FORMULATION RECORD

Name: Nystatin Oral Paste
Strength: 16.7% w/w
Dosage Form: buccal
Route of Administration: buccal

Date of Last Review or Revision: 10/24/03
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
<th>Physical Description</th>
<th>Solubility</th>
<th>Therapeutic Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nystatin</td>
<td>16.7% w/w</td>
<td>yellow to light tan powder, cereal-like odor; not less than 5000 USP Nystatin Units/mg</td>
<td>slightly soluble in water and alcohol</td>
<td>antifungal antibiotic</td>
</tr>
<tr>
<td>Orabase Plain</td>
<td>qs</td>
<td>contains gelatin, pectin, sodium carboxymethylcellulose in polyethylene and mineral oil gel</td>
<td>NA</td>
<td>vehicle</td>
</tr>
</tbody>
</table>

Additional Information:

Nystatin USP used in extemporaneous compounding must be at least 5,000 Nystatin USP units.

Equipment Required:

- Class A prescription balance
- pile tile

Method of Preparation:

- Accurately weigh the required amount of each ingredient.
- Levigate the nystatin with a small portion of the base.
- Incorporate the remaining portion of the base using geometric dilution.

Description of Finished Product:

Golden color gel with high viscosity; approximates the consistence of a paste

Quality Control Procedures:

Product weight
No apparent particles aggregates on spreading

Packaging Container:

Tight, light-resistant containers

Storage Requirements:

Store in a refrigerator

Beyond-Use Date Assignment:

Stability demonstrated to be at least 3 months (Egodage KL et al, Pharm. Res. (Suppl);14:S659, 1997)

Label Information:
For Buccal Use Only
Protect From Light
Store in Refrigeration

Source of Recipe:


Literature Information: