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: ___________________________

<table>
<thead>
<tr>
<th>INGREDIENTS</th>
<th>MANUFACTURER</th>
<th>LOT #</th>
<th>MAN. EXPIRY DATE</th>
<th>FORMULA QUANTITY</th>
<th>QUANTITY USED</th>
<th>MFG BY</th>
<th>CHK BY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole 30 mg capsule</td>
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<td>5</td>
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<tr>
<td>Sodium bicarbonate 8.4% injection</td>
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<td>qs to 50 mL</td>
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**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.

**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
- Calgary Health Region Children’s Hospital Formula
- Verbal communication with IWK (Nov 2010 by AB)

**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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