

Spirolactone 5 mg/mL and Hydrochlorothiazide 5 mg/mL Suspension—Formulation 1

INGREDIENTS:

Spirolactone 25 mg/hydrochlorothiazide 25 mg tablet 24 tablets
Ora-Plus/Ora-Sweet* 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—Non-antineoplastic hazardous drug: 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 cherry syrup (cherry syrup concentrate diluted 1:4 with simple syrup) or 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: hazardous drug. 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 clear plastic (polyethylene terephthalate [PET]) prescription oval with low-density polyethylene foam cap lining

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Spironolactone 5 mg/mL and Hydrochlorothiazide 5 mg/mL Suspension—Formulation 1 (continued)

Referenced Manufacturers — Spironolactone/hydrochlorothiazide tablets (Mylan); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC); cherry syrup concentrate (Robinson Laboratories, Inc); simple syrup (not specified).

Stability-Indicating Study — Yes

REFERENCE

1. Allen LV Jr, Erickson MA 3rd. Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *Am J Health Syst Pharm.* 1996;53(19):2304-2309.