

Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: SOTALOL 5mg/mL SUSPENSION

Date Prepared: _____

FINAL PRODUCT CHECKED BY: _____

EXPIRY DATE: _____

INGREDIENTS	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Sotalol 80 mg tablet				1			
Ora-Blend ®	Paddock			qs to 16 mL			

EQUIPMENT

- Mortar and pestle
- Graduated cylinder

MANUFACTURING DIRECTIONS

1. Crush tablets in mortar and reduce to a fine powder.
2. Levigate powder with a small amount of the vehicle to make a fine paste.
3. Continue to add vehicle until product is 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.

SAMPLE LABEL

SOTALOL 5 mg/mL Suspension

Shake well. Refrigerate.

Date Prepared: _____

Date Expired: _____

STABILITY

90 days in fridge or at room temperature.

REFERENCE(S)

- Nahata MC, Morosco RS. Stability of Sotalol in two liquid formulations at low temperatures. Ann Pharmacother 2003; 37: 506-9

Master Sheet Revision Dates: 16 Nov 06 Final Approval By: CM/JH

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