the glossiness test.

Non-volatile content

It is recommended that the non-volatile content be at least 20% in order to get good coverage on the nail plate [33]. The concentration of polymers utilized affects non-volatile content, and it was shown that the two were directly related. A table containing the results of our investigation into the non-volatile components of the various formulas F1 through F6 can be found here.

Evaluation of water resistance

According to the Bureau of Indian Standards IS 9245: 1994, the percentage of weight reduction was less than ten percent [34-40]. According to the results of the water-resistant test, the formulations' capacity to withstand water increased in proportion to the increase in the concentration of polymers. There is a summary of the findings shown in **Table 3**.

Viscosity

Across the board, the viscosity of the formulations ranged from 60 to 83 cps. Having a viscosity that falls anywhere between 140 and 160 cps led to formulations that were shiny and had good adhesion. Any viscosity that falls outside of this range will result in clouding and a reduction in gloss, neither of which are acceptable from a cosmetic standpoint [41-44]. The viscosities of all of the formulas that were created are presented in **Table 3**.

In-vitro film adhesion

There should be no more than ten percent of the time that the film peels off. In terms of adhesion to the nail, the formulations that contained E-RL 100 (F1-F3) and also contained CA oil as the plasticizer were the most successful. However, formulations that contain ethyl cellulose as a polymer and castor oil as a plasticizer (F4-F6) adhere to one another effectively, although they are not the ideal combinations. The results demonstrated that the recipes that included castor oil as a plasticizer adhered to the items in a satisfactory manner. Formulas that contain Eudragit RL 100 also work better. **Table 3** shows the results.

Table 2. Drying time, Smoothness to flow, Glossiness of formulas [F1-F6]

NM Code	Drying time [seconds]	Smoothness to flow	Glossiness
F1	125	good	Fair
F2	140	good	Fair
F3	180	Fair	Fair
F4	55	Fair	Good
F5	64	Fair	Good
F6	93	Fair	Fair

Table 3. Drying time, Smoothness to flow, Glossiness of formulas [F1-F6]

NM Code	Viscosity [Cps]	Water resistant test [%weight loss]	%Non-volatile content	Film adhesion [%peel off]
F1	135	13	28	0
F2	146	7	39	0
F3	151	5	50	0
F4	145	14	29	33.33
F5	155	10	37	0
F6	157	9	55	22,4

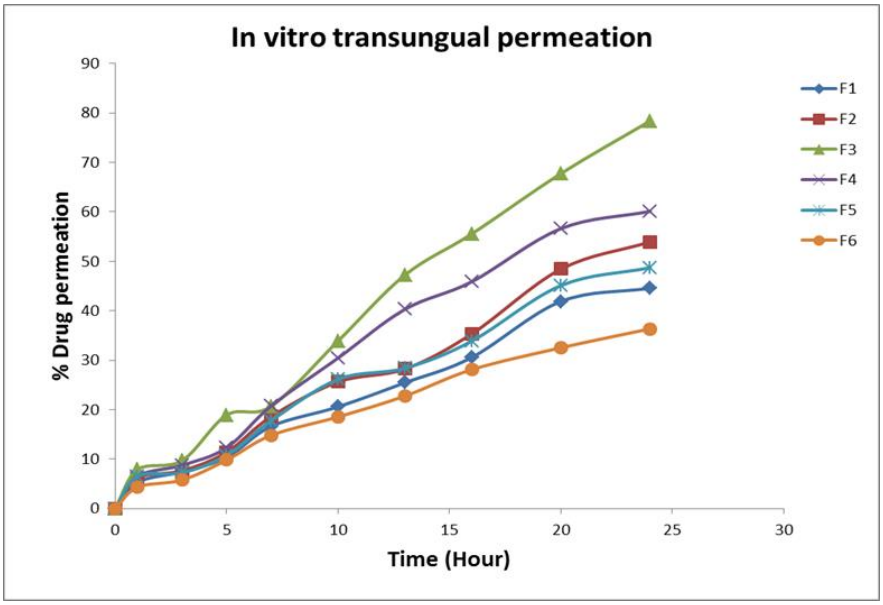

Figure 1. Transungual penetration of clotrimazole nail lacquer *in vitro*

In-vitro transungual permeation

For this twenty-four-hour experiment, all formulations were evaluated on sheep hooves that had been immersed in a phosphate buffer solution with a pH of 7.4. Different amounts of Eudragit RL 100 are used in the formulations F1 through F3. According to the researchers, the percentage of drug penetration increased with the concentration of Eudragit RL 100. On the other hand, as the concentration of ethyl cellulose in the formula grew, the amount of clotrimazole released decreased. However, it was discovered that the formulations [F4-F6], including ethyl cellulose, were highly sticky and viscous, with no smooth flow or good gloss. **Figure 1** shows the results.

Selection of the best formula

To decide which of the six formulations was the most effective, we considered criteria such as great penetration, viscosity, high gloss and flow, appropriate drying time, and good film adhesiveness. Consequently, the optimal formula has been found to be F3, which contains 16% w/v Eudragit RL 100 as a polymer. Drug permeation experiments show that formula F3 is the best since It is the most effective nail lacquer in terms of all of the characteristics that are considered and offers the best drug penetration for a full day.

Conclusion

The target of this study was to develop nail lacquer formulation. Transungual drug delivery is better than oral drug delivery because the drug reaches the specific site. Because of its superior adhesion and penetration, that nail lacquer is used to treat nail infections. When applied to the nail surface, it leaves a thin layer that allows the medicament to be released to the infection site at a regulated rate. In light of the fact that the formulation was able to produce full and sustained drug release for a period of up to forty-eight hours, it is appropriate for use three times per week. As a result of the incorporation of rate-modifying polymers like Eudragit RL100 and ethyl cellulose, as well as N-acetyl cysteine, which functions as a permeability enhancer, this was made possible. For nail lacquer, parameters such as nonvolatile content, drying rate, gloss, smoothness to flow, water resistance, percentage of adhesion, and percentage of permeation were measured. With a 180-second drying time and good glossiness, flowability, and adhesiveness, F3 was the best of the six formulas. At 24 hours, the optimal formulation, F3, provided 78.4% drug penetration. According to the research that was discussed earlier, the newly developed medicated nail lacquer formulation has the potential to be an effective replacement for the formulations that are now being used to treat nail illnesses.

Acknowledgments: The University of Baghdad's College of Pharmacy for providing the apparatus for achieving this study.

Conflict of interest: None

Financial support: None

Ethics statement: None

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