

Formulation Record

Name: _____ Dihydroergotamine mesylate _____
Strength: _____ 2.5 mg/ml _____
Dosage Form: _____ Nasal Spray _____
Route of Administration: _____ Inhalation _____

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

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Dihydroergotamine mesylate	0.25 g	white	1 g/125 ml water, 1 g/90 ml alcohol	smooth muscle stimulant
Alcohol USP	12 ml	clear liquid	miscible with water	solvent
Glycerin USP	15 ml	clear, viscous liquid	miscible with water and alcohol	solvent, humectant
Methylparaben	0.2 g	white powder	1 g/400 ml water, freely soluble in alcohol	preservative
Sterile Water for Injection*	qs 100 ml	clear liquid	NA	solvent

Additional Information:

- The dosing of DHE mesylate is usually 1 mg at the onset of a migraine headache, followed by 1 mg every hour for a total administration of 3 mg. For the spray, 2 mg is usually administered; 0.5 mg in each nostril initially, followed in 15 minutes by another dose of 0.5 mg in each nostril.
- Using a solution concentration of 2.5 mg/ml, 0.2 ml of solution would be needed to dispense 0.5 mg.
- *A pH 7.5 sterile buffer solution might be substituted for the Sterile Water for Injection.

Example Calculations:

- **The nasal spray bottle will need to be calibrated for each individual patient.** Weigh the container with the solution. Have the patient hold the container in an upright position and deliver ten sprays into a disposable plastic bag. Weigh the container a second time, subtract the original weight, and divide by ten. This will be "an approximate" weight delivered per squeeze. Convert the weight to a volume assuming a specific gravity of 1. Adjust the labeling as needed based on this information.

Equipment Required:

- prescription balance
- disposable sterile filter
- sterile nasal spray bottle

Method of Preparation:

1. Calibrate a 100 ml beaker.
2. Accurately weigh the powders.
3. Dissolve the dihydroergotamine mesylate in the alcohol and glycerin.
4. Dissolve methylparaben in the alcohol/glycerin mixture. Mix well.
5. qs with sterile buffer.
6. Filter sterilize through a 0.22 μ m disposable filter into a sterile nasal spray bottle.

Description of Finished Product:

Clear liquid with low viscosity

Quality Control Procedures:

Record the following information. Use 10 squeezes keeping in mind to apply equal pressure on each side of the container with the same degree of pressure.

Original Weight of Container with Solution	
Weight After 10 Squeezes	
Weight Difference	
Weight per Squeeze	
Volume Dispensed per Squeeze	
Amount of DHE Dispensed per Squeeze	

Packaging Container:

Package in plastic nasal spray bottle

Storage Requirements:

Store at room temperature.

Beyond-Use Date Assignment:

USP Guidelines:

Aqueous solutions:

When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Due to the intended use of this prescription, it would be advisable to dispense as small as quantity as possible. Ideally, several small bottles could be dispensed instead of one large bottle. Each small bottle would contain enough drug for one migraine headache attack. The bottle could discard the container after the attack was over.

The presence of methylparaben as a preservative allows the beyond-use date to be extended past 14 days. Consideration must be given as outlined above. Assign a beyond-use date of 30 days once the container is opened.

Label Information:

For nasal use only. Protect from light. Do not use if discolored.

Source of Recipe:

International Journal of Pharmaceutical Compounding 2:149, 1998

Literature Information:

Remington: The Science and Practice of Pharmacy, 19th edition, p. 1053, © 1995