Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: **AMIODARONE** 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
Amiodarone 200 mg tablet				2.5			
Methylcellulose 1%				50 mL			
Simple Syrup				qs to 100 mL			

EQUIPMENT

- Mortar and pestle
- Graduated cylinder

MANUFACTURING DIRECTIONS

1. Crush tablets in mortar and reduce to a fine powder.
2. Measure the volume needed of methylcellulose 1% on a graduated cylinder.
3. Levigate powder with a small amount of methylcellulose to make a fine paste.
4. Continue to add methylcellulose until product liquid enough to transfer to a graduated cylinder.
5. Rinse mortar several times with methylcellulose and add to product in graduated cylinder.
6. QS to final volume with simple syrup.
7. Dispense in amber plastic or glass bottle

SAMPLE LABEL

AMIODARONE 5 mg/mL Suspension
Shake well. Refrigerate/Room Temperature.
Date Prepared: Date Expired:

STABILITY

April 2019- Updated BUD based on review of reference
-14 days room temperature, 42 days refrigerated*. (* when refrigerated for 90 days, as in original recipe, product settles into sticky, unsuspendable residue).

FINAL APPEARNACE NOTES

White (may have slight pink tinge from tablets) suspension

REFERENCE(S)

• Nahata, MC. Stability of amiodarone in an oral suspension stored under refrigeration and at room temperature. Ann Pharmacother. 07/1997, Volume 31, Issue 7, pp. 851 - 852

***NOTE:* DO NOT USE recipe with Ora Blend® – suspension is granular and separates.**

Master Sheet Revision Dates: *17 Apr 03; 03 Nov 04; 02 Mar 06; april 2019*