

## Formulation Record

**Name:** Theophylline - Guaifenesin Syrup  
**Strength:** 10 mg/ml - 6.0 mg/ml  
**Dosage Form:** Solution  
**Route of Administration:** Oral

**Date of Last Review or Revision:** 09/07/00

**Person Completing Last Review or Revision:** RPS

**Formula:**

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Theophylline USP	4.73 g	white powder	1 g/120 ml water; soluble in hot water	bronchodilator
Guaifenesin USP	2.84 g	white powder	1 g/20 ml water; more in hot water; soluble in glycerin	expectorant
Glycerin USP	95.0 ml	clear, very viscous liquid	miscible with water	sweetener, solvent
10% NaOH solution	24.0 ml	clear liquid	soluble in water	pH adjuster
Water	75.0 ml	clear liquid	N/A	solvent
Sodium Citrate Anhydrous USP	0.473 gm	white powder	soluble in 1.3 parts water	buffer component
Citric Acid Hydrous USP	3.8 gm	white powder	59.2% w/w in water at 20°C; 84.0% at 100°C	buffer component
Sodium Saccharin USP	0.165 gm	white powder	1 g/1.5 ml water	sweetening agent
Lemon Oil	2-3 drops	clear, slightly yellow, slightly viscous liquid	miscible with glycerin	aromatic flavoring agent
Lime Oil	1 drop	clear, slightly green, slightly viscous liquid	miscible with glycerin	aromatic flavoring agent
Sorbitol Solution 70% USP	qs 473 ml	clear, viscous liquid, consistency of syrup	miscible with water	solvent, sweetener, reduce saccharin aftertaste

**Example Calculations:**

Least Weighable Quantity (LWQ) on Class A Prescription Balance is 120 mg. In quantities less than 344 ml, sodium saccharin will need to be added as a lactose trituration. In quantities less than 120 ml, sodium citrate anhydrous will need to be added as a lactose trituration.

NaOH solutions should be freshly prepared. Generally suitable for 1 week after preparation.

**Equipment Required:**

- Class A prescription balance meeting USP specifications
- adapta-cap bottle - glycerin (viscous liquid)
- low temperature hot plate - aid in powder dissolution
- 50 ml and 100 ml graduated cylinder - sodium hydroxide solution and water

**Method of Preparation:**

1. Using the prescription balance, weigh the powders. Mark each weigh boat with the drug name.
2. Put the guaifenesin in a 600 ml beaker.
3. Add the glycerin to the beaker, and stir the guaifenesin to disperse it in the glycerin.
4. Heat at low heat (not exceeding 80°C) for 10 minutes, then add theophylline with stirring.

5. Add water and continue heating until powders dissolve.
6. Turn the hot plate off and remove the beaker from the hot plate.
7. Add sodium saccharin, sodium citrate, and citric acid. Stir until dissolved.
8. Add a portion of the sorbitol (150 ml), mix and add sodium hydroxide solution. Mix.
9. Transfer the mixture into a calibrated prescription bottle.
10. Add the lemon oil and the lime oil directly to the prescription bottle.
11. Rinse the beaker with portions of sorbitol, adding each portion to the product in the prescription bottle.
12. Bring the solution to final volume.

**Description of Finished Product:**

Clear solution with "lemon - lime" type aroma

**Quality Control Procedures:**

Product should be free of any visible particles.  
Product should be well mixed.

**Packaging Container:**

16 oz. plastic prescription bottle with tight closure

**Storage Requirements:**

Store in refrigerator. See beyond-use assignment for explanation

**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.

Glycerin has some preservation properties. It will preserve "free water" equal to its volume.

Saturated sorbitol solutions are self-preserving (Thompson: *A Practical Guide to Contemporary Pharmacy Practice*, p. 21.4). Solutions that are diluted will require refrigeration or preservatives.

Sorbitol 70% is resistant to some organisms, but is not self-preserving. Preservatives are required (*Handbook of Pharmaceutical Excipients*, 1998).

**Label Information:**

Store in refrigerator.

**Source of Recipe:**

RPS/PCL staff

supporting web page: <http://www.unc.edu/courses/phar051/>, then select Pharmaceutical Solutions 1: Simple, Saturated, Syrups

**Literature Information:**

J.E. Thompson: *A Practical Guide to Contemporary Pharmacy Practice*, p. 21.4, Williams & Wilkins, 1998.

*Handbook of Pharmaceutical Excipients*, 1998