

## Pantoprazole Solution 2 mg/mL—Formulation 1

### INGREDIENTS:

Pantoprazole 40 mg tablet	6 tablets
Sodium bicarbonate powder	10.1 g
Sterile water for irrigation	QSAD: 120 mL

### EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, beaker, magnetic stirrer, graduated cylinder, pharmaceutical analytical scale

### PREPARATION DETAILS:

1. Remove imprint from tablets by gently rubbing with a paper towel dampened with ethanol.
2. Allow tablets to air-dry for a few minutes.
3. Triturate tablets to a fine powder with a mortar and pestle.
4. Transfer the contents of the mortar to an appropriately sized beaker.
5. Add 100 mL of sterile water for irrigation and place the beaker on a magnetic stirrer.
6. Add 5 g of sodium bicarbonate powder and continue to stir for approximately 20 minutes until all tablet remnants have disintegrated and the coating has dissolved.
7. Add remaining sodium bicarbonate powder and stir for approximately 5 minutes until the powder dissolves.
8. Add enough sterile water for irrigation to achieve the final volume indicated.
9. Transfer the solution into an appropriately sized amber bottle.
10. 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 62 days.

### STABILITY STUDY DETAILS:

**Study Container Type** — Amber polyethylene terephthalate (PET) bottle with child-resistant cap

**Referenced Manufacturers** — Pantoprazole tablets (Protonix, Wyeth-Ayerst Laboratories); sterile water for irrigation (Abbott Laboratories); sodium bicarbonate powder (Spectrum Chemical Manufacturing Corp).

**Stability-Indicating Study** — Yes

### REFERENCE

1. Dentinger PJ, Swenson CF, Anaizi NH. Stability of pantoprazole in an extemporaneously compounded oral liquid. *Am J Health Syst Pharm.* 2002;59:953-956.