

Ursodiol Suspension 25 mg/mL

INGREDIENTS:

Ursodiol 300 mg capsule	10 capsules
Glycerin USP	10 mL
Ora-Plus	60 mL
Orange syrup NF	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, glass 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 glycerin to form a paste.
4. Add Ora-Plus 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 or refrigerate. Shake well before use.

Storage Conditions/Stability — Store at room temperature or refrigerate. Stable for 60 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle

Referenced Manufacturers — Ursodiol capsules (Summit Pharmaceuticals); glycerin, orange syrup (Humco); Ora-Plus (Paddock Laboratories, LLC).

Stability-Indicating Study — Yes

REFERENCE

1. Mallett MS, Hagan RL, Peters DA. Stability of ursodiol 25 mg/mL in an extemporaneously prepared oral liquid. *Am J Health Syst Pharm.* 1997;54:1401-1404.