

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:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Niacin	5.0 g	white 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	slowly dissolves in water	suspending agent
Purified Water	45.0 ml	clear, nonviscous liquid	used as a solvent	solvent
Suspension Structured Vehicle NF	qs 150 ml	opaque, moderately viscous 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:

- 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 $\pm 10\%$ 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