

Zonisamide Syrup 10 mg/mL*

INGREDIENTS:

Zonisamide 100 mg capsule	12 capsules
Simple syrup*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

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

PREPARATION DETAILS:

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

1. Open capsules and empty contents into a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with a small amount of vehicle 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.

Special Instructions — *Dissolve 102 g of sucrose in purified water to make a volume of 120 mL simple 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. 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 28 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic bottle

Referenced Manufacturers — Zonisamide capsules (Mylan); sucrose powder (PCCA); purified water (not specified).

Stability-Indicating Study — Yes

REFERENCE

1. Abobo CV, Wei B, Liang D. Stability of zonisamide in extemporaneously compounded oral suspensions. *Am J Health Syst Pharm.* 2009;66(12):1105-1109.