Tacrolimus Monohydrate Suspension 0.5 mg/mL

INGREDIENTS:

Tacrolimus monohydrate powder	60 mg
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—Non-antineoplastic hazardous drug: 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: hazardous drug. For oral use only. Store in refrigerator. Shake well before use.

Storage Conditions/Stability — **Refrigerate. Stable for 90 days.**

STABILITY STUDY DETAILS:

Study Container Type — Low-actinic, light-resistant prescription bottle

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

Stability-Indicating Study — Yes

REFERENCE

1. Polonini H, da Silva SL, Brandão MAF, et al. Compatibility of baclofen, carvedilol, hydrochlorothiazide, mercaptopurine, methadone hydrochloride, oseltamivir phosphate, phenobarbital, propranolol hydrochloride, pyrazinamide, sotalol hydrochloride, spironolactone, tacrolimus monohydrate, ursodeoxycholic acid, and vancomycin hydrochloride oral suspensions compounded with SyrSpend SF pH4. *Int J Pharm Compd*. 2018;22(6):516-526.

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