Dantrolene Sodium Syrup 5 mg/mL

INGREDIENTS:

Dantrolene sodium 50 mg capsule	10 capsules
Citric acid monohydrate powder	150 mg
Sterile water for irrigation	10 mL
Simple syrup BP	QSAD: 100 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Open capsules and empty contents into a mortar.
2. Triturate contents to a fine powder.
3. Dissolve citric acid monohydrate in the volume of sterile water for irrigation indicated above.
4. Levigate powder with citric acid solution to form a paste.
5. Add vehicle in increasing amounts while mixing thoroughly.
6. Transfer contents of the mortar to a graduated cylinder.
7. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
8. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
9. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
10. Shake well to mix.

Quality-Control Procedures — Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

Labeling Requirements — Extemporaneously compounded preparation. For oral use only. Store at room temperature or refrigerate. Shake well before use.

Storage Conditions/Stability — **Store at room temperature or refrigerate. Stable for 150 days.**

STABILITY STUDY DETAILS:

Study Container Type — Amber high-density polyethylene bottle with polypropylene cap without insert

Referenced Manufacturers — Dantrolene sodium capsules (Dantrium, Procter & Gamble Australia Pty Ltd); citric acid monohydrate (BDH Chemicals Ltd); simple syrup (Pharmaceuticals Sales & Marketing Ltd).

Stability-Indicating Study — Yes

Footnote — Simple syrup BP contains 0.15% methyl hydroxybenzoate as preservative.

REFERENCE

1. Fawcett JP, Stark G, Tucker IG, et al. Stability of dantrolene oral suspension prepared from capsules. *J Clin Pharm Ther*. 1994;19(6):349-353.

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