TITLE: MEASURING AND MIXING	
SOP NUMBER: 2.4	**VERSION NUMBER: 1**
Written By:	Date: MM/DD/YYYY
Authorized By:	Date:
Date Effective: MM/DD/YYYY	

1. PURPOSE

1.1 The purpose of this SOP is to provide instructions for measuring and mixing (geometric dilution).

2. RESPONSIBILITY

2.1 The Designated Person(s) shall supervise this procedure.

2.1.1 Designated Person(s) – <Job Title>

2.2 Compounding laboratory personnel

3. REFERENCES

3.1 SOP 4.0 – Use, Verification and Maintenance of the Balance

4. DEFINITIONS

4.1 API: Active Pharmaceutical Ingredient

4.2 Barrel: Part of a syringe that is a reservoir for holding liquid, clearly graduated to allow accurate and visual measurement of the contents.

4.3 Geometric dilution: The process of mixing two or more powders of different quantities to create a uniform mixture.

4.4 Meniscus: The curved surface of a liquid in a tube.

4.5 Plunger: A piston-like device inside the syringe barrel.

4.6 Syringe stopper: The portion of the plunger in contact with material inside the syringe. Typically made of rubber but may be made from other materials.

4.7 Triturate: To reduce particle size of a substance by shear force.

5. FREQUENCY

5.1 Each time measuring or mixing is required.

6. EQUIPMENT & SUPPLIES

6.1 Measuring equipment (graduated cylinders, syringes, beakers, etc.)

6.2 Mortar and pestle

6.3 12 x 12 ointment paper

6.4 Rubber spatula

7. PROCEDURE

7.1 Measurement system

7.1.1 The metric system is the system of measurement used in pharmacy.

7.1.1.1 Metric weights: microgram (mcg), milligram (mg), gram (gm)

7.1.1.2 Metric liquid measures: milliliter (mL), liter (L)

7.2 Measuring liquid volume

7.2.1 Measuring liquid volumes may be done with a calibrated graduated cylinder, beaker or a syringe.

7.2.2 Using a calibrated beaker or graduated cylinder

7.2.2.1 Select a beaker or graduated cylinder that is suitable for the volume being measured and the application it is being used for.

7.2.2.2 Confirm that the beaker or cylinder is clean and dry.

7.2.2.3 Pour the liquid into the beaker or cylinder.

7.2.2.4 Place the container on a flat surface and examine the volume of liquid in the container at eye level.

7.2.2.5 Read the measurement at the bottom of the meniscus.

7.2.3 Using a syringe

7.2.3.1 Select a syringe that is suitable for the volume to be measured. When possible, use a syringe where the amount being measured is no less than 30% of its capacity.

7.2.3.2 Make sure that the plunger is pressed down to the bottom of the barrel.

7.2.3.3 Place the syringe tip in the liquid that you want to measure.

7.2.3.4 Draw back on the plunger, allowing the liquid to flow into the syringe.

7.2.3.5 Fill the syringe barrel to the appropriate amount needed by lining the end of the plunger up with the desired marking on the barrel.

7.2.3.6 Remove the syringe from the liquid.

7.3 Mixing

7.3.1 Precise mixing instructions are required in order to produce uniform preparations within specification. Mixing instructions include the order of mixing and any environmental or other conditions that should be monitored, such as temperature and duration of mixing.

7.3.1.1 Mixing instructions are a component of the Master Formulation and shall be documented to have been performed on the Compounding Record.

7.3.2 Geometric dilution using a mortar and pestle

7.3.2.1 Weigh the required powders as described in SOP 4.0 Use, Verification and Maintenance of the Balance.

7.3.2.2 Place a piece of 12 x 12 ointment paper under the mortar to help contain any powder spillage that might occur during the mixing process.

7.3.2.3 Place a small amount of diluent in the bottom center of the mortar and use the pestle to triturate to fill any potential micro cracks within the mortar.

7.3.2.4 Place the API along with dye (if using) in the bottom center of the mortar on top of the diluent that is already in the mortar.

7.3.2.5 Add a portion of the diluent equal in volume to the API and diluent to the mortar.

7.3.2.6 Place the pestle in the center of the mortar and triturate in a circular motion, beginning in the center and working out towards the edges and then back down towards the center again.

7.3.2.7 Occasionally the pestle should be scraped with a rubber spatula to remove packed powder from the pestle. It may also be necessary to scrape the sides and bottom of the mortar with a spatula to remove any packed powder back towards the center of the mortar.

7.3.2.8 Continue mixing until a uniform color is obtained, indicating proper dilution.

7.3.2.9 Repeat steps 7.3.2.5 – 7.3.2.9 until all the diluent is utilized and the mixture has a uniform color.

8. ATTACHMENTS

8.1 N/A

9. HISTORY

Version Number	Date Effective	Description of Change
1		New SOP.

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