Formulation Record

Name: Co-enzyme Q10 Troches
Strength: 100 mg/troche
Dosage Form: Soft Lozenge (Troche)
Route of Administration: Buccal

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

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Co-enzyme Q10	2.4 g	yellow-orange powder	insoluble in water and alcohol	antineoplastic agent
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
Acacia	0.5 g	light tan powder	soluble in water (1 g/2.7 ml)	suspending and emulsifying agent
Citric acid monohydrate	0.7 g	white powder	1 g/1 ml water; 1.5 ml alcohol	flavoring agent
Flavoring oil	2-3 drops	liquid	miscible with PEG 1450	flavor
Polyethylene glycol 1450	qs	white powder	miscible with water	troche base

Example Calculations:

***Calibration of Mold*:**

1. Troches that contain only the base are made first. The troches are weighed and the average weight per troche for that base is calculated.

$(\text{average weight})_{base} = 1.075\ g$

2. Troches that contain all of the ingredients are made. The troches are weighed and the average weight per troche for the formulation is calculated.

$(\text{average weight})_{formulation} = 1.134\ g$

3. The weight of ingredients is calculated from the formula. The average weight per troche is calculated.

$(\text{average weight})_{ingredients} = 0.183\ g$

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

$(\text{average weight})_{formulation} - (\text{average weight})_{ingredients} = 1.134\ g - 0.183\ g = 0.951\ g$

5. Calculate the weight of base displaced by the ingredients.

$(\text{average weight})_{base} - 0.951\ g = 1.075\ g - 0.951\ g = 0.124\ g$

6. Calculate the density factor of the ingredient in the troche base.

$$\text{Density Factor} = \frac{\text{Weight of ingredients}}{\text{Weight of base displaced}} = \frac{0.183\,\text{g}}{0.124\,\text{g}} = 1.48$$

***Calculation for Batch Compounding*:**

Make 24 troches each containing 0.183 g of ingredients. Use the density factor determined above. Allow a 10% excess.

1. Weight of ingredients needed.

    24 troches x 0.183 g/troche = 4.392 g

2. Weight of base needed.

    If blank suppositories, 24 troches x 1.075 g/troche = 25.800 g
    Weight of base displaced by 4.392 g of ingredients = 4.392 g / 1.48 = 2.968 g
    Weight of base needed = 25.800 g – 2.968 g = 22.832 g

3. Allow 10% excess.

    4.392 g x 1.1 = 4.831 g of ingredients
    22.832 g x 1.1 = 25.115 g of base

Equipment Required:

- low temperature hotplate
- prescription balance
- mortar and pestle - triturate powders to reduce particle size and improve speed of dissolution
- large glassine papers
- troche mold
- wax 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 (~ 100 ml) and begin heating. DO NOT ADD A STIR BAR AT THIS POINT.
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, 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. While adding the powders, turn the heat off.
9. Once the powders have been added to the PEG 1450, remove the beaker, allow to cool until it is “just warm to the back of the hand.”
10. Add flavoring and stir with glass stirring rod.
11. Pour the mixture into the mold beginning at the B2 position, and pour quickly, overfilling each cavity.
12. Move a 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.
13. When the mixture has solidified in the mold, “polish” the surface with a hot air gun
14. Once the polish has hardened, add a piece of wax paper on top of the troches, and complete the package.

Description of Finished Product:

Moderately soft troche with bright orange or yellow-orange color.

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 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 manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product's expiration date, or 6 months, whichever is earlier.

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:

Source of Recipe:

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

Literature Information:

Incompatible with calcium gluconate, ascorbic acid, tetracyclines, urea, epinephrine (Merck Index p. 730, 12th edition)