Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: TACROLIMUS 0.5 mg/mL SUSPENSION

Date Prepared: _____ **FINAL PRODUCT CHECKED BY:** _____

EXPIRY DATE: _____

INGREDIENTS	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Ora Plus				12 mL			
Simple Syrup				12 mL			
Tacrolimus 5 mg capsule				2			
Vehicle	As above			qs to 20 mL			

EQUIPMENT

- Mortar and Pestle
- Graduated Cylinder
- Gloves

MANUFACTURING DIRECTIONS

1. Mix vehicle.
2. **PROTECT HANDS WITH GLOVES**. Open capsules into a mortar.
3. Levigate powder with a small amount of the suspending vehicle to make a fine paste.
4. Continue to add suspending vehicle until product is liquid enough to transfer to a graduated cylinder.
5. Rinse mortar several times with suspending vehicle and add to product in graduated cylinder.
6. QS to final volume with suspending vehicle.
7. Dispense in amber plastic bottles. Stable at room temperature.

SAMPLE LABEL

TACROLIMUS 0.5 mg/mL Suspension
Shake Well. Room Temperature.
Date Prepared: Date Expired:

STABILITY

56 days at room temperature.

REFERENCE(S)

- Anon, Compounded Drug Formulas, Alberta Children's Hospital, Calgary Regional Health Authority, May 2000, pp 176
- Taketomo CK, Hodding JH, Kraus DM, Pediatric Dosage Handbook, 12th Ed. 2005, pp 1201-1204
- Han J et al. Physical and microbiological stability of an extemporaneous tacrolimus suspension for paediatric use. J Clin Pharm Ther 2006; 31 (2): 167-172

***Master Sheet Revision Dates**: 11 Jan 99; 25 Nov 02* ***Final Approval By:** KS/CA/CMB*