

## Ursodiol Syrup 60 mg/mL—Formulation 2\*

### INGREDIENTS:

Ursodiol powder	7.2 g
Glycerin USP	10 mL
Simple syrup NF	QSAD: 120 mL

### EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, glass 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 in refrigerator. Shake well before use.

**Storage Conditions/Stability** — Refrigerate. Stable for 35 days.

### STABILITY STUDY DETAILS:

**Study Container Type** — Amber type III glass prescription bottle with child-resistant cap

**Referenced Manufacturers** — Ursodiol powder (Ciba-Geigy Corp); glycerin (Brite Life); simple syrup (Humco).

**Stability-Indicating Study** — Yes

### REFERENCE

1. Johnson CE, Nesbitt J. Stability of ursodiol in an extemporaneously compounded oral liquid. *Am J Health Syst Pharm.* 1995;52(16):1798-1800.