Formulation Record

Name: Enalapril Maleate Tablet Triturates
Strength: 10.0 mg/tablet
Dosage Form: Tablet
Route of Administration: Oral

Date of Last Review or Revision: 01/12/15
Person Completing Last Review or Revision: RPS

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Enalapril Maleate USP	500 mg	Off white crystalline powder	Freely soluble in methanol; soluble in alcohol; sparingly soluble in water	β1 blocker, ACE inhibitor
Sucrose FCC	qs	White, crystalline powder	Very soluble in water slightly soluble in alcohol	Sweetener, hardening agent
Lactose, monohydrate	qs	White, free-flowing powder	Freely but slowly soluble in water; practically insoluble in alcohol.	diluent

Additional Information:

Tablet triturate mold is 50 cavities, approximately 100 mg capacity.

Example Calculations:

Tablet triturate base:

sucrose, powder	30%
lactose, hydrous	70%

***Calibration of Mold*:**

1. Tablets that contain only the powder base are made first. The tablets are weighed as a batch and the average weight per tablet for that base is calculated.

$$(\text{average weight})_{\text{base}} = 94.0 \text{ mg}$$

2. The average weight per tablet of the active drug is determined. Generally, just a few cavities are used in this determination. Tablets containing only the active drug are made and the average weight per tablet for the drug is calculated.

$$(\text{average weight})_{\text{drug}} = 55.9 \text{ mg}$$

3. The quantity of drug that will be required in the prescription per tablet is divided by the average weight per tablet of the active drug. This will give a percentage of the cavity volume that will be occupied by the active drug.

$$\frac{\text{quantity of drug/tablet}}{(\text{average weight})_{\text{drug}}} = \frac{10.0 \text{ mg}}{55.9 \text{ mg}} = 17.9\%$$

4. Subtracting the percentage in step 3 from 100% will give the percentage of the cavity volume that will be occupied by the tablet base.

$$100\% - 17.9\% = 82.1\%$$

5. Determine the weight of the base per tablet:

82.1% x 94.0 mg = 77.2 mg

Each tablet will have	Each mold will have
10.0 mg of drug 77.2 mg of base	10.0 mg x 50 = 500 mg 77.2 mg x 50 = 3,860 mg

6. It is prudent to prepare a slight excess of powder mixture (5–10%). This will allow for any variance in the approximate and actually capacity of the mold, and will also allow for powder loss during the compounding procedure.

500.0 mg + 50.0 mg = 550.0 mg of active drug

3,860 mg + 386 mg = 4,246 mg of base

base is 30% sucrose, 70% lactose

4,246 mg $\times$ 0.3 = 1,273.8 mg sucrose

4,246 mg $\times$ 0.7 = 2,972.2 mg of lactose

Wetting solution:

75% Alcohol USP, 25% Purified Water. If a flavor is desired, add the flavoring agent to the wetting solution.

Equipment Required:

- mortar and pestle - triturate powders to reduce particle size and improve speed of dissolution
- dropper bottle – wetting solution
- tablet triturate mold

Method of Preparation:

1. Accurately weigh ingredients using the prescription balance.
2. Mix the powders using the geometric dilution technique in the mortar using the pestle.
3. Pass the powder mixture through a 40 mesh sieve onto a glass pill tile.
4. Using the wetting solution, wet the powder mixture scrapping with a rubber-maid spatula until it all “sticks” to the pestle. Add 3 additional drops.
5. Transfer the wetted powder to the cavity plate of the tablet trituration mold. Ensure that every cavity is completely filled to its capacity. Use sufficient pressure with the hard rubber spatula to ensure that each cavity is tightly packed.
6. Slowly and carefully lower the cavity plate onto the peg plate until the tablets are removed from the cavity plate.
7. Allow the tablets to air dry on the peg plate without removing the cavity plate.
8. When the tablets have dried, remove them from the peg plate and package.
9. Wash and dry the tablet trituration mold.

Description of Finished Preparation:

Moderately hard tablet of white color.

Quality Control Procedures:

Select 10 tablets from the preparation and determine the weight variation. Acceptable weight variation would be $\pm$ 10% of the calculated theoretical value.

Packaging Container:

Package in a suitable container.

Storage Requirements:

Store at room temperature. Store in dry location. Do not store in bathroom, kitchen, refrigerator, etc.

Beyond-Use Date Assignment:

USP <795> default BUD: The beyond use date is not later than the time remaining until the earliest expiration date of any ingredient, or 6 months, whichever is earlier.

Label Information:

Source of Recipe:

Literature Information: