Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: URSODIOL 50 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
Ursodiol 250 mg tablet	**Axcan**			10 tablets			
Ora-Blend®	**Paddock Labs**			qs to 50 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 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.

FINAL APPEARANCE

Opaque white suspension

SAMPLE LABEL

URSODIOL 50 mg/mL Suspension
Shake well. Refrigerate/Room Temperature.
Date Prepared: Date Expired:

STABILITY

60 days refrigerated or at room temperature.

REFERENCE(S)

- Johnson CE, Streetman DD. Stability of oral suspension of ursodiol made from tablets. Am J Health-Syst Pharm. 2002; 59: 361-3

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