

Children's Hospital of Eastern Ontario

MASTER FORMULA SHEET – NON-STERILE MANUFACTURING

PRODUCT: LANSOPRAZOLE 3 mg/mL SUSPENSION [CHEO Sodium Bicarbonate 8.4%]

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 capsules	Abbott ONLY			10 capsules			
Sodium Bicarbonate USP powder	PCCA			8.4 g			
Sterile Water for Irrigation	Baxter			100 ml			

EQUIPMENT

- Glass mortar and pestle
- Graduated cylinder
- Glass stirring rod
- Large glass beaker
- Magnetic stirrer

MANUFACTURING DIRECTIONS

1. *Make the Sodium Bicarbonate solution:*
 - Dissolve 8.4 g sodium bicarbonate powder in 100 ml of sterile water for irrigation. A magnetic stirrer is recommended.
 - Solution is ready when it is clear. Put aside.
2. Empty the contents of Lansoprazole capsules [beads] into a mortar.
3. Add a small amount of the sodium bicarbonate solution to the beads and let stand to soften the beads. This may take several minutes.
4. 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.
5. Transfer contents into the graduated cylinder.
6. Rinse the mortar and pestle with sodium bicarbonate and pour into graduated cylinder.
7. QS to final volume with sodium bicarbonate. Stir well.
8. Dispense in amber bottles. Glass is recommended for best stability. Refrigerate.

SAMPLE LABEL

LANSOPRAZOLE 3 mg/mL SUSPENSION

Shake Well. Refrigerate.

Date Prepared: _____ Date Expired: _____

FINAL APPEARANCE

Milky white suspension

STABILITY

7 days in fridge, 4 hours Room Temperature. Lansoprazole is temperature-sensitive; larger volumes should be divided into smaller bottles, and only one bottle should be in use at a time. This reduces the amount of time each bottle would be out of the fridge.

REFERENCE(S)

- Ann Pharmacother . 2000; 34(5):600-4.
- Pediatric Drug Formulations, 4th ed., Cincinnati, Ohio USA: Harvey Whitney Books, 2000.
- Ensom, Decarie, Sheppard. Stability of Lansoprazole in Extemporaneously Compounded Suspensions for Nasogastric or Oral Administration. CJHP. Vol 60, No. 3; June 2007: 184-91.
- Lexi-comp's Clinical Reference Library. Version 2004.4 Providence, RI USA: Electronic Book Technologies, Inc. Lexi-comp
- Trissel's Stability of Compounded Formulations, 6th edition. APhA, 2018.

Master Sheet Revision Dates: Nov 05; Jan 06; Sep 06; Feb 07; Nov 10 , Dec 10 , Dec 15(change to NaHCO3 pdr) ; apr 2018 (7 days BUD); mar 2020.

The non-sterile manufacturing formulas are provided for informational purposes for qualified health care professionals. The hospital will not assume responsibility for the continued currency of the information, any errors or omissions, and/or any consequences arising from the use of the information outside of CHEO.

