



**BACLOFEN 5 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
Baclofen 20 mg tablets	Apotex/ Novartis			25 tablets			
Glycerin liquid				A few mL (~3 mL) to levigate			
Simple Syrup 85%				Qs to 100 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
- Oral syringe to measure the glycerin
- **Glass bottle** for final product
- 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 glycerin over the tablets before levigating.
2. Using the pestle, levigate tablets to create a smooth paste.
3. Continue to levigate, adding simple syrup in small amounts until the product is liquid enough to transfer to a graduated cylinder.
4. Rinse mortar several times with simple syrup and add product to the graduated cylinder.
5. QS to final volume with simple syrup.
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: uniform, smooth, opaque whitish suspension. Slightly thick, but pourable even when cold
- Packaging: amber GLASS bottles
- Storage & BUD: 35 days refrigerated
- **Note:** Re-formulated May 2012 from 10 mg/ml to 5 mg/ml, then again Dec 2014 to 5 mg/mL using a higher strength tablet. Original suspensions were too thick and unpleasant.



**Sample Label:**

<b>Children's Hospital of Eastern Ontario</b>	
<b>BACLOFEN 5 MG/ML ORAL SUSPENSION</b>	
SHAKE WELL. REFRIGERATE	
Quantity:	
LOT:	Expiry:

**Reference(s):**

- Nahata MC, Hipple TF, Pediatric Drug Formulations, 4th ed, 2000 pp 19
- Johnson CE. Stability of extemporaneously compounded baclofen oral liquid. Am J Health-sys Pharm. 1993; 50: 2353-55

**Formulation Review:**

**Master Sheet Revision Dates:** Nov 2011; May 2018; Sept 2018; April 2019.