Zonisamide Suspension 10 mg/mL—Formulation 2

INGREDIENTS:

Zonisamide powder	1.2 g
SyrSpend SF PH4	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

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

PREPARATION DETAILS:

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

1. Weigh out powder and add to 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.

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 90 days.**

STABILITY STUDY DETAILS:

Study Container Type — Low-actinic prescription bottle

Referenced Manufacturer — Zonisamide powder, SyrSpend SF PH4 (Fagron).

Stability-Indicating Study — Yes

REFERENCE

1. Ferreira AO, Polonini HC, Silva SL, et al. Feasibility of amlodipine besylate, chloroquine phosphate, dapsone, phenytoin, pyridoxine hydrochloride, sulfadiazine, sulfasalazine, tetracycline hydrochloride, trimethoprim and zonisamide in SyrSpend SF PH4 oral suspensions. *J Pharm Biomed Anal*. 2016;118:105-112.

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