

FORMULATION RECORD

Student Version

Name: PCL Stomatitis Mouthwash
Strength: 1.25% tetracycline, 20,000 units/ml nystatin
Dosage Form: Suspension
Route of Administration: Buccal

Date of Last Review or Revision: 09/09/06
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Tetracycline USP	1.25g	yellow, odorless, crystalline powder	very slight soluble in water, sparingly soluble in alcohol	antibiotic
Diphenhydramine hydrochloride USP	125.0 mg	white, odorless, crystalline powder	freely soluble in water and alcohol	local anesthetic
Nystatin USP	2 million units	yellow to light tan powder, cereal-like odor; not less than 5000 USP Nystatin units/mg	slightly soluble in water and alcohol	antifungal antibiotic
Glycerin USP	10 ml	clear, colorless, odorless, viscous liquid with a sweet taste	sp. gr. = 1.25 miscible with water and Alcohol USP	sweetening agent
Ora-Plus	50 ml	gray, moderately viscous, opaque, solution with lotion-like appearance	will dilute up to 50% with water, flavoring agents, or syrups, pH ~ 4.2	suspending vehicle
Ora-Sweet	qs 100 ml	clear, moderately viscous, light pink solution with raspberry odor	flavoring vehicle, pH ~ 4.2	sweetening vehicle

Calculations:

Nystatin USP used in extemporaneous compounding must be at least 5,000 USP Nystatin units/mg. Nystatin used in laboratory is 5,828 USP Nystatin units/mg.

Equipment Required:

- prescription balance
- mortar and pestle
- 50 ml, 100 ml graduated cylinder

Method of Preparation:

- Accurately weigh the tetracycline, diphenhydramine hydrochloride, and nystatin.
- Blend the powders together in a mortar and make a paste using the glycerin.
- Add the Ora-Plus into the mortar with mixing until the consistency is uniform.
- Transfer mixture in the mortar into a precalibrated bottle.
- Add sufficient Ora-Sweet to volume rinsing the mortar thoroughly.
- Mix well.

Description of Finished Product:

opaque, golden (custard-like) color, modest viscosity, suspension with slight raspberry odor

Quality Control Procedures:

weight measurement
pH
color

Packaging Container:

package in a 4 oz. prescription bottle (tight, light-resistant container)

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

Source of Recipe:

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- tetracycline loses potency in solutions that have pH < 2, and is rapidly destroyed by alkali hydroxide solutions
- diphenhydramine hydrochloride slowly darkens on exposure to light
- nystatin is affected by long exposure to light, heat, and air

Literature Information: