Children's Hospital of Eastern Ontario
Pharmacy Department

Ursodiol 50 mg/mL Oral Suspension

Date Prepared: _____ /_____ / 20_____ **LOT: NS _____**

Expiry Date: _____ /_____ / 20_____ **Final Checked By: _____**

INGREDIENTS	MFR	LOT #	EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	PREPARED	CHECKED
Ursodiol 250 mg tablets	Axcan or PMS			10 tablets			
Ora-Blend				QS to 50 mL			

Risk Summary:

Always follow policies & procedures for risk assessment/NAPRA level as determined by your own pharmacy department.

Equipment and PPE:

- Mortar and pestle
- Graduated cylinder
- Glass stirring rod
- Standard CHEO Level B PPE (hair bonnet, mask, +/- beard cover, clean gown and nitrile gloves)

Procedure:

Always follow departments training protocols and policies and procedures that are currently in place.

1. Place tablets in mortar and pour a small amount of vehicle over the tablets before levigating.
2. Using the pestle, levigate tablets to create a smooth paste.
3. Continue to levigate, adding vehicle in small amounts until the product is liquid enough to transfer to a graduated cylinder.
4. Rinse mortar several times with vehicle and add product to the graduated cylinder.
5. QS to final volume with vehicle.
6. Stir well and transfer to amber bottle. Label bottle appropriately.
7. Before washing, rinse equipment into medication disposal bin, and not directly into sink.

Quality Control:

- Final Appearance: opaque white suspension
- Packaging: amber plastic bottles
- Storage & BUD: 60 days refrigerated or at room temperature

Sample Label:

Children's Hospital of Eastern Ontario
Ursodiol 50 mg/ml Oral Suspension
SHAKE WELL. REFRIGERATE or ROOM TEMPERATURE.
Quantity:
LOT: Expiry:

Reference(s):

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

Formulation Review:

Master Formula Revision Dates: *16 Nov 06; sep 2018; june 2021.*