

Tetracycline Hydrochloride Suspension 25 mg/mL— Formulation 1

INGREDIENTS:

Tetracycline hydrochloride 500 mg capsule	6 capsules
Ora-Plus/Ora-Sweet*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

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 — *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). Stable for 7 days when refrigerated and 2 days when stored at room temperature. Also may substitute vehicle with 60 mL of Ora-Plus mixed with 60 mL of Ora-Sweet SF or OraBlend SF. Stable for 10 days when refrigerated and 7 days when stored at room temperature.

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 28 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber clear polyethylene terephthalate (PET) prescription ovals with a low-density polyethylene foam cap lining

Referenced Manufacturers — Tetracycline hydrochloride capsules (Mylan); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC); cherry syrup concentrate (Robinson Laboratories, Inc); simple syrup (not specified).

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Tetracycline Hydrochloride Suspension 25 mg/mL— Formulation 1 (continued)

Stability-Indicating Study — Yes

REFERENCE

1. Allen LV Jr, Erickson MA 3rd. Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *Am J Health Syst Pharm.* 1998;55(17):1804-1809.