Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: URSODIOL 50mg/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			
Ora-Blend®	**Paddock**			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 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

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

STABILITY

90 days in fridge or at room temperature.

REFERENCE(S)

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

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