**Formulation Record**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Furosemide Tablet Triturates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength:</td>
<td>10.0 mg/tablet</td>
</tr>
<tr>
<td>Dosage Form:</td>
<td>Tablet</td>
</tr>
<tr>
<td>Route of Administration:</td>
<td>Oral</td>
</tr>
<tr>
<td>Date of Last Review or Revision:</td>
<td>01/10/10</td>
</tr>
<tr>
<td>Person Completing Last Review or Revision:</td>
<td>RPS</td>
</tr>
</tbody>
</table>

<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>Furosemide USP</td>
<td>500 mg</td>
<td>Off-white powder</td>
<td>Slightly soluble in water; soluble in methanol, aq solns &gt; pH 8.0</td>
<td>Diuretic, antihypertensive</td>
</tr>
<tr>
<td>Sucrose, powder FCC</td>
<td>qs</td>
<td>White powder</td>
<td>Soluble in water</td>
<td>Sweetener, hardening agent</td>
</tr>
<tr>
<td>Lactose, hydrous NF</td>
<td>qs</td>
<td>White powder</td>
<td>Soluble in water</td>
<td>diluent</td>
</tr>
</tbody>
</table>

**Additional Information:**

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

**Example Calculations:**

*Tablet triturate base:*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>sucrose, powder</td>
<td>30%</td>
</tr>
<tr>
<td>lactose, hydrous</td>
<td>70%</td>
</tr>
</tbody>
</table>

**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.

   \[
   (\text{average weight})_{\text{base}} = 111.0 \text{ mg}
   \]

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.

   \[
   (\text{average weight})_{\text{drug}} = 77.8 \text{ mg}
   \]

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.

   \[
   \frac{10 \text{ mg}}{(\text{average weight})_{\text{drug}}} = \frac{10 \text{ mg}}{77.8 \text{ mg}} = 12.9\%
   \]

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.

   \[
   100\% - 12.9\% = 87.1\%
   \]
5. Determine the weight of the base per tablet:

\[ 87.1\% \times 111.0 \text{ mg} = 96.7 \text{ mg} \]

<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 \times 50 = 500.0 mg</td>
</tr>
<tr>
<td>96.7 mg of base</td>
<td>96.7 mg \times 50 = 4,835.0 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.

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

\[ 4835.0 \text{ mg} + 484.0 \text{ mg} = 5,319.0 \text{ mg of base} \]

- Base is 30% sucrose, 70% lactose

\[ 5,319.0 \text{ mg} \times 0.3 = 1,595.7 \text{ mg sucrose} \]
\[ 5,319.0 \text{ mg} \times 0.7 = 3,723.3 \text{ mg of lactose} \]

**Wetting solution:**

50% Alcohol USP, 50% Purified Water. If a flavor is desired, add the flavoring agent to the wetting solution.

**Equipment Required:**
- Prescription balance
- Mortar and pestle
- 40 mesh sieve
- Hard rubber spatula
- 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 until it has the consistency of “Play Dough.” Use a hard rubber spatula.
5. Transfer the wetted powder to the cavity plate of the tablet triturate 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. Allow the wetted powder to sit in the cavity plate at least 10 minutes after packing.
7. Slowly and carefully lower the cavity plate onto the peg plate until the tablets are removed from the cavity plate.
8. Allow the tablets to air dry on the peg plate without removing the cavity plate.
9. When the tablets have dried, remove them from the peg plate and package.
10. Wash and dry the tablet triturate mold, and store in proper location.

**Description of Finished Product:**
Moderately hard tablet of white color. May be a slight gray color.

**Quality Control Procedures:**
Select 10 tablets from the formulation and determine the weight variation. Acceptable weight variation would be \( \pm 10\% \) of the calculated theoretical value.
**Packaging Container:**
Package in plastic prescription vial.

**Storage Requirements:**
Can be stored at room temperature. Store in dry location (tablets will easily dissolve in moisture or water). Do not store in bathroom, kitchen, etc. Do not refrigerate since refrigerators have higher humidity compared to 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:**

**Source of Recipe:**
Pharmaceutics Care Laboratory, University of North Carolina

**Literature Information:**
Furosemide is incompatible with calcium gluconate, ascorbic acid, tetracyclines, urea, epinephrine (March Index p. 730, 12th edition)