

INSTRUCTIONS FOR

Airless-Metered Dispensing Pumps (#10393, 10394 & 10395)

The airless-metered dispensing pump consists of four parts:

1. The cap
2. The pumping mechanism/nozzle
3. The barrel or body of the container
4. The piston

As the pumping mechanism is depressed, the contents will be expelled from the nozzle. As an airless device, it does not utilize a plastic extension tube to aid in the pumping process. When the barrel is filled, calibrated and assembled properly the compound will not be exposed to air. When the pumping nozzle is depressed, a vacuum is created and draws the piston up to expel metered amounts of the contents of the container.

Filling the pump:

1. Remove the cap and unscrew the pumping nozzle.
2. Depending upon the amount of compound being placed in the pump, you may need to alter the start position of the piston. To lower the piston to its lowest position at the bottom of the barrel, insert a clean stirring rod through the top opening and gently push the piston to the bottom.
3. Tare the container barrel and add the correct amount of your preparation.
4. Fasten the pumping nozzle by screwing it onto the container. Gently tighten until snug - don't over tighten.
5. Prime the pump by expelling the remaining air by depressing the pumping nozzle until contents begin to exit the nozzle of the unit.
6. Replace the cap and label appropriately.

Calibrating the pump:

Each pump batch and preparation should be tested for weight accuracy. The Airless-Metered Dispensing Pump consistently delivers a fixed volume of cream base (almost any consistency from liquid to viscous). The volume delivered has a fixed weight. This allows the compounding pharmacist to prepare formulas that can be dosed accurately. Although the pumps deliver consistent accurate doses they must be calibrated for each base and formula.

To calibrate the pump containers:

1. Use plain base cream.
2. Fill the barrel or body of the container.
3. Tap the container on a hard surface to remove air pockets.
4. Attach the pumping nozzle.
5. Prime the pump and expel the remaining air by depressing the pumping nozzle until the base cream begins to flow.
6. Depress the pumping nozzle and deliver 4 or 5 full strokes of cream onto a weighing paper discard.
7. Tare a piece of weighing paper.
8. Apply 10 strokes onto the paper.
9. Weigh the paper and base cream.
10. Divide the weight by 10.
11. This is the average weight per stroke of the base cream.
12. Repeat the process for three samples of 10 strokes.
13. Average the weight and determine the range of weight delivered.

Again this calibration step is required for each base and formula used. Once this step is completed for each type of base used in your practice it doesn't need to be repeated.

Now you have a starting point for calibrating an active ingredient in the base cream.

Calibrating an active ingredient in a base:

1. Prepare a compound in the same cream base

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2. For very small concentrations of active ingredient, the weight per stroke will be the same as the base alone.
3. This may not be the case for higher concentrations. The compounding pharmacist is responsible for determining the dispensing accuracy of these devices.

It is found that the airless-metered dispensing pump consistently delivers 0.2 grams of base cream per full stroke. This does not seem to change as the container is emptied. Testing has shown that weights per stroke, when the container is near empty, are almost identical as to when the container is full. The pumping mechanism operates on a volume basis and the weight accuracy is consistent from pump to pump. This feature allows the compounding pharmacist to be confident that the amount delivered per pump is accurate and consistent. It is recommended that the above calibration steps be done for each size container (30, 50 and 100mL) for validation purposes.

Frequently Asked Questions:

1. **What should be put on the label of the container as instructions to the patient?
What should be said to the patient when dispensing the container?**

Through the calibration step, it was determined that each stroke of the pumper delivers 200mg (0.2Gm) of cream + active. When compounding a 25% testosterone cream that delivers 250mg in each ONE gram, each pump delivers a fifth of a gram, or 50mg. If a person was to dose 50mg twice daily, the label could read "Apply one pump twice daily."

If the patient needed less than 50mg, a different formula may be warranted. Also volume is important - too much is messy and too little isn't efficient. The "standard" has been an eighth to a quarter teaspoonful. That's somewhere around ½ - 1 mL. The ½ mL dose seems efficient so try compounding your preparations so that the amount used is ½ mL or 2 pumps with the pumper.

2. **Would you show the patient exactly what they need to do to get the desired dose or have a sample of container with just base in it that they can try?**

A sample pumper at the counter is a good idea, especially when getting started. Using this pump device may be considered easier than the use of a syringe. The pump looks more elegant and less clinical.

3. **Why are there three different sizes of airless-metered dispensing pumps?**

Compounders can manipulate the dosing to maximize the use of the pump. Compounders need to keep in mind that 2 pumps a day calls for a LOT of doses. In a 30mL pumper they would get 150 pumps. That's 75 doses at 2 pumps per dose. There may be a concern about stability and lack of refills. So the compounder may want to use 4 to 5 pumps per dose (still at or under 1mL). For example, 4 pumps is 0.8 grams, so a 30mL size would optimally provide 37.5 days worth of the preparation. Dispense a little less than 30 or change the amount to 5 pumps.

4. **Why use this pump?**

The price is reasonable and the compounding pharmacist can really simplify his/her process. Filling numerous syringes is labor intensive and you ignore all the issues with air bubbles in syringes.

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