

Mexiletine Solution 10 mg/mL

INGREDIENTS:

Mexiletine 150 mg capsule	8 capsules
Distilled water	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

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

Alternatives — May substitute vehicle with sorbitol. Stable for 28 days when refrigerated and 14 days when stored at room temperature.

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 91 days when refrigerated or 70 days when stored at room temperature.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle

Referenced Manufacturers — Mexiletine capsules (Boehringer Ingelheim); distilled water (Magnetic Springs Bottled Water Co); sorbitol (Paddock Laboratories, LLC).

Stability-Indicating Study — Yes

REFERENCE

1. Nahata MC, Morosco RS, Hipple TF. Stability of mexiletine in two extemporaneous liquid formulations stored under refrigeration and at room temperature. *J Am Pharm Assoc (Wash)*. 2000;40(2):257-259.