

Eslicarbazepine Acetate Suspension 40 mg/mL

INGREDIENTS:

Eslicarbazepine acetate 600 mg tablet	8 tablets
Ora-Plus/Ora-Sweet*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), glass mortar and pestle, graduated cylinder

PREPARATION DETAILS:

Caution: Hazardous Drug—Reproductive hazards: Must be prepared in compliance with USP <800>.

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. Use mixture as vehicle or use Ora-Blend.

Alternatives — May substitute vehicle with 60 mL of Ora-Plus mixed with 60 mL of Ora-Sweet SF or Ora-Blend SF.

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. Caution: reproductive hazards. 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 — Eslicarbazepine acetate tablets (Aptiom, Sunovion Pharmaceuticals, Inc); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Perrigo Co).

Stability-Indicating Study — No

REFERENCE

1. Zhao F, Dave VS, Mar MZ, et al. Formulation and stability study of eslicarbazepine acetate oral suspensions for extemporaneous compounding. *Int J Pharm Compd*. 2018;22(5):433-439.