

Formulation And Evaluation of Medicated Nail Lacquer by Using Ethanolic Leaf Extract of *Euphorbia Hirta*.

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ABSTRACT:

A fungal/bacterial infection of the fingernails or toenails called paronychia results in thickening, detachment from the nail bed, and discoloration of the nails. It affects everyone from aged people, kids to the patients with compromised immune systems are more likely to contract that infection. The goal of the current study was to create and formulate a therapeutic nail lacquer using the ethanolic leaf extract of *Euphorbia hirta* to treat the condition of paronychia. It is an antifungal agent and also established anti-inflammatory drug, in this study. Nail lacquer was made using a simple mixing process. This type of formulation reduces application compliance and application frequency was decreased to thrice a week by using polymers such as ethyl cellulose to sustain medication release for up to 36 hours. Salicylic acid will function as a permeation enhancer, increasing the drug's ability to permeate the nail bed. Drying time, non-volatile content, viscosity, water resistance test, and the aim was to optimize the formulation with respect to the polymer concentration. The ideal drug viscosity for the optimized formulation was around 64 cps, and the drying period was 3 min. As a result, ethanolic leaf extract of *Euphorbia hirta*'s nail lacquer with desired ratio of ethyl cellulose concentration was effectively created.

KEY WORDS: *Euphorbia hirta*, ethyl cellulose, nail lacquer, antimicrobial activity, antifungal activity, paronychia.

I. INTRODUCTION:

Nails are the hard coverings located on the extremities of fingers and toes. They are prone to various nail infections such as paronychia [1].

The elderly and people with impaired immune systems are particularly susceptible to these

nail conditions. Due to its non-invasiveness, medication targeting to the site of action, reduction of side effects associated with systemic therapy, increased patient compliance, and reduced treatment costs, topical therapy is a desirable choice [2].

The poor permeability of the nail plates to the topically administered drugs was the main reason why topical therapy had little success. Enhancing unguinal drug penetration is necessary for topical therapy across the nail plate to be successful [3].

However, gel, cream, or liquid formulations are not adequate for the trans unguinal delivery since they are easily removed by washing or rubbing. This phenomenon at the site of application accounts for their inefficacy. Few days lasting drug delivery is considered as essential requirement for pharmaceutical formulations applied topically on the nail. Film-forming systems for trans unguinal drug delivery are used in clinical practice, but their ability to deliver therapeutic doses of active substances remains critical for efficient paronychia treatment. Mechanical characteristics and water resistance make nail lacquers a promising alternative for paronychia topical treatment. Lacquer film is formed during solvents evaporation after lacquer application. Films formed by nail lacquers must establish attachment to the nail surface which is a necessary prerequisite of efficient drug delivery [4].

The medicated nail lacquers are modification of the cosmetic nail lacquers by addition of rate controlling polymers into it which will sustain the drug release into the nail bed. The nail lacquer once applied will leave a film on the nail plate whereas the polymers will act as a depot of drug and release it slowly from the film into the unguinal space [5].

The introduction of the herbal based medicated nail lacquer will reduce the side effects of

the synthetic formulation. By using ethanolic leaf's extract of *Euphorbia hirta* plant as antimicrobial agent will significantly use for paronychia [6].

It functions as antimicrobial agent in nail lacquer the ethanolic leaf extract of *Euphorbia hirta* provide both antibacterial, anti-fungal by inhibiting proliferation of bacteria's then healing infection. It's reported that glycerine also has significant microbial infection [7].

II.PLANT PROFILE:

Euphorbia hirta is (asthma plant) is a pantropical weed, originates from all over the tropical regions of world, it is a hairy herb that grows in the grasslands, roadside and pathways [fig 1].

It is widely used in traditional herbal medicine across many regional cultures, particularly for asthma, skin care and hypertension. It is also consumed in herbal tea and also a 'decoction potion' in many rural regions on various cultures.[6]



Fig: 1 *Euphorbia hirta*

Taxonomical classification:

Kingdom: Plantae
Phylum: Tracheophyta
Class: Magnoliopsida
Order: Malpighiales
Family: Euphorbiaceae
Genus: Euphorbia
Species: Euphorbia hirta L.

III.MATERIALS AND METHODS:

Materials

Ethyl cellulose, salicylic acid, were purchased from research lab. Glycerine was procured from market. The solvent ethanol is of analytical grade, ethanolic leaf extract of *Euphorbia hirta* plant was obtained by standard extraction procedure process.

Table 1: Role of ingredients

Ingredients	Role
<i>Euphorbia hirta</i> 's extract % w/v	Anti-microbial activity
Ethyl cellulose %w/v	Film forming polymer (&) emulsifier
Salicylic acid %w/v	Keratolytic-agent
Glycerine/v	plasticizer
Ethanol [up to 20ml]	Solvent

Table 2: Formulation of medicated nail lacquer

Ingredients	Formulation				
	F1	F2	F3	F4	F5
<i>Euphorbia hirta</i> 's extract v/v	6ml	6ml	6ml	6ml	6ml
Ethyl cellulose w/v	30mg	40mg	50mg	60mg	70mg
Salicylic acid w/v	10mg	10mg	10mg	10mg	10mg

Glycerine v/v	0.5ml	0.5ml	0.5ml	0.5ml	0.5ml
Ethanol [up to 20ml]	20ml	20ml	20ml	20ml	20ml

Preparations of nail lacquer

Prepare ethanol phase with polymer. Measured amount of ethanol into a beaker (covered to minimize evaporation). Sprinkle previously weighted ethyl cellulose gradually into ethanol with continuous stirring (magnetic stirrer, 100–200 rpm) until a clear/near-clear polymer solution forms; this may take 30–60 minutes. Add accurately weighed salicylic acid (10 mg for 20 mL) to the ethyl-cellulose solution. Continue stirring until completely dissolved; mild warming in a water bath (not above 40–45 °C) can be used if needed. Add (plasticizer) measured glycerine (0.5mL) slowly to the above solution with stirring. Stir until you obtain a uniform, homogeneous solution (no separation or streaks). Incorporate measured antimicrobial ethanolic extract of *Euphorbia hirta*, first dissolve the required amount of extract in a small volume of ethanol, then add this solution slowly to the polymer mixture with stirring. Check for clarity; Make up volume and deaerate to transfer the mixture to a calibrated cylinder or volumetric flask and make up to 20 mL with ethanol. Gently stir/sonicate to remove air bubbles; allow to stand covered for 12–24 hours to equilibrate viscosity. Fill and store Filter through a fine nylon/0.45 µm filter if any undissolved particles remain. Fill into amber glass nail-lacquer bottles with brush applicator, cap tightly and store at room temperature away from heat and flame. [8]

IV.CHARACTERIZATION AND EVALUATION OF DEVELOPED FORMULATION:

FTIR Analysis:

Fourier Transform Infrared (FTIR) spectroscopy was employed to identify the functional groups present in the sample. The FTIR spectrum was recorded using an FTIR spectrophotometer equipped with an Attenuated Total Reflectance (ATR)

accessory. A small amount of the sample was placed directly onto the ATR crystal, ensuring good contact with the surface. Prior to sample analysis, a background spectrum was collected under identical conditions. Spectral data were acquired in the range of 4000–400 cm⁻¹ with a resolution of 4 cm⁻¹ by averaging 16 scans. The obtained spectrum was analysed by comparing the characteristic absorption bands with standard reference data to identify the functional groups present in the sample.

Drying time:

A thin layer of lacquer is spread or flowed out on a clear glass panel and observed. The time taken to dry is measured using stop watch and is checked by pressing the film with a finger until no mark remains on the surface. This procedure was repeated thrice [9]

Smoothness of flow:

This is the character of the film. The sample was poured from a high of approximately 1.5 inches on to a glass plate and easily spread on a glass plate and made it to rise vertically [10]

pH:

pH of the medicated nail lacquer was measured by using digital pH meter

Gloss:

Gloss of the film was determined visually by applying it over the nail evenly and smoothly and comparing it with marketed cosmetic nail lacquer formulation. [9]

Non-volatile content:

10ml of sample was taken in a Petri dish and the initial weight of sample was recorded and the dish was placed in the oven at 105° C for one hour and the petri was removed from the oven and then it was cooled and weighed. The difference in weight was recorded. Average of triplicate reading was noted. This procedure was repeated thrice [11]

$$\% \text{ Non - volatile content} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Viscosity:

The viscosity of the formulated nail lacquer was calculated by using Brookfield viscometer at room temperature by using spindle number 63 at different RPM. The sample should be taken in a closed jar to

minimize the solvent evaporation This procedure was repeated thrice. [9]

Drug content estimation:

Nail lacquer equivalent to 200mg was mixed in 50ml phosphate buffer solution of pH7.4. Then the solution

was ultrasonicated for 15 minutes and the solution was filtered and made up to 100ml with phosphate buffer solution of pH 7.4. From the above solution 10ml was taken and made up to 100ml with PBS of pH 7.4. The diluted solution was estimated spectrophotometrically at a wavelength of 662 ± 3 nm and determining the drug content. This procedure was repeated thrice. [12]

In vitro diffusion studies:

Diffusion studies were performed by Franz diffusion cell using cellophane which is an artificial membrane of $0.8 \mu\text{m}$. The membrane soaked in the solvent system for 10 hours and the receptor compartment was filled with solvent. Nail lacquer sample of 200mg was applied thoroughly on the surface of the membrane. The prepared membrane was mounted on the cell very carefully so as to avoid entrapment of air bubbles under the membrane. The whole assembly was maintained at 37°C and the speed of stirring was kept constant for 24 hours. The 5ml aliquot of the drug sample was taken at time intervals of 2hr, 4hr, 6hr, 8hr, 10hr, 12hr, 16hr, and 20hr and was replaced by the fresh solvent. Samples were analysed by double beam UV spectrophotometer as per the method mentioned in drug content estimation. Each experiment was repeated thrice.

In-Vitro Anti-Microbial Activity:

Preparation of Bacterial & Fungal strains:

Staphylococcus aureus (MTCC 3160), *Candida albicans* (MTCC 183), were obtained from the Microbial Type Culture Collection (IMTECH, Chandigarh, India). All the bacterial strains were cultured in Muller Hinton Broth (MHB), at 37°C for 24 hr with 200rpm agitation. All the fungal strains were cultured in Potato Dextrose Broth at 37°C for 24 hr.

Agar Well Diffusion Method:

The antimicrobial activity of Plant extract against the selected Gram positive and Gram-negative pathogens was carried out using Agar Well Diffusion Susceptibility Test Method followed by NCCLS (1993) and Awoyinka *et al.*, (2007). The microbial strains were spread on the Mueller-Hinton agar (MHA)/PDA (Merck, Germany) using sterile cotton swab. Using sterile forceps, the filter papers (6 mm diameter) containing 125, 250 and 500 μl of Plant extract and standard solution as Streptomycin and Fluconazole 30 μl were laid down on the surface of inoculated agar plate. The plates were incubated at 37°C for 24 hr for the bacteria and 48 hr. for yeast strains. Sample was tested in triplicate.

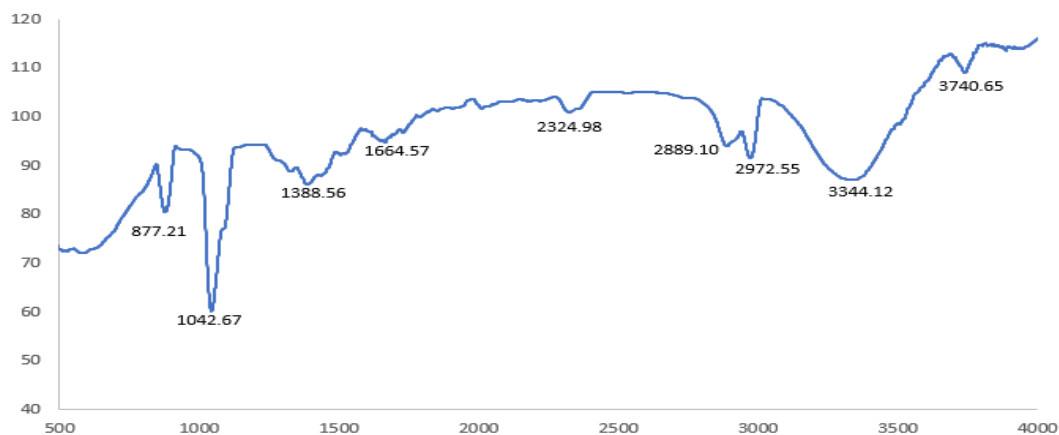
V. RESULT AND DISCUSSION:

The objective of the present study was to formulate a nail lacquer for preventing fungal and bacterial growth on toe nails of finger nails so that the appearance of the nails is improved. Hence utilizing ethanolic leaf extract of *Euphorbia hirta* as anti-bacterial and anti-fungal a medicated nail release, better drug permeation, and desirable anti-fungal effectiveness. The prepared formulation included salicylic acid as keratolytic agent and permeation enhancer, ethyl cellulose as film former for modifying release and ethanol as solvent system

Evaluation of Nail lacquer:

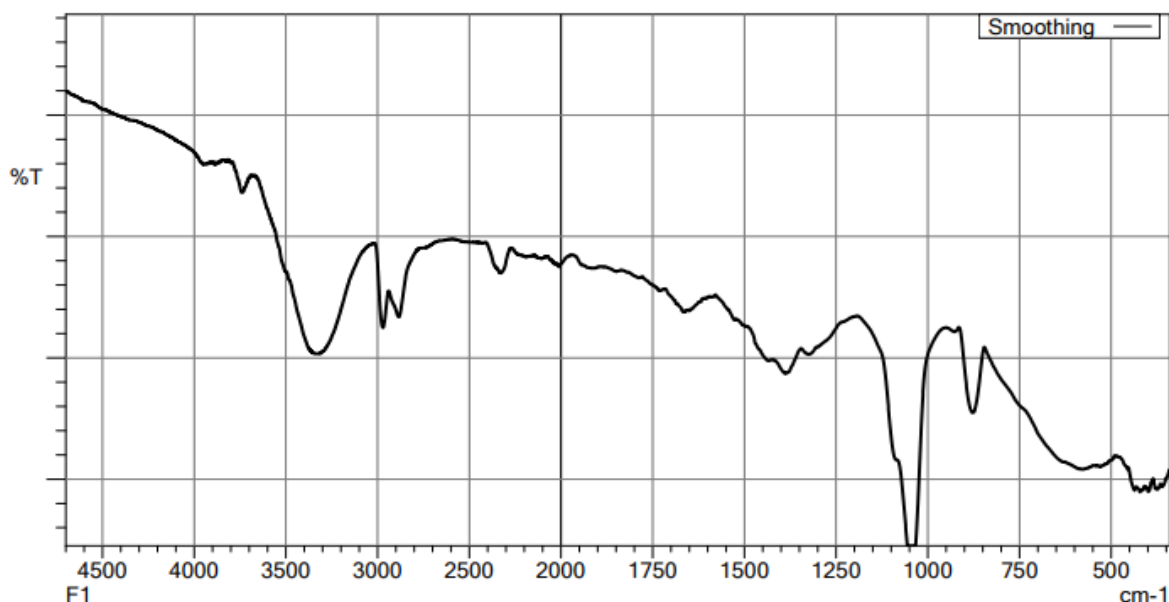
FTIR Analysis of plant extracts:

The surface chemistry of the sample was revealed by the appearance in the FTIR spectra of IR bands at 877.93 , 1043.39 , 3329.86 and 3734.95cm^{-1} and by the peaks which correspond to various groups.



FTIR Analysis of Formulation:

The surface chemistry of the sample was revealed by the appearance in the FTIR spectra of IR bands at 877.22, 2329.97, 2884.83 and 3329.14 cm^{-1} and by the peaks which correspond to various groups.



FTIR of formulation:

The FTIR spectral analysis of the *Euphorbia hirta* plant extract revealed the presence of characteristic absorption bands corresponding to various functional groups. The peaks observed at around 3734.95 cm^{-1} and 3329.86 cm^{-1} indicate O–H and N–H stretching vibrations, confirming the presence of phenolic compounds, alcohols, and secondary amines. The band at 1043.39 cm^{-1} corresponds to C–N stretching of aromatic amines, while the peak at 877.93 cm^{-1} is attributed to C=C bending vibrations of alkenes.

The FTIR spectrum of the formulation showed absorption peaks at 3329.14 cm^{-1} and 2884.83 cm^{-1} , indicating N–H stretching of secondary amines and amine salts, suggesting the retention of nitrogen-containing phytoconstituents in the formulation.

Overall, the FTIR results confirm that the major functional groups present in the plant extract are retained in the formulation, indicating compatibility between the extract and formulation components. The presence of phenolic, amine, aromatic, and alkene functional groups supports the antimicrobial potential of *Euphorbia hirta*, as reported in the antimicrobial activity study. Thus, FTIR analysis validates the successful incorporation of bioactive constituents into the formulation without significant chemical interaction or degradation.

Drying time:

Drying time for formulations F1 to F5 was found between 145 seconds to 200 seconds. It was found that as the polymer concentration increase, the drying time also increases respectively. The time required for the solvent to evaporate from the more viscous solution is more than the less viscous solution. Formulation F3 showed optimum drying time of about 165 sec.

Table 3: Drying time of various batches

Formulations	Drying time (Seconds)
F1	135(±)2
F2	150(±)4
F3	165(±)2
F4	185(±)3
F5	200(±)3

Non-Volatile Content of Nail Lacquer:

The increase in polymer concentration causes increase in non-volatile content of nail lacquer. Thus, higher the polymer concentration higher is the non-volatile content of nail Lacquer. The non-volatile content of the formulation batches are given in table 4

Table:4 Non-volatile contents

Formulations	Non-volatile (%)
F1	22(±)2
F2	28(±)3
F3	37(±)2
F4	46(±)4
F5	53(±)2

Viscosity:

The viscosity of the sample varied from 59 to 74 centipoise (cps) This viscosity range provided good adherence and flow property. The viscosity of various formulation batches is given in Table 5

Table 5: Viscosity of formulated batches

Formulations	Viscosity (cps)
F1	59(±)2
F2	62(±)4
F3	64(±)2
F4	69(±)3
F5	74(±)3

pH:

There is no desired change in the pH of the formulation though there is change in polymer concentration

Table 6: pH

Formulations	pH
F1	5.1
F2	5.1
F3	5.1
F4	5.1
F5	5.1

Drug content estimation:

Percentage drug content for all the formulation batches was found to be satisfactory and in between 96.9 %- 97.4 % which is reported in Table

5. Highest % of drug content was found to be 98.2% (F3) and the lowest 96.9% of drug content (F1). If the drug content is more than 90 % the formulation shows high amount of drug present in it. This, ensure better therapeutic response.

Table 7: Drug content estimation

Formulations	Drug content (%)
F1	96.9(±)0.7
F2	97.5(±)0.8
F3	98.2(±)0.5
F4	97.8(±)0.3
F5	97.4(±)0.1

Smoothness to flow and Gloss:

Formulation F3 when poured onto the glass plate was found to have satisfactory flow property and result in a uniform smooth film, as compared to other formulation batches.

In vitro diffusion studies:

As polymer concentration increases the diffusion rate decrease. By comparing values the control release of drug for 36hrs could attain by f3 formulation.

Table 8: In vitro diffusion studies

Formulations	In vitro diffusion studies (%)
F1	58.51
F2	44.67
F3	31.55
F4	15.32
F5	10.30

Antimicrobial activity of Selected formulation:

By comparing the above evaluation test reports, it confirms that F3 formulation is best among the all formulation. So, the anti-microbial study was performed for F3 formulation

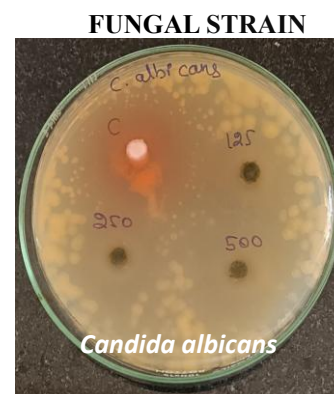
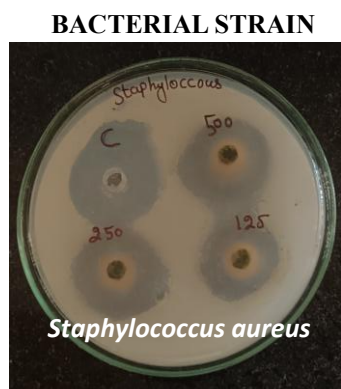
Antimicrobial activity of Formulation using agar well diffusion method:

Si. No	Name of the Organisms	Formulation (Zone of Inhibition mm)			
		Positive control	125 µl	250 µl	500 µl
BACTERIAL STRAIN					

1	<i>Staphylococcus aureus</i>	30 ± 0.15	20 ± 0.02	25 ± 0.28	29 ± 0.11
FUNGAL STRAIN					
1	<i>Candida albicans</i>	30 ± 3.1	25 ± 0.5	28 ± 0.25	30 ± 0.36

Table 9: Antimicrobial activity

Values expressed as Mean ± SD for triplicates, **Standard:** Chloramphenicol (Bacteria), Fluconazole (Fungal); **mm:** Millimetre



VI. CONCLUSION:

As a chronic, recurrent microbial nail infection, Paronychia necessitates long-term management and regular adherence to the advised therapy. The goal of the current study was to create a patient-friendly nail lacquer formulation using ethanolic leaf extraction of *Euphorbia hirta*, a known anti-fungal and anti-bacterial agent with the potential to increase penetration. The prolonged drug release up to 48 hours was achieved with the addition of rate-modifying polymer, namely ethyl cellulose, making it acceptable for thrice-weekly application. The best formulation out of the five was F3 shows good gloss, flowability, consistency and the anti-microbial activity of this F3 formulation was good with the desired ethyl cellulose concentration. The proposed formulation can therefore be a prospective replacement for current Paronychia therapy.

SOME OF THE ADVANAGES FROM THE ABOVE RESULTS:

- Proved antimicrobial activity of *Euphorbia hirta* in the formulation.
- Change in the concentration of polymer (ethyl cellulose) alter the properties of the formulation.

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