IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 24, Issue 3 Ser. 6 (March. 2025), PP 26-31
www.iosrjournals.org

Formulation and Evaluation of Herbal Nail Lacquer for the Treatment of Onychomycosis

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Abstract
Nail lacquer is primarily used for decorative purposes and to protect nail plates. However, herbal formulations offer safer alternatives for treating onychomycosis via trans-ungual drug delivery. This study aimed to formulate and evaluate an herbal nail lacquer containing polyherbal extracts. Neem, Tulasi, and betel leaf extracts were incorporated into a nail lacquer base. The formulated lacquer was evaluated for physicochemical properties such as drying time, adhesion, gloss, non-volatile content, and antifungal efficacy. The zone of inhibition of the optimized formulation was found to be 28 mm, comparable to the marketed formulation (30 mm). The findings suggest that herbal nail lacquer has promising antifungal potential, but further research is required to optimize its safety and efficacy.

Keywords: *Onychomycosis, trans-ungual drug delivery, herbal nail lacquer, antifungal activity.*

Date of Submission: 13-03-2025 Date of Acceptance: 27-03-2025

I. Introduction

Onychomycosis: A Fungal Nail Infection

Onychomycosis is a chronic fungal infection of the nail unit, caused predominantly by dermatophytes, yeasts, and non-dermatophytic molds. It is one of the most common nail disorders, accounting for nearly 50% of all nail-related diseases. The condition is characterized by nail discoloration, thickening, brittleness, and separation from the nail bed, which can lead to pain and discomfort. The prevalence of onychomycosis is higher in older adults, individuals with diabetes, immunocompromised patients, and those with poor peripheral circulation.

Fungal nail infections typically begin when fungi invade the nail through cracks or separations between the nail plate and the nail bed. The slow-growing nature of nails and their keratin-rich composition make fungal infections difficult to treat, as the infection persists for extended periods without visible symptoms in the initial stages. Onychomycosis can significantly impact the quality of life, causing embarrassment, discomfort, and secondary bacterial infections if left untreated.

Treatment options include oral antifungal agents such as terbinafine and itraconazole, as well as topical formulations like medicated nail lacquers. However, systemic antifungals pose risks of hepatotoxicity and drug interactions, making topical treatments a safer alternative. Despite their potential, traditional topical treatments face challenges in penetrating the thick, keratinized nail plate. This has led to the development of specialized drug delivery systems, such as nail lacquers, which enhance drug retention and penetration into the nail.

Nail Lacquers: An Effective Drug Delivery System

Nail lacquers, originally developed for cosmetic purposes, have been adapted as therapeutic formulations for delivering antifungal agents directly to the affected nail. Medicated nail lacquers offer a non-invasive, patient-friendly treatment approach, providing localized drug delivery with minimal systemic absorption. These formulations contain film-forming agents that create a polymeric film over the nail plate, allowing sustained release of the active ingredient.

The effectiveness of antifungal nail lacquers depends on key formulation factors such as adhesion, drying time, non-volatile content, water resistance, and drug permeability. The presence of film-forming polymers like nitrocellulose ensures prolonged drug retention, while penetration enhancers improve drug diffusion through the nail plate. Herbal nail lacquers, incorporating plant-derived antifungal agents, are gaining attention as natural alternatives to synthetic antifungal formulations.

This study focuses on developing an antifungal nail lacquer using herbal extracts from Neem (*Azadirachta indica*), Tulasi (*Ocimum tenuiflorum*), and Betel (*Piper betle*), known for their potent antifungal

properties. By utilizing a trans-ungual drug delivery approach, the goal is to enhance drug penetration, improve treatment efficacy, and minimize the adverse effects associated with systemic antifungals.

Fig 1: Onychomycosis: A Fungal Nail Infection

II. Materials and Methods

Materials:

Herbal Extracts: Neem, Tulasi, and Betel leaves were shade-dried, powdered, and extracted using conventional methods.

Lacquer Base: Nitrocellulose, ethyl cellulose, ethyl acetate, salicylic acid, dibutyl phthalate, acetone, and alcohol.

Formulation of Antifungal Nail lacquer:

1. Extraction of anti-fungal principles from Neem and Tulasi:

15 ml of coconut oil was poured into the beaker and it was boiled for 5 min. Then 15g of dried neem leaves powder and 5g of dried Tulasi leaves powder were added to the previously boiled coconut oil mixture and the mixture was stirred continuously for some time with a glass rod. Then the mixture was allowed to boil for 15min.The mixture was kept aside for 2 hrs. Then the mixture was filtered through muslin cloth and then the filtrate was collected.

2. **Extraction of anti-fungal principles from Betel leaf:**

Piper betel leaves were collected from the local market. Then the leaves were dried under shade for 10 days. The dried leaves were powdered and 20g of finely powdered betel leaf was taken and dispensed into 80 ml of water. Then the contents were soaked for 72 hours. The solution was filtered carefully with the help of muslin cloth into 100 ml of the sterile conical flask. The obtained filtrate was stored at 4℃until we use the solution.

3. Preparation of Antifungal Nail lacquer:

Required quantity of nitrocellulose was taken into the beaker and to that required amount of ethyl cellulose was added and then both mixtures were dissolved in ethyl acetate. Then the following ingredients are weighed accurately 5g of salicylic acid, 5g of dibutyl phthalate, 5 ml of acetone, and some alcohol were added to the above mixture. The above mixture was kept in a magnetic stirrer at 100 rpm and stirred continuously. After that the herbal extract mixture of neem, Tulasi 2ml, and betel leaf extract 1ml was added to the above solution. The above mixture was mixed continuously until a clear solution was formed.

Fig 2: Formulated Product

Table 1: Formula to prepare Antifungal Nail lacquer

S.NO	INGREDIENTS	QUANTITY [g/ml]			USES
		F1	F2	F3	
1.	Nitrocellulose	7.5	2	3	Film-forming polymer
2.	Ethyl-cellulose	11	5	2.5	Coating agent and film former
3.	Ethyl acetate	8	5	3	Solvent
4.	Salicylic acid	6	5	2.5	preservative
5.	Dibutyl phthalate	7	5	3.5	Plasticizing agent
6.	Acetone	10	5	4	Manufacture lacquers
7.	Neem, Tulasi extract	5	2	1	Anti-fungal agent
8.	Betel extract	2	1	1.5	Anti-fungal agent
9.	Alcohol	Q.S	Q.S	Q.S	Remover

Evaluation of Formulated Antifungal Nail lacquer:

1. Appearance: Transparent colored viscous liquid.

2. Drying Time:

A thin layer of lacquer was applied to a clean and clear nail, and the time taken to dry was measured with a stopwatch. The drying process was checked by pressing the film with a finger until no mark remained. The test was performed under controlled conditions (25℃, 50% relative humidity).

Table 2: Drying time

S.No	Formulation	Drying time
1.	F1	15min
2.	F2	11min
3.	F3	13min

3. Adhesion & Gloss:

The lacquer was applied on the nail surface, and visual assessment was performed to check for smoothness and uniform gloss. A comparison was made with marketed formulations for quality evaluation.

4. Smoothness:

This is characteristic of the film. The film is applied onto a surface and the surface characteristics of the film are studied microscopically. Before applying the nail lacquer, moisture and traces of soil have to remove for good adhesion and gloss. The nail lacquer was observed smooth.

Table 3: Smoothness

S.No	Formulation	Smoothness
1.	F1	Slightly smooth
2.	F2	Smooth
3.	F3	Not smooth

5. Determination of non-volatile content:

The amount of non-volatile content in the nail lacquer is determined by taking a definite amount of lacquer and applying it on the surface of the nail. Then heating of the nail is done for 3-4 hours at 80℃, heating should be discontinued immediately when the solvent odor disappears. Weigh of the residual matter of the film after evaporation of solvent indicates the non-volatile content. The non-volatile content of 11% mass was recorded. According to Indian standards [IS: 9245-1994] prescribe a minimum limit of 20% by mass.

Table 4: Non-volatile content

S.No	Formulation	Non-volatile Content mass
1.	F1	13%
2.	F2	11%
3.	F3	10%

6. Colour:

Color comparison with master color standards by applying on nails and comparing with side by side moving the thumb standard right then on the left.

Table 5: Colour

S.No	Formulation	Colour
1.	F1	Slightly green colour
2.	F2	Transperent colour
3.	F3	Pale colour

7. Water Resistance:

Coated artificial nails were weighed, immersed in distilled water at 37℃ for 24 hours, then dried and reweighed. The difference in weight indicated water absorption, with a lower increase denoting better water resistance.

Table 6: Water Resistance

S.No	Formulation	Water Resistance
1.	F1	4 Grams
2.	F2	6 Grams
3.	F3	3 Grams

8. Spread ability:

Spread ability of nail lacquer is checked by applying of nail lacquer on nail- by-nail paint brush. Good spread ability was found.

Table 7: Spread ability

S.No	Formulation	Spread ability
1.	F1	Medium spread ability
2.	F2	Good Spread ability
3.	F3	Average spread ability

9. Antifungal Activity (Zone of Inhibition Test):

Agar well diffusion method was used with *Aspergillus niger* as the fungal strain. Soya bean casein agar was prepared, and wells were made using a sterile cork borer. The formulated lacquer was applied in one well, and the marketed formulation in another. Plates were incubated at 25℃ for 48 hours, and the inhibition zone was measured using a scale.

Medium: Soya bean casein agar medium.

Table 8: Casein medium Composition

S.No	Ingredients	Quantity[g/ml]
1.	Pancreatic digest of casein	15
2.	Pancreatic digest of soya bean	5
3.	Sodium chloride	5
4.	Agar	15

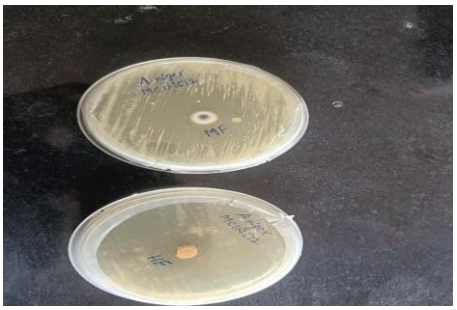

Fig 3: Zone of inhibition of product

III. Results and Discussion

The formulation and evaluation of Herbal nail lacquer were performed Successfully and Tabulated. The prepared nail lacquer was shown in the figure. The organoleptic parameters for formulated formulations F1, F2 and F3 were determined. The colour was found to be transparent colour and have a good appearance as well.The formulated products f1, f2, and f3 drying rates was found to be 15min, 11min and 13min. The of inhibition studies were carried out for the optimized formulation and compared with marketed formulation such as Amoroline nail lacquer[fungicros] and the zone of inhibition of F2 was found to be 28mm and the marketed formulation was found to be 30mm.Other tests like water resistance and non-volatile content were also performed and obtained optimum results. Out of 3 developed Anti-fungal nail lacquers F2 was found to be optimum with better anti-fungal property. Further research has to beconducted to evaluate the Quality and stability of herbal nail lacquer. The optimized formulation (F2) demonstrated the best drying time (11 min) and superior spreadability. The formulation exhibited good adhesion and gloss compared to commercial products. Water resistance was satisfactory, with minimal weight gain upon immersion. The antifungal activity (28 mm zone of inhibition) was comparable to the marketed product (30 mm), confirming the efficacy of herbal extracts.

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Table 4: Zone of Inhibition Study

Formulation	Zone of Inhibition (mm)
F1	25
F2	28
Marketed	30

Figure 1: Formulated Herbal Nail Lacquer
Figure 2: Drying Time Test Results
Figure 3: Water Resistance Evaluation
Figure 4: Zone of Inhibition Study

Figure 5: Extraction of Herbal Constituents
Figure 6: Application of Nail Lacquer

Conclusion

Herbal nail lacquer formulated with Neem, Tulasi, and Betel extracts demonstrated significant antifungal activity and satisfactory physicochemical properties. It offers a promising alternative to synthetic antifungal treatments with improved safety and patient compliance. Further research is needed to enhance stability and optimize the formulation for commercial application.

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