

Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: LANSOPRAZOLE 3 mg/mL SUSPENSION (external version)

Date Prepared: _____

FINAL PRODUCT CHECKED BY: _____

EXPIRY DATE: _____

INGREDIENTS	MANUFACTURER	LOT #	MAN. EXPIRY DATE	FORMULA QUANTITY	QUANTITY USED	MFG BY	CHK BY
Lansoprazole 30 mg capsule				5			
Sodium bicarbonate 8.4% injection				qs to 50 mL			

EQUIPMENT

- Glass mortar and pestle
- 125 mL graduated cylinder
- Glass stirring rod

MANUFACTURING DIRECTIONS

1. Empty the contents of capsules into the mortar.
2. Add a small amount of sodium bicarbonate to the beads and let stand 3 to 4 minutes to soften the beads.
3. Levigate beads with small amounts of sodium bicarbonate until a smooth paste is formed. Add more sodium bicarbonate to the paste until a liquid is formed.
4. Transfer contents into the graduated cylinder.
5. Rinse the mortar and pestle with sodium bicarbonate and pour into graduated cylinder.
6. QS to final volume with sodium bicarbonate. Stir well.
7. Dispense in amber plastic bottle. Refrigerate.

If sodium bicarbonate 8.4% injectable is unavailable, use this as a substitute: Dissolve 8.4 g of sodium bicarbonate (baking soda) in 100 mL of boiled and cooled water

FINAL APPEARANCE

Milky white suspension

SAMPLE LABEL

LANSOPRAZOLE 3 mg/mL suspension

Shake Well. Refrigerate.

Date prepared:

Date Expired:

STABILITY

7 days in fridge

REFERENCE(S)

- Extemporaneous Formulations for pediatric, geriatric, and special needs patients, 3rd ed, Bethesda, MD USA: ASHP 2016
- Morrison JT, Lugo RA, Thigpen JC, et al. Stability of Extemporaneously Prepared Lansoprazole Suspension at Two Temperatures. *J Pediatr Pharmacol Ther.* 2013 Apr-Jun; 18(2):122–127
- Calgary Health Region Children's Hospital Formula
- Verbal communication with IWK (Nov 2010 by AB)
- DiGiacinto JL, Olsen KM, Bergman KL, et al. Stability of suspension formulations of lansoprazole and omeprazole stored in amber-colored plastic oral syringes. *Ann Pharmacother* 2000; 34:600-5
- *Gastroen.* 1999;116:A89.
- Pediatric Drug Formulations, 4th ed., Cincinnati, Ohio USA: Harvey Whitney Books, 2000.
- Lexi-comp's Clinical Reference Library. Version 2004.4 Providence, RI USA: Electronic Book Technologies, Inc. Lexi-comp Inc

Master Sheet Revision Dates: Nov 05; Jan 06; Sep 06; Feb 07; Nov 10, Dec 10, Apr 16 **Final Approval by:** AB/CMB/CM

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