

Ursodiol Suspension 50 mg/mL

INGREDIENTS:

Ursodiol 250 mg tablet	24 tablets
Ora-Plus/Ora-Sweet SF*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, glass mortar and pestle, graduated cylinder

PREPARATION DETAILS:

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

Special Instructions — *Mix 60 mL of Ora-Plus with 60 mL of Ora-Sweet SF. Use mixture as vehicle or use Ora-Blend SF.

Alternatives — May substitute vehicle with 60 mL of Ora-Plus mixed with 60 mL of strawberry syrup. Strawberry syrup is prepared by mixing 80 mL of simple syrup NF with 15 mL of strawberry fountain syrup.

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 90 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle with child-resistant cap

Referenced Manufacturers — Ursodiol tablets (Urso, Axcan Pharma US, Inc); Ora-Plus, Ora-Sweet SF (Paddock Laboratories, LLC); simple syrup (Humco); strawberry fountain syrup (Gordon Food Service).

Stability-Indicating Study — Yes

REFERENCE

1. Johnson CE, Streetman DD. Stability of oral suspensions of ursodiol made from tablets. *Am J Health Syst Pharm.* 2002;59(4):361-363.