

Tacrolimus Suspension 1 mg/mL*

INGREDIENTS:

Tacrolimus 5 mg capsule	24 capsules
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. 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.

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. Shake well before use.

Storage Conditions/Stability — Store at room temperature. Stable for 120 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic bottle

Referenced Manufacturers — Tacrolimus capsules (Prograf, Fujisawa USA, Inc); Ora-Plus, Ora-Sweet (Paddock Laboratories, LLC).

Stability-Indicating Study — Yes

REFERENCE

1. Elefante A, Muindi J, West K, et al. Long-term stability of a patient-convenient 1 mg/mL suspension of tacrolimus for accurate maintenance of stable therapeutic levels. *Bone Marrow Transplant.* 2006;37(8):781-784.