Tacrolimus Suspension 0.5 mg/mL

INGREDIENTS:

Tacrolimus 5 mg capsule	12 capsules
Ora-Plus/simple syrup NF*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), glass 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 simple syrup NF. Use mixture as vehicle.

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 56 days.**

STABILITY STUDY DETAILS:

Study Container Type — Glass or plastic amber prescription bottle with child-resistant cap

Referenced Manufacturers — Tacrolimus capsules (Fujisawa USA, Inc); Ora-Plus (Paddock Laboratories, LLC); simple syrup (Humco).

Stability-Indicating Study — Yes

REFERENCE

1. Jacobson PA, Johnson CE, West NJ, et al. Stability of tacrolimus in an extemporaneously compounded oral liquid. *Am J Health Syst Pharm.* 1997;54:178-180.

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