

Midazolam Hydrochloride Gelatin 1 mg/mL

INGREDIENTS:

Midazolam hydrochloride 5 mg/mL injection	45 mL
Gelatin, flavored	3 oz
Distilled water	180 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, 1 × 18-G needle, 1 × 50-mL syringe, graduated cylinder, beaker, hot plate, thermometer

PREPARATION DETAILS:

1. Measure 180 mL of water and add to beaker. Heat to boiling.
2. Add 3 oz of flavored gelatin to water and stir until dissolved.
3. Allow solution to cool to 40°C.
4. Add injectable solution and stir well.
5. Accurately measure desired volume of solution and place in unit dose plastic cups.
6. Place cups in refrigerator and allow gelatin to become firm (1–2 hours).

Special Instructions — Place in a food storage bag in refrigerator.

Quality-Control Procedures — Visually inspect for physical appearance of formulation.

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

Storage Conditions/Stability — Refrigerate. Stable for 14 days. Stable for 28 days when stored at –20°C.

STABILITY STUDY DETAILS:

Study Container Type — Plastic medicine cup

Referenced Manufacturers — Midazolam hydrochloride injection (Versed, Roche Laboratories, Inc); gelatin, flavored (gelatin dessert, tropical punch flavor Jell-O, Kraft General Foods, Inc); distilled water (not specified).

Stability-Indicating Study — No

Commercially available as 2-mg/mL syrup — Use extemporaneously prepared formulation only when commercial product is unavailable or a lower concentration gelatin is desired.

REFERENCE

1. Bhatt-Mehta V, Johnson CE, Kostoff L, et al. Stability of midazolam hydrochloride in extemporaneously prepared flavored gelatin. *Am J Hosp Pharm.* 1993;50:472-475.