Amitriptyline Hydrochloride Syrup 1 mg/mL

INGREDIENTS:

Amitriptyline hydrochloride powder	100 mg
Glycerin USP	2 mL
Simple syrup	QSAD: 100 mL

EQUIPMENT AND SUPPLIES:

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

PREPARATION DETAILS:

1. Weigh out powder and add to a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with glycerin 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.

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. Shake well before use.

Storage Conditions/Stability — **Store at room temperature. Stable for 21 days.**

STABILITY STUDY DETAILS:

Study Container Type — Amber glass bottle

Referenced Manufacturers — Amitriptyline hydrochloride powder (Professional Compounding Centers of America); glycerin (not specified); simple syrup (Humco).

Stability-Indicating Study — Yes

REFERENCE

1. Gupta VD. Chemical stability of amitriptyline hydrochloride in oral liquid dosage forms. *Int J Pharm Compd*. 2009;13(5):445-446.

DOI 10.37573/9781585286522.011