Formulation Record

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

Date of Last Review or Revision: 01/10/10
Person Completing Last Review or Revision: RPS

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Furosemide USP	500 mg	Off-white powder	Slightly soluble in water; soluble in methanol, aq solns > pH 8.0	Diuretic, antihypertensive
Sucrose, powder FCC	qs	White powder	Soluble in water	Sweetener, hardening agent
Lactose, hydrous NF	qs	White powder	Soluble in water	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.

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

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.

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

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.

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

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% x 111.0 mg = 96.7 mg

Each tablet will have	Each mold will have
10.0 mg of drug	10.0 mg x 50 = 500.0 mg
96.7 mg of base	96.7 mg x 50 = 4,835.0 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

4835.0 mg + 484.0 mg = 5,319.0 mg of base
base is 30% sucrose, 70% lactose
5,319.0 mg × 0.3 = 1,595.7 mg sucrose
5,319.0 mg × 0.7 = 3,723.3 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 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. 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 trituration 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 ± 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)