

Formulation Record

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

Date of Last Review or Revision: Today
Person Completing Last Review or Revision: RPS

Formula:

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.

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

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. The percentage of active drug in the cavity volume and the percentage of base in the cavity volume are used to calculate the appropriate amounts of base and drug to weigh. For example, if the mold contains 50 cavities and each will hold approximately 100 mg, then 5000 mg of mixture will be needed to fill the mold. The amount of base and drug to weigh can be determined by multiplying 5000 mg by the two different percentages determined in the preceding steps.

$$5000 \text{ mg} \times 0.129 = 645.0 \text{ mg of active drug}$$

$$5000 \text{ mg} \times 0.871 = 4355.0 \text{ mg of base}$$

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

$$645.0 \text{ mg} + 64.5 \text{ mg} = 709.5 \text{ mg of active drug}$$

$$4355.0 \text{ mg} + 435.5 \text{ mg} = 4790.5 \text{ mg of base}$$

base is 30% sucrose, 70% lactose

$$4790.5 \text{ mg} \times 0.3 = 1437.2 \text{ mg sucrose}$$

$$4790.5 \text{ mg} \times 0.7 = 3353.4 \text{ mg of lactose}$$

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 of 75% Alcohol USP and 25% Purified Water.
- 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 80 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. 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 Product:

Moderately hard tablet of white 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 small glass container with air tight cap. Glass container may be placed inside a plastic prescription vial.

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:****Literature Information:**

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