FORMULATION RECORD

Name: PCL Stomatitis Mouthwash
Strength: 1.25% tetracycline, 20,000 units/ml nystatin
Dosage Form: Suspension
Route of Administration: Buccal

Date of Last Review or Revision: 09/09/06
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>Tetracycline USP</td>
<td>1.25g</td>
<td>yellow, odorless, crystalline powder</td>
<td>very slight soluble in water, sparingly soluble in alcohol</td>
<td>antibiotic</td>
</tr>
<tr>
<td>Diphenhydramine hydrochloride USP</td>
<td>125.0 mg</td>
<td>white, odorless, crystalline powder</td>
<td>freely soluble in water and alcohol</td>
<td>local anesthetic</td>
</tr>
<tr>
<td>Nystatin USP</td>
<td>2 million units</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>Glycerin USP</td>
<td>10 ml</td>
<td>clear, colorless, odorless, viscous liquid with a sweet taste</td>
<td>sp. gr. = 1.25 miscible with water and Alcohol USP</td>
<td>sweetening agent</td>
</tr>
<tr>
<td>Ora-Plus</td>
<td>50 ml</td>
<td>gray, moderately viscous, opaque, solution with lotion-like appearance</td>
<td>will dilute up to 50% with water, flavoring agents, or syrups, pH ~ 4.2</td>
<td>suspending vehicle</td>
</tr>
<tr>
<td>Ora-Sweet</td>
<td>qs 100 ml</td>
<td>clear, moderately viscous, light pink solution with raspberry odor</td>
<td>flavoring vehicle, pH ~ 4.2</td>
<td>sweetening vehicle</td>
</tr>
</tbody>
</table>

Calculations:

Nystatin USP used in extemporaneous compounding must be at least 5,000 USP Nystatin units/mg. Nystatin used in laboratory is 5,828 USP Nystatin units/mg.

Equipment Required:
- prescription balance
- mortar and pestle
- 50 ml, 100 ml graduated cylinder

Method of Preparation:
- Accurately weigh the tetracycline, diphenhydramine hydrochloride, and nystatin.
- Blend the powders together in a mortar and make a paste using the glycerin.
- Add the Ora-Plus into the mortar with mixing until the consistency is uniform.
- Transfer mixture in the mortar into a precalibrated bottle.
- Add sufficient Ora-Sweet to volume rinsing the mortar thoroughly.
- Mix well.
Description of Finished Product:

opaque, golden (custard-like) color, modest viscosity, suspension with slight raspberry odor

Quality Control Procedures:

weight measurement
pH
color

Packaging Container:

package in a 4 oz. prescription bottle (tight, light-resistant container)

Storage Requirements:

Store in refrigerator

Beyond-Use Date Assignment:

USP Guidelines:
Aqueous solutions:
When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Label Information:

Shake Well

Source of Recipe:

• tetracycline loses potency in solutions that have pH < 2, and is rapidly destroyed by alkali hydroxide solutions
• diphenhydramine hydrochloride slowly darkens on exposure to light
• nystatin is affected by long exposure to light, heat, and air

Literature Information: