

## Nifedipine Solution 10 mg/mL

### INGREDIENTS:

Nifedipine powder	3.2 g
Glycerin USP	127 mL
Peppermint oil NF	3.2 mL
Polyethylene glycol 400 NF	QSAD: 320 mL

### EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, beaker, graduated cylinder, magnetic stirrer, hot plate, thermometer, 1.2- $\mu$ m glass microfiber filter

### PREPARATION DETAILS:

*Solution should be prepared in a dimly lit room to prevent photo-degradation of nifedipine.*

1. Measure polyethylene glycol 400 and add to a beaker.
2. Weigh nifedipine powder and add to polyethylene glycol 400 while stirring.
3. Measure glycerin and add to polyethylene glycol 400 and nifedipine while stirring.
4. Heat the cloudy yellow liquid to approximately 95°C while stirring and maintain that temperature until all the nifedipine dissolves.
5. Filter the hot, clear solution through a 1.2- $\mu$ m glass microfiber filter and stir until the liquid cools to room temperature.
6. Add peppermint oil and pour the solution into an amber glass bottle.

**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 at room temperature. Protect from light. Shake well before use.

**Storage Conditions/Stability** — Store at room temperature. Protect from light. Stable for 35 days when stored in amber glass bottle and 14 days when stored in amber oral syringes, both wrapped in aluminum foil.

### STABILITY STUDY DETAILS:

**Study Container Type** — Amber glass bottle with child-resistant cap and 5-ml amber polypropylene oral syringe with silicon elastomer tip

**Referenced Manufacturers** — Nifedipine powder, polyethylene glycol 400 NF (Spectrum Chemical Manufacturing Corp); glycerin (Humco); peppermint oil NF (City Chemical Corp).

**Stability-Indicating Study** — Yes

### REFERENCE

1. Dentinger PJ, Swenson CF, Anaizi NH. Stability of nifedipine in an extemporaneously compounded oral solution. *Am J Health Syst Pharm.* 2003;60:1019-1022.