

**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 tablets				1 tablet			
Ora-Blend ®	<b>Paddock Labs</b>			qs to 16 mL			

**EQUIPMENT**

- Mortar and pestle
- Graduated cylinder

**SAMPLE LABEL**

**SOTALOL 5 mg/mL Suspension**  
 Shake well. Refrigerate/Room Temperature.  
 Date Prepared: \_\_\_\_\_ Date Expired: \_\_\_\_\_

**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 by geometric dilution 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.

**STABILITY**

60 days refrigerated or at room temperature.

**REFERENCE(S)**

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

**FINAL APPEARANCE**

Tablets can be blue, but overall the suspension is still opaque, whitish.

**Master Sheet Revision Dates: 16 Nov 06; aug 2018**

The non-sterile manufacturing formulas are provided for informational purposes for qualified health care professionals. The hospital will not assume responsibility for the continued currency of the information, any errors or omissions, and/or any consequences arising from the use of the information outside of CHEO.