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Formulation, Optimization and Transungual Penetration Study of an Antifungal Nail Polish Containing 1% Itraconazole

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A lion’s share of the Onychomycosis is caused by *Trichophyton rubrum*. The prevalence of onychomycosis is 50% in a population of patients suffering from nail disorders. It is known to have an incidence of 10-40% in a population and accounts for about 80% of overall fungal infections. Abnormal nail thickening and a substantial nail plate discoloration are manifestations of overall fungal infections. Abnormal nail thickening and a substantial nail plate discoloration are manifestations of Onychomycosis. Age is an inevitable predisposing factor for Onychomycosis, however conditions such as diabetes, HIV infection, immunosuppression, presence of athlete’s foot, obesity, smoking, outdoor recreational activities and tight clothing also prevail.

**HYPOTHESIS**

*Inclusion of Salicylic acid, Papain and Urea in an Itraconazole (1%) nail lacquer will have the highest transungual penetration on application to the nail plate.*

**OBJECTIVE**

To formulate, optimize and evaluate an antifungal nail lacquer, containing Itraconazole as the active pharmaceutical ingredient, which when applied topically onto the dorsal surface of the nail plate will facilitate the transungual penetration.

**METHOD**

To conduct an invitro, transungual penetration study on the formulations using a custom-made nail-Franz Cell

**METHODOLOGY**

**Active Pharmaceutical Ingredient (API):**

- Itraconazole (1% w/w)---Anti fungal agent

**Penetration Enhancers:**

- Urea 2.80%w/w
- Papain 5%w/w
- Salicylic acid 5%w/w

**Solvent System:**

- Butyl Acetate 6.6%v/w
- Ethyl Acetate 6.6%v/w
- Isopropyl alcohol 70% 17.50%v/w

**Stabilizers:**

- Citric Acid (0.1N)
- Span 80

**Marketed nail lacquer:** Sally Hansen Ultimate Shield Base & Top Coat™

**Analysis for drug content:**

- High Performance Liquid Chromatography (HPLC)

**RESULTS AND DISCUSSION**

**Check for precipitation**

No precipitation under microscope

**Transungual penetration**

**Accelerated stability**: As per ICH guidelines (40°C ± 2°C / 75% ± 5% RH) for seven days in a stability chamber.

**Statistical data analysis**

One-way ANOVA based on the data obtained from the transungual penetration studies. A Post hoc test will be conducted using the Tukey HSD test. A proof of concept will be executed to establish reproducibility.

**Conclusions**

The nail plate is a rigid, keratinized structure comprising of around 80-90 sheets of dead flattened. Water loss rate: 1.94 mg/cm²/h Max swelling capacity: 1.94 mg/cm²/h

**Chemical enhancement**

- Thiols/ Mercaptans, Hydrogen peroxide, Urea, Hydration and Occlusion, Keratolytic enhancers (Papain and Salicylic acid), SEPA® (2-n-nonyl-1,3-dioxolane), enhancers (Papain and Salicylic acid)

**Mechanical enhancement**

- Abrasion, Avulsion, Physical enhancement, Acid Etching, Microperoration, Micro needle, Microsurgical laser, Ultra-Violet (UV) light, Hydration Occlusion, Carbon dioxide laser, Photodynamic therapy, Low frequency ultra sound (Sonophoresis/Photophoresis), Pulsed lasers, Iontophoresis

**Table no.5:** Drying time for Sally Hansen Ultimate Shield Base & Top Coat™

<table>
<thead>
<tr>
<th>Trial Formulation with all three enhancers</th>
<th>Drying time</th>
<th>Spreadability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set 1</td>
<td>2 min 16 sec</td>
<td>68.50%</td>
</tr>
<tr>
<td>Set 2</td>
<td>2 min 18 sec</td>
<td>70%</td>
</tr>
<tr>
<td>Set 3</td>
<td>2 min 20 sec</td>
<td>70%</td>
</tr>
<tr>
<td>Set 4</td>
<td>2 min 20 sec</td>
<td>68.50%</td>
</tr>
</tbody>
</table>

**Additional references upon request**


**REFERENCE**