Nifedipine Suspension 1 mg/mL

INGREDIENTS:

Nifedipine powder	120 mg
Hypromellose 1%*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, pharmaceutical analytical scale, glass mortar and pestle, graduated cylinder

PREPARATION DETAILS:

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

1. Weigh out powder and add to a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with a small amount of vehicle to form a paste.
4. Add vehicle in increasing amounts while mixing thoroughly.
5. Transfer contents of the mortar to a graduated cylinder.
6. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
7. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
8. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
9. Shake well to mix.

Special Instructions — *See page 85 for preparation directions of hypromellose 1%.

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 or refrigerate. Protect from light. Shake well before use.

Storage Conditions/Stability — **Store at room temperature or refrigerate. Protect from light. Stable for 28 days.**

STABILITY STUDY DETAILS:

Study Container Type — 2-mL Discardit syringe with Kombi-Stopfen cap

Referenced Manufacturers — Nifedipine powder (Orion Corp); hypromellose powder (Methocel E50LV, Ph.Eur.); purified water USP (not specified).

Stability-Indicating Study — No

REFERENCE

1. Helin-Tanninen M, Naaranlahti T, Kontra K, et al. Enteral suspension of nifedipine for neonates. Part 2. Stability of an extemporaneously compounded nifedipine suspension. *J Clin Pharm Ther.* 2001;26(1):59-66.

DOI 10.37573/9781585286522.115