Children's Hospital Of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: PROPRANOLOL 5 mg/mL ORAL SUSPENSION

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

EXPIRY DATE: _____

INGREDIENT	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Propranolol 40 mg tablet	Apotex			15			
Ora-Blend® SF	Paddock			qs to 120 mL			

EQUIPMENT

- Mortar and pestle
- Graduated cylinder

MANUFACTURING DIRECTIONS

1. Crush **tablets** to make a fine powder in a mortar.
2. Levigate powder with a small amount of the vehicle to make a fine paste.
3. Continue to add vehicle until product liquid enough to transfer to a graduated cylinder.
4. Rinse mortar several times with vehicle and add to product in graduated cylinder.
5. QS to final volume with vehicle.
6. Dispense in amber plastic bottles. Refrigerate or Room Temperature

FINAL APPEARANCE

Opaque light green suspension

SAMPLE LABEL

PROPRANOLOL 5 MG/ML ORAL SUSPENSION
Shake well. Refrigerate or Room Temperature.
Date Prepared: Date Expired:

STABILITY

120 days in fridge (4C) or room temperature (25C)

"*Propranolol suspension 5 mg/mL stored at 25°C maintained at least 94.7% of initial concentration for 120 days, and suspension stored at 4°C maintained at least 93.9% of initial concentration for 120 days. There were no notable changes in pH, and all samples remained physically unchanged except for a slight change in colour, around day 70, of suspensions stored at room temperature.*"

REFERENCE(S)

Ensom MHH, Kendrick J, Rudolph S, Decarie D. Stability of Propranolol in Extemporaneously Compounded Suspensions Can J Hosp Pharm 2013;66(2):118-124

Master Sheet Dates: *Dec. 2013* ***Final Approval By:*** *ND/CB*

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