

Children's Hospital Of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: BACLOFEN 5 mg/mL SUSPENSION

Date Prepared: _____

FINAL PRODUCT CHECKED BY: _____

EXPIRY DATE: _____

INGREDIENT	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Baclofen 20 mg tablets	Apotex			25 tablets			
Glycerin liquid	Medisca			A few ml (~3 ml) to levigate			
Simple Syrup 85%	Medisca			qs to 100 mL			

EQUIPMENT

- Glass mortar and pestle
- Graduated cylinder
- Oral syringe to measure the glycerin
- Glass bottle for final product

MANUFACTURING DIRECTIONS

1. Crush tablets to make a fine powder in a mortar.
2. Levigate powder with a small amount of glycerin to make a fine paste.
3. Add Simple Syrup, by geometric dilution, until product liquid enough to transfer to a graduated cylinder.
4. Rinse mortar several times with the Simple Syrup and add to product in graduated cylinder.
5. QS to final volume with Simple Syrup.
6. Dispense in amber **glass** bottle. Refrigerate

FINAL APPEARANCE

- Uniform, smooth, opaque whitish suspension. Slightly thick, but pourable even when cold

SAMPLE LABEL

BACLOFEN 5 mg/mL Suspension

Shake well. Refrigerate.

Date Prepared: _____ Date Expired: _____

STABILITY

35 days refrigerated. Shake well. Store in amber **glass** bottle.

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

*** 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***

Master Sheet Revision Dates: Nov 2011; May 2018; Sept 2018; april 2019

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