# 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  

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

## 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:

\[ 82.1\% \times 94.0 \text{ mg} = 77.2 \text{ mg} \]

<table>
<thead>
<tr>
<th>Each tablet will have</th>
<th>Each mold will have</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.0 mg of drug</td>
<td>10.0 mg x 50 = 500 mg</td>
</tr>
<tr>
<td>77.2 mg of base</td>
<td>77.2 mg x 50 = 3,860 mg</td>
</tr>
</tbody>
</table>

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.

\[ 500.0 \text{ mg} + 50.0 \text{ mg} = 550.0 \text{ mg of active drug} \]

\[ 3,860 \text{ mg} + 386 \text{ mg} = 4,246 \text{ mg of base} \]

base is 30% sucrose, 70% lactose

\[ 4,246 \text{ mg} \times 0.3 = 1,273.8 \text{ mg sucrose} \]

\[ 4,246 \text{ mg} \times 0.7 = 2,972.2 \text{ mg of lactose} \]

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 triturating 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 ± 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:**