

# Formulation And Evaluation of Itraconazole Antifungal Nail Lacquer

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## Abstract

*In present, this study an antifungal nail polish was developed. The goal was to provide sustained release of anti-inflammatory drugs over a longer period of time, reducing the frequency of administration, increasing clinical effectiveness, and improving patient compliance.*

*Fungal nail disease, onychomycosis, the most common nail disorder, requires effective systemic treatment given the adverse effects of antifungal therapy. Onychomycosis is a common nail infection that mostly affects the elderly and athletes. Antibiotics such as itraconazole are one of the drugs of choice in the treatment of onychomycosis. The current study focused on the preparation and development of itraconazole-filled nail polish.*

*The main aim of this study is to develop and evaluate a chitosan nanoparticle-based hydrogel for the treatment of onychomycosis. There are different nail treatments such as cream, solution, gel and nail polish. The nail is a small piece of muscle. Therefore, nail polish will be more effective than other methods, especially oral application. - The nail polish is prepared using a mixture of nitrocellulose, ethyl cellulose, ethyl acetate, salicylic acid (acts as a penetrant), dibutyl phthalate and oils of various extracts and *Syzygium Aromaticum* of *Calendula Officinalis*, *Origanum vulgare*, *Allium sativum*, *Melaleuca alternifolia*, *cymbopogon*, *Ocimum tenuiflorum* and *Menthapiperita* .*

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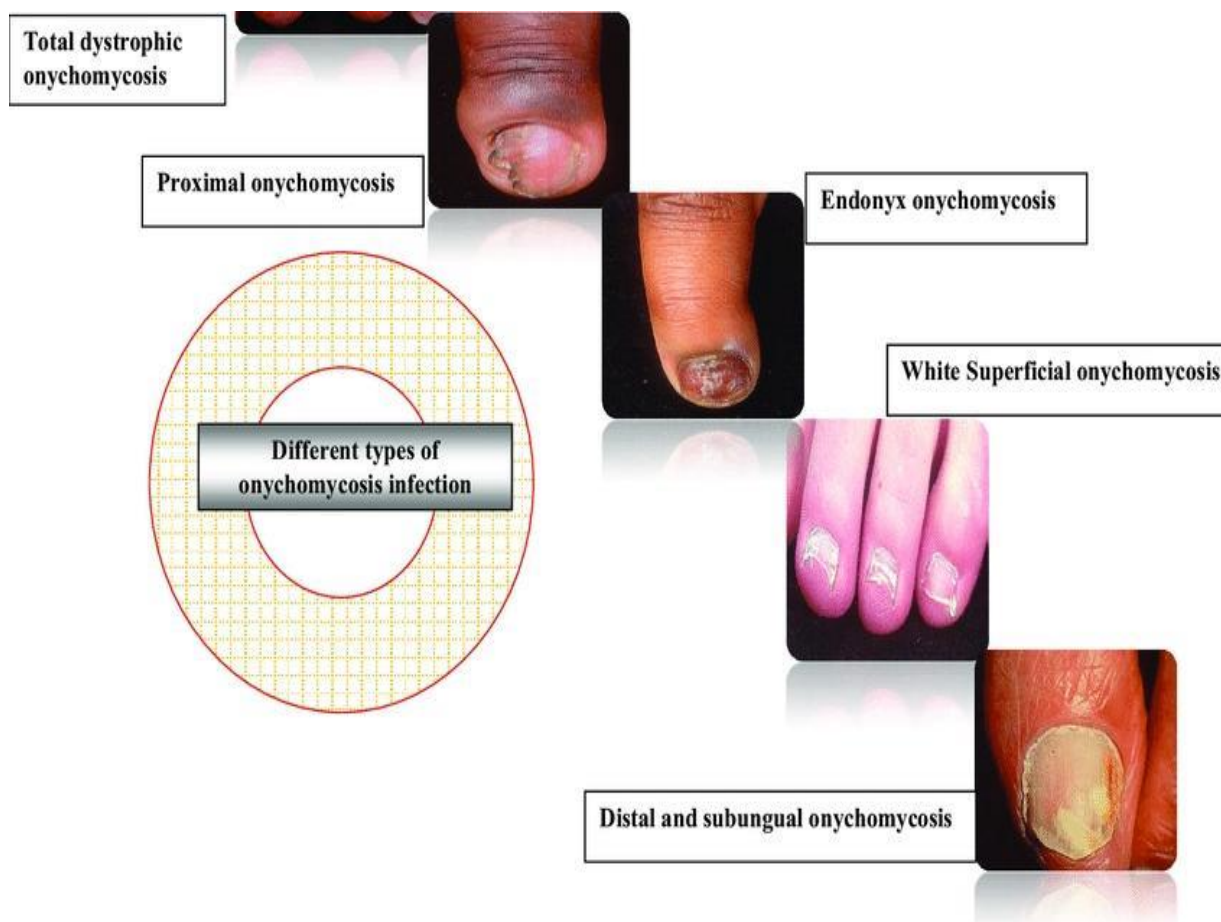
## Introduction

Onychomycosis was first described by German medical student Meissner in 1853. Onychomycosis is defined as a fungal infection that mainly affects the fingers and toes. It is estimated to affect approximately 19% of the population worldwide and is responsible for approximately 50% of all nail diseases. (1)

Onychomycosis can infect both fingernails and toenails, but onychomycosis of the toenail is much more prevalent.(2)

The Greek words “onyx” (nail) and “mykes” (mold) were combined to form the word “onychomycosis”. These nails are more common in people, especially the elderly and those with weakened immune systems. The most common cause is the yeast *Candida albicans*. Onychomycosis is more common in diabetic patients than in non-diabetic patients. As a result of the pressure, the patient develops thick, damaged nails that damage the nail bed and infect the surrounding skin

Oral antifungal therapy is still the most commonly used treatment for onychomycosis;(3). Nail fungus and



onychomycosis are one of the most common nail diseases. It is characterized by discoloration, mass and swelling of the infected nail and is caused mainly by dermatophytes, but also by dermatophytes and yeasts.(4)

The need to maintain nail-hygiene is paramount to one's overall health and well-being. Besides problems of etiquette, unkempt and unwashed nails can lead to a host of medical problems and adversely impact an individual's health. Aesthetic need for healthy-looking nails has made the consumer aware and conscious of nail hygiene and the harmful effects of numerous nail disorders. Corpus unguis, commonly known as the nail plate, is considered to be a hydrophilic gel matrix.(5) Onychomycosis is considered as one of the common

dermatology based conditions. Enhanced survey on the prevalence of the disease as well as inventions of newer antifungal agents resulted in higher concern among the patients to get cure of the disease and also among medical practitioners to constitute an effective therapy. However, there has been an issue regarding the treatment which may be prescribed without prior knowledge of infection, i.e. effectiveness of several antifungals against the fungus is not well understood and drugs are open recommended for in appropriate time periods. (6)

Itraconazole is known to be an efficient broad-spectrum antifungal agent whose mechanism of action involves impeding CYP450 enzymes that play a

critical role in the production of ergosterol, a principal component of a fungal cell wall. (7) A person's nail plate is much more complex than it seems. It protects the part of the nail bed, that is, the part filled with blood vessels under the nail plate; and the nail matrix, the layer responsible for cell proliferation and nail growth on the ventral surface of

the nail. Although small, the nail plate contains 80-90 layers of dead cells and consists mainly of keratin; 4/5 hard type hair keratin and 1/5 soft skin-keratin; and is mainly related to stem cell function(8)

Long surgeries can lead to side effects and liver damage, and high blood pressure means the goal can only be reached in less than a minute. As a result, primary care is considered a viable option. Although the local government system has many advantages. Gels, creams or liquid ointments are not enough to cover the tongue and can be removed by brushing or flossing. This is happening on (9)

**Aim-** Formulation and evaluation of antifungal nail lacquer for the treatment Onychomycosis.

**Objective-** Use in the treatment of onychomycosis.

### Material and methods:

Itraconazole was purchased from Kusum Healthcare Pvt Ltd, India. Itrastred gel (itraconazole 1% w/w) was purchased from Leeford Healthcare Ltd, India. Dibutyl phthalate is purchased from Loba Chemie Laboratories and Fine Chemicals Mumbai, India. TGA and polyethylene glycol 400 (PEG 400) were purchased from Thomas Baker Chemical Pvt. Little, Mumbai, India. Ethanol was purchased from Changshu Hongsheng Fine Chemicals Co., Ltd. Ltd., China. Hydroxylpropyl methylcellulose (HPMC) was purchased from

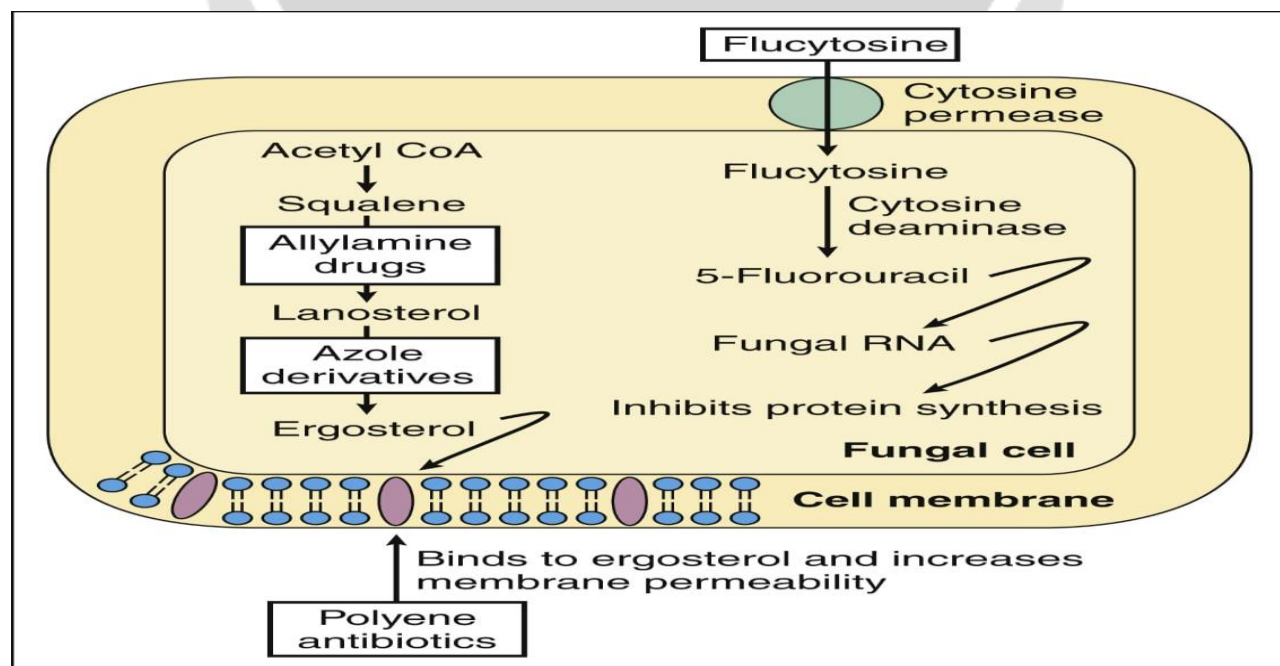
Titan Biotech Limited, Rajasthan, India. Eudragit RL-100 was purchased from Rohm Pharma, Germany. Dichloromethane was purchased from Drug House (P) Ltd. New Delhi, India. (10)

- **Drug**

#### Itraconazole-

Itraconazole is a medication used in the management and treatment of fungal infections.

#### •Mechanism of action of Itraconazole-



• **Formula-**

Ingadients	Quantity
Itraconazole	0.044
Methyl cellulose	2
Paraffin	1ml
Salicylic acid	0.60
Ethyl acetate	0.5
Dibuthylphthalate	0.2
Acetone	0.1

• **Dose preparation-**

**Preparation of salicylic acid**

2 gm salicylic acid powder was dissolved in 6.6ml ethanol to form pure form salicylic acid.

**preparation of nail Lacquer**

- Methyl cellulose and paraffin were dissolved in sufficient quantity of ethyl acetate to get clear solution.
- Salicylic acid dissolved in above mixture.
- Dibuthylphthalate was added.
- Drug also was added in above mixture.
- Acetone were added with continuous stirring at 100rpm on magnetic stirrer. (11)

**Evaluation parameters :-**

**1) Organoleptic Evaluation**

Different physical features such as color, odor and look, were examined for organoleptic properties. (12)

**2) Non-volatile content:**

8 million samples were taken into an 8 cm petri dish. The samples were evenly distributed. The plate was placed in the oven at 105°C for 1 hour, the petri dishes were removed, cooled and weighed. The difference in weight of the sample after drying was determined and the present volatile content was obtained. Weight differences were recorded.

**3) Drying time:**

Each nail is poured into a special plate 1.5 centimeters thick, spread and lifted vertically, then carefully examine whether the film is smooth. (13)

#### 4) Smoothness to flow

Each nail is poured into a special plate 1.5 centimeters thick, spread and lifted vertically, then carefully examine whether the film is smooth.

#### 5) Gloss

The gloss was observable after the nail lacquer formulation was applied over the nail. (14)

#### 6) Test for Viscosity:

It is the most important factor that determines equality of application. Viscosity can be measured using a Brookfield viscometer. This can be easily done by examining the applicant's product and comparing it with the standard product

#### 7) Test For Stability:

It is its measure of long lasting ability of the product. It can be done by using the acceleration stability test. (15)

#### 8) Drug content estimation

Nail polish equivalent to 200 mg dissolved in 50 ml of phosphate buffer pH 7.4. The solution was then ultrasonicated for 15 minutes. The resulting solution was filtered with phosphate buffer at pH 7.4 to 100 ml. Take 10 ml of the above solution consisting of 100 ml of PBS with pH 7.4. The drug is then determined by comparing the extracted solution with a spectrophotometer at 223 nm. (16)

### Results and discussion

#### 1) Organoleptic Evaluation

Organoleptic evaluation for various sensory characteristics like colour, odour, appearance, etc. was noted. The results from the four formulations are consistent. These parameters colour, smell, and appearance provide nails with an elegant appearance that increases consumer acceptance.

#### 2) Non-volatile content

Non-volatile content appeared with the entire vanishing of volatile matter and the parting of a thin film it ranges from 25-38%. Among all formulations, the formulation showed good non-volatile content assistance for filmmaking by the evanescence of volatile content. It was noticed that as the concentration of polymer increased non-volatile content also increased. Non-volatile content depends and varies upon the concentration of polymer used.

#### 3) Drying time

The drying rate increases from 62sec to 79 sec . Formulation showed a relatively short drying rate because it consists of a larger amount of polymer concentration with a rise in viscosity, which tends to result in a short drying time that was appropriate for the individual to keep the nail wet with nail lacquer for a shorter time. The implementation and concert attributes of nail covering are hugely affected by the volatility features of its specific solvent and consequently it's drying time. As the polymer concentration increases drying time is increased.

#### 4) Smoothness to flow

Uniform smooth film was formed when the nail lacquer was poured onto the glass plate and raised to spread on it. The gloss of the prepared nail lacquer was compared with marketed cosmetic sample. The prepared nail lacquer had similar gloss.

#### 5) Gloss

Glossiness was found to be good in the formulation as can be observed. Glossiness was deemed as being essential for providing the patient with nail lacquer that has been cosmetically appealing.

### 6) Test for Viscosity

The viscosity of the formulation increased as polymer concentration increased. The viscosity of the formulation differs from 100 to 220 centipoises while it was noticed that 96 to 150 centipoises resulted in clear and glossy. Viscosity beyond this range results in clouding and diminishes luster, which is inappropriate from a decorative perspective.

### 7) Test for stability

Stability studies were used to determine a product's shelf life and storage condition. formulation was discovered to be stable for a month to verify the changes in physical characteristics such as color, odor gloss, and smoothness, drying time at ( $40 \pm 2^\circ\text{C}$ ) for 1 month. The stability study input reveals that the values didn't significantly change.

### 8) Drug content estimation-

Drug content estimation, All formulations' drug content percentages were deemed to be acceptable and were between 88.5 to 92.5%.

### Conclusion

The intracanzol antifungal nail lacquer formulation shows promise as an effective treatment for fungal nail infections. Its targeted application directly to the affected area offers localized treatment with potentially fewer systemic side effects. Further research and clinical trials are warranted to assess its efficacy, safety, and long-term effects for widespread use.

From all the data, it can be concluded that medicated nail lacquers can be used as a tool for the unguial drug delivery system in the treatment of onychomycosis. Apart from treating the nail infections, the medicated nail lacquers can be also used for beautification of nails with ease of application. This improves patient compliance and acceptability.

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