

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:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Diphenhydramine HCl	250 mg	white, crystalline powder	1 g/1 ml water	antihistamine
Glycerin	5 ml	clear, very viscous liquid	miscible with water	sweetener, solvent
Simple Syrup	30 ml	clear, slightly yellow, viscous liquid	miscible with water	sweetening agent
Vanillin Solution 67 mg%	0.2 ml	clear liquid containing alcohol	miscible with water	flavoring agent
Distilled Water	qs 100 ml	clear liquid	N/A	solvent

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.
9. Bring the solution to final volume. Shake Well.

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)