Formulation Record

Name: Metoprolol Tablet Triturates
Strength: 12.5 mg/tablet
Dosage Form: Tablet
Route of Administration: Oral

Date of Last Review or Revision: 01/12/14
Person Completing Last Review or Revision: Robert Shrewsbury

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Metoprolol Tartrate USP	625 mg	White powder	>1000 mg/ml in water; >500 mg/ml in methanol	β1 blocker
Sucrose, powder NF	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.
- Metoprolol reacts with hard rubber spatula.
- Metoprolol will lose about 70% of bulk volume when wetted.

Example Calculations:

Tablet triturate base:

sucrose, powder	40%
lactose, hydrous	60%

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.

$$(\text{average weight})_{base} = 106.0 \text{ mg}$$

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.

$$(\text{average weight})_{drug} = 75.6 \text{ mg}$$

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.

$$\frac{12.5 \text{ mg}}{(\text{average weight})_{drug}} = \frac{12.5 \text{ mg}}{75.6 \text{ mg}} = 16.5\%$$

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.

$$100\% - 16.5\% = 83.5\%$$

5. Determine the weight of the base per tablet:

83.5% x 106.0 mg = 88.5 mg

Each tablet will have	Each mold will have
12.5 mg of drug	12.5 mg x 50 = 625.0 mg
88.5 mg of base	88.5 mg x 50 = 4,425.0 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 actual capacity of the mold, and will also allow for powder loss during the compounding procedure.

625.0 mg + 62.5 mg = 687.5 mg of active drug

4,425.0 mg + 442.5 mg = 4,867.5 mg of base
base is 40% sucrose, 60% lactose
$4{,}867.5 \text{ mg} \times 0.4 = 1{,}947.0$ mg sucrose
$4{,}867.5 \text{ mg} \times 0.6 = 2{,}920.5$ 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:
- prescription balance
- mortar and pestle
- rubber-maid spatula
- stainless steel 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. Using the wetting solution, wet the powder mixture scrapping with a rubber-maid spatula until it all "sticks" to the pestle. Add 6 additional drops.
4. Transfer the wetted powder to the cavity plate of the tablet trituration mold. Fill each cavity using a stainless steel spatula and sufficient pressure to ensure that every cavity is completely filled and tightly packed. Move quickly filling 2 rows at a time.
5. Carefully lower the cavity plate onto the peg plate until the tablets are removed from the cavity plate.
6. Allow the tablets to air dry on the peg plate without removing the cavity plate.
7. When the tablets have dried, remove them from the peg plate and package the tablets as appropriate.
8. Wash and dry the tablet trituration mold. Wash all equipment and return them to the workstation.

Description of Finished Product:
Small, hard tablet of white color

Quality Control Procedures:

Record the following information for 3 randomly selected tablets.

Place one tablet in an empty scintillation vial and add 20 ml of distilled water. Read the absorbance at 280 nm with a spectrophotometer using methacrylate cuvettes. Use distilled water as the blank. Use the standard curve provided in the lab to determine the metoprolol content in each tablets.

Number	Absorbance @ 280 nm	Concentration of Metoprolol (mg/20 ml)	Weight of Metoprolol in Tablet (mg)
1			
2			
3			

Average metoprolol content in 3 tablets: _____ mg

Packaging Container:
Package in a plastic prescription vial.

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

Beyond-Use Date Assignment:
USP Guidelines: for nonaqueous preparations as not later than the time remaining until the earliest expiration date of any API (also to include any ingredient), or 6 months, whichever is earlier.

Label Information:
Store in dry location

Source of Recipe:
Pharmaceutics and Compounding Laboratory, University of North Carolina, http://pharmlabs.unc.edu

Literature Information:
none applicable to the formulation