Tacrolimus 10mg/mL Stock Solution
Version number: 1.0
Volume: 50mL

Tacrolimus Monohydrate	0.5 g*
Polyethylene Glycol 300, NF	q.s. 10mL

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs.
*Check Tacrolimus Monohydrate certificate of analysis for water content, which may be up to 4% and adjust amount to measure accordingly. See USP Chapter <1160> for Pharmaceutical Calculations.

SUGGESTED COMPOUNDING PROCEDURES

1. Calibrate clean appropriate size beaker to final volume with spin bar in beaker.
2. Add approximately 50% of final volume of Polyethylene Glycol 300 to step 1.
3. Add Tacrolimus Monohydrate to step 2 and bring to final volume. Mix until dissolved.
4. Filter step 3 through a 0.22 micron Teflon filter into a sterile container.

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours
Cold Temperature: not more than 3 days
Refer to USP chapter <797>.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date.
It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date is estimated to be 90 days.

Precautions

Hazardous drugs should be handled according to USP <800>, NIOSH standards and pharmacy SOPs. This preparation should be compounded in a primary engineering control (PEC) that meets USP Chapter <800> standards. Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate personal protective equipment.

02/18rd