Formulation Record

Name: Niacin Suspension
Strength: 500 mg/15 ml
Dosage Form: Suspension
Route of Administration: Oral

Date of Last Review or Revision: 01/02/05
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>Niacin</td>
<td>5.0 g</td>
<td>white crystal</td>
<td>1 g/60 ml water</td>
<td>antilipidemic agent</td>
</tr>
<tr>
<td>Cetylpyridinium Chloride</td>
<td>0.015 g</td>
<td>white powder</td>
<td>freely soluble in water</td>
<td>preservative</td>
</tr>
<tr>
<td>Xanthan Gum</td>
<td>0.23 g</td>
<td>cream colored powder</td>
<td>slowly dissolves in water</td>
<td>suspending agent</td>
</tr>
<tr>
<td>Purified Water</td>
<td>45.0 ml</td>
<td>clear, nonviscous liquid</td>
<td>used as a solvent</td>
<td>solvent</td>
</tr>
<tr>
<td>Suspension Structured Vehicle NF</td>
<td>qs 150 ml</td>
<td>opaque, moderately viscous</td>
<td>miscible with water</td>
<td>suspending and sweetening</td>
</tr>
</tbody>
</table>

Example Calculations:

Prepare a fresh stock solution of cetylpyridinium chloride (15 mg/5 ml) in distilled water. With each compounding, take 5 ml of the stock solution and add to 40 ml of distilled water.

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

Method of Preparation:
1. Calibrate the final container for 150 ml using water.
2. Accurately weigh the niacin and xanthan gum. Place in a mortar.
3. Add the cetylpyridinium chloride stock solution and the water together in a small beaker.
4. Add portions of the aqueous solution to the mortar and triturate after each addition. Remove clumps of xanthan gum with each addition.
5. Add portions of the Suspension Structured Vehicle NF to the mortar to aid in rinsing the mortar.
6. Continue rinsing the mortar with Suspension Structured Vehicle NF until the final product volume is attained.

Description of Finished Product:
Moderately sweet tasting opaque suspension

Quality Control Procedures:
Content assay required; should be ±10% of the labeled concentration.

Packaging Container:
Package in plastic prescription bottle with sufficient room to allow vigorous shaking.

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
Store in Refrigerator

Source of Recipe:
Structured Suspension Vehicle NF, USP 25/NF 20, p. 2632

Literature Information:
Suspension Structure Vehicle NF has a beyond use date of 30 days when stored at room temperature: USP 25/NF20, p. 2632