

Lansoprazole Solution 3 mg/mL*

INGREDIENTS:

Lansoprazole 30 mg capsule	12 capsules
Sodium bicarbonate 8.4% injection	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, beaker, magnetic stirrer, graduated cylinder

PREPARATION DETAILS:

1. Open capsules and empty contents into a beaker.
2. Add vehicle to the beaker to achieve the total volume indicated above.
3. Place the beaker on a magnetic stirrer and stir for 30 minutes.
4. Transfer solution into an appropriately sized amber bottle.
5. Shake well to mix.

Quality-Control Procedures — Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

Labeling Requirements — Extemporaneously compounded preparation. For oral use only. Store in refrigerator. Shake well before use.

Storage Conditions/Stability — Refrigerate. Stable for 7 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic oral syringe

Referenced Manufacturers — Lansoprazole capsules (Prevacid, TAP Pharmaceuticals); sodium bicarbonate injection (Abbott Laboratories).

Stability-Indicating Study — Yes

Footnote — According to DiGiacinto et al,¹ stable for 14 days when refrigerated. According to Morrison et al,² stable for 7 days when refrigerated. Used conservative stability dating of 7 days.

REFERENCES

1. 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(5):600-605.
2. Morrison JT, Lugo RA, Thigpen JC, et al. Stability of extemporaneously prepared lansoprazole suspension at two temperatures. *J Pediatr Pharmacol Ther.* 2013;18(2):122-127.