

Formulation Record

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

Date of Last Review or Revision: _____ Today _____
Person Completing Last Review or Revision: _____ RPS _____

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Niacin	5.0 g	cream colored crystal	1 g/ 60 ml water	Antilipidemic agent
Cetylpyridinium Chloride	0.015 g	white powder	freely soluble in water	preservative
Xanthan Gum	0.23 g	cream colored powder	dissolves water, but slowly	suspending agent
Purified Water	45.0 ml	clear liquid		solvent
Suspension Structured Vehicle	qs 150 ml	opaque solution	miscible with water	suspending and sweetening vehicle

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:

- prescription balance
- stirring hotplate
- mortar and pestle
- plastic prescription bottle

Method of Preparation:

1. Accurately weigh the niacin and xanthan gum.
2. Add the cetylpyridinium chloride stock solution and the water to a small beaker. Create a small vortex with the stirring hotplate and **slowly** sprinkle in the xanthan gum. Allow each addition to dissolve before adding the next addition.
3. Triturate the niacin to create a uniform particle size.
4. Sprinkle niacin into the solution vortex.
5. Add a portion of the Suspension Structured Vehicle into the solution vortex.
6. Transfer the suspension from the beaker to a calibrated plastic prescription bottle.
7. Continuously rinse the beaker with Suspension Structured Vehicle, adding each rinse to the prescription bottle until the required volume is reached.

Description of Finished Product:

Modestly sweet tasting opaque suspension

Quality Control Procedures:

Content assay required; should be $\pm 10\%$ of the labeled concentration.

Packaging Container:

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

Storage Requirements:

Do not 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.

Preservatives are present both in this formula and in the Suspension Structured Vehicle. Assign beyond use date of 14 days.

Label Information:

Shake Well

Source of Recipe:

Structured Suspension Vehicle, USP 24/NF 19, p. 2637-2638

Literature Information: