

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**

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