Formulation Record

Name: Diphenhydramine Hydrochloride Solution
Strength: 2.5 mg/ml
Dosage Form: Solution
Route of Administration: Oral

Date of Last Review or Revision: 08/21/04
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>Diphenhydramine HCl</td>
<td>250 mg</td>
<td>white, crystalline powder</td>
<td>1 g/1 ml water</td>
<td>antihistamine</td>
</tr>
<tr>
<td>Glycerin</td>
<td>5 ml</td>
<td>clear, very viscous liquid</td>
<td>miscible with water</td>
<td>sweetener, solvent</td>
</tr>
<tr>
<td>Simple Syrup</td>
<td>30 ml</td>
<td>clear, slightly yellow, viscous liquid</td>
<td>miscible with water</td>
<td>sweetening agent</td>
</tr>
<tr>
<td>Vanillin Solution 67 mg%</td>
<td>0.2 ml</td>
<td>clear liquid containing alcohol</td>
<td>miscible with water</td>
<td>flavoring agent</td>
</tr>
<tr>
<td>Distilled Water</td>
<td>qs 100 ml</td>
<td>clear liquid</td>
<td>N/A</td>
<td>solvent</td>
</tr>
</tbody>
</table>

Example Calculations:
Least Weighable Quantity (LWQ) on Class A Prescription Balance is 120 mg. No trituration aliquot of diphenhydramine HCl is needed for this prescription.

Vanillin solution: 67 mg% means there is 67 mg of vanillin per 100 ml of alcohol. A stock solution must be prepared since 67 mg is below the LWQ.

Simple syrup is 85 g sucrose per 100 ml of water.

Equipment Required:
- prescription balance
- 50 ml graduated cylinder
- 150 ml beaker

Method of Preparation:
1. Using the prescription balance, weight the diphenhydramine HCl.
2. Transfer the diphenhydramine HCl into a 150 ml beaker.
3. Using an adapt-a-cap syringe, measure and transfer glycerin into the beaker.
4. Using an adapt-a-cap syringe, measure and transfer vanillin solution into the beaker.
5. Using a graduated cylinder, measure and transfer the simple syrup.
6. Add a portion of water to the beaker, add a stirring bar, and stir the mixture gently until solution occurs.
7. Transfer the mixture into a calibrated prescription bottle.
8. Rinse the beaker with portions of water, adding the rinsing to the prescription bottle.

Description of Finished Product:
Clear solution with "vanilla" type aroma

Quality Control Procedures:
Product should be free of any visible particles.
Product should be well mixed.
Packaging Container:
4 oz. plastic prescription bottle with tight closure

Storage Requirements:
Can be stored at room temperature. Glycerin, simple syrup, and alcohol from vanillin solution can act as preservatives.

Beyond-Use Date Assignment:
Diphenhydramine hydrochloride: stable under ordinary conditions (Merck Index, P. 561, 12th edition).

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.
Assign 14 days. Storage in cold temperature is not be needed due to presence of 3 preservatives.

Label Information:
Diphenhydramine hydrochloride causes drowsiness in about 70% of patients.
"May cause Drowsiness" auxiliary label would be appropriate.

Source of Recipe:
Pharmaceutics Laboratory Web page: pharmlabs.unc.edu

Literature Information:
Diphenhydramine hydrochloride: slowly darkens on exposure to light (Merck Index, P. 561, 12th edition)