Formulation Record

Name of Formulation: Menthol and Phenol Soft Lozenge
Strength: 15 mg Phenol, 10 mg Menthol per Lozenge
Dosage Form: Soft Lozenge (Troche)
Route of Administration: Buccal

Date of Last Review or Revision: 02/03/06
Person Completing Last Review or Revision: Robert Shrewsbury

Formula for a 24 troche mold:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Phenol USP	0.36 g	color to light pink crystals or mass	soluble in water 1g/15 ml; very soluble in alcohol, glycerin; very soluble in fixed and volatile oils.	disinfectant, anesthetic
Menthol USP	0.24 g	colorless hexagonal crystals or mass. peppermint-like odor	slightly soluble in water; very soluble in alcohol; freely soluble in fixed and volatile oils.	cooling agent; irritant; analgesic
Aspartame	0.55 g	off white granules	sparingly soluble in water; slightly soluble in alcohol	sweetener
Silica gel	0.24 g	fluffy, white powder	insoluble in water	suspending agent
citric acid monohydrate	0.7 g	white granules	1 g/1 ml water; 1.5 ml alcohol	flavor enhancer
Acacia	0.5 g	light tan powder	soluble in water (1 g/2.7 ml)	suspending and emulsifying agent
Polyethylene glycol 1450	q.s.	off white flakes	miscible with water	base

Additional Information:
Warning: avoid skin contact with phenol: severe burns will result.

Phenol crystals form a hard mass; it is difficult to remove a portion to weigh. Liquefied Phenol USP is phenol USP 90% and distilled water 10% (density is 1.07). Recommend using instead of phenol crystals.

Example Calculations:

***Calibration of Mold*:**

1. Lozenges that contain only the base are made first. The lozenges are weighed and the average weight per lozenge for that base is calculated.

$$(\text{average weight})_{\text{base}} = 1.118 \text{ g}$$

2. Lozenges that contain all of the ingredients are made. The lozenges are weighed and the average weight per lozenge for the formulation is calculated.

$$(\text{average weight})_{\text{formulation}} = 1.290 \text{ g}$$

3. The weight of ingredients is calculated from the Formulation Record. The average weight per lozenge is calculated.

$$(\text{average weight})_{\text{ingredients}} = 0.108 \text{ g}$$

4. Calculate the weight of troche base in each formulated troche.

$$(\text{average weight})_{\text{formulation}} - (\text{average weight})_{\text{ingredients}} = 1.290 \text{ g} - 0.108 \text{ g} = 1.182 \text{ g}$$

5. Calculate the **weight of base displaced** by the ingredients. (absolute value)

$$(\text{average weight})_{\text{base}} - (\text{average weight})_{\text{formulated troche}} = 1.118\text{ g} - 1.182\text{ g} = -0.064\text{ g}$$

6. Calculate the **density factor of the ingredients** in the troche base.

$$\text{Density Factor} = \frac{\text{Weight of ingredients}}{\text{Weight of base displaced}} = \frac{0.108\text{ g}}{0.064\text{ g}} = 1.688$$

***Calculation for Batch Compounding*:**

Make 24 lozenges each containing 0.108 g of ingredients. Use the density factor determined above.

1. Weight of ingredients needed.

   24 troches x 0.108 g/troche = 2.59 g

2. Weight of base needed.

   If blank lozenges, 24 troches x 1.118 g/ lozenge = 26.83 g
   Weight of base displaced by 2.59 g of ingredients = 2.59 g / 1.688 = 1.53 g
   Weight of base needed = 26.83 g – 1.53 g = 25.30 g

3. Allow 10% excess.

   2.59 g x 1.1 = 2.85 g of ingredients
   25.30 g x 1.1 = 27.83 g of base

Equipment Required:

- low temperature hotplate
- prescription balance
- 50 ml beaker
- mortar and pestle
- 40 mesh sieve
- large glassine paper

Method of Preparation:

1. Turn on the low temperature hotplate to about 60^{o}C.
2. While hotplate heats, accurately weigh ingredients using the prescription balance.
3. Place the PEG 1450 into a small beaker (50 ml) and begin heating. DO NOT ADD A STIR BAR AT THIS TIME.
4. Mix the remaining powders using the geometric dilution technique in the mortar using the pestle.
5. Pass the powder mixture through a 40 mesh sieve onto a glassine sheet.
6. Once the PEG 1450 has melted, reduce the heat, add a stir bar and set at lowest spin rate.
7. Sprinkle the powders into the melted PEG 1450 ensuring each addition is wetted before adding additional powder.
8. Once the powders have been added to the PEG 1450, remove the beaker from the hotplate, allow to cool until it is “just cool to the back of the hand.”
9. Pour the mixture into the mold beginning at the B2 position, and pour quickly, overfilling each cavity.
10. Move a stainless steel spatula over the mold just touching the melted powder mixture. DO NOT TOUCH THE MOLD. This will spread the mixture evenly over the mold, and still allow each cavity to be overfilled.
11. When the mixture has solidified in the mold, “polish” the surface with a hot air gun.
12. Once the polish has hardened, add a piece of wax paper (or glassine paper) on top of the troches, and complete the package.

Description of Finished Product:

Moderately soft opaque lozenge with yellow to gold color. Strong odor of menthol and phenol.

Quality Control Procedures:

Select 5 troches from the formulation and determine the weight variation. Acceptable weight variation would be ± 10% of the calculated theoretical value.

Packaging Container:

Package in plastic 24 troche mold with wax paper between the troches and the top of the mold case.

Storage Requirements:

Can be stored at room temperature.

Beyond-Use Date Assignment:

USP Guidelines:

Nonaqueous liquids and solid formulations:

If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months. Assign 6 months.

Label Information:

May cause drowsiness

Source of Recipe:

Modified from International Journal of Pharmaceutical Compounding, Volume 4: p. 129, 2000

Literature Information: