Formulation Record

Name: Calamine

Strength: 15%

Dosage Form: Dusting Powder

Route of Administration: Topical

Date of Last Review or Revision: 02/23/01

Person Completing Last Review or Revision: RPS

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>Calamine</td>
<td>15%</td>
<td>light pink powder</td>
<td>insoluble in most solvents</td>
<td>protectant, astringent</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>1%</td>
<td>white powder</td>
<td>insoluble in water and ethanol</td>
<td>lubricating agent</td>
</tr>
<tr>
<td>Talc</td>
<td>q.s. 50 g</td>
<td>white powder</td>
<td>insoluble in most solvents</td>
<td>vehicle</td>
</tr>
</tbody>
</table>

Additional Information:

Caution: Talc will aerosolize easily

Example Calculations:

Equipment Required:
- prescription balance
- sieve, 40 mesh, 5"

Method of Preparation:
1. Accurately weigh the powders.
2. Combine the powders using geometric dilution.
3. Sieve through a 40 mesh, 5" sieve.
4. Package in appropriate container.

Description of Finished Product:
Very light pink powder with easy flow properties

Quality Control Procedures:
Inspect the product to ensure a uniform blend of the calamine.

Packaging Container:
Sift powder can
Important: Remove hole plug in lid before assembling the powder can.

Storage Requirements:
Can be stored at refrigerator or room temperature.
Beyond-Use Date Assignment:
USP Guidelines:

*Nonaqueous liquids and solid formulations:*

If the source of the ingredient(s) is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product’s expiration date, or 6 months, whichever is earlier.

If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months.

Assign 6 months.

Label Information:
External Use Only

Source of Recipe:

Literature Information: