Hypromellose Suspension 10 mg/mL

INGREDIENTS:

Hypromellose powder	10 g
Purified water USP	QSAD: 1,000 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, autoclave, pharmaceutical analytical scale, beaker, heater, magnetic stirrer, graduated cylinder

PREPARATION DETAILS:

1. Weigh out hypromellose powder and add to a beaker.
2. Add one-third of the water to the beaker and heat to 90°C while stirring vigorously until agglomerates disappear and particles are thoroughly wetted.
3. Add cold water (5°C) to total volume indicated above and continue stirring gently until mixture is homogeneous.
4. Allow solution to cool in icy water until thoroughly hydrated, and then allow it to gradually warm to ambient temperature.
5. Autoclave at 121°C for 20 minutes.
6. Allow solution to cool to room temperature.

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. Shake well before use.

Storage Conditions/Stability — **Storage condition unknown. Should use to prepare nifedipine suspension immediately after preparation. Stability unknown.**

STABILITY STUDY DETAILS:

Study Container Type — Not specified.

Referenced Manufacturer — Hypromellose powder (Methocel E50LV, Ph.Eur.); purified water USP (not specified).

Stability-Indicating Study — No

Footnote — This formulation was based on preparation instructions for nifedipine suspension 1 mg/mL. No stability information was reported for hypromellose suspension 10 mg/mL without nifedipine. This formulation should ONLY be used to prepare nifedipine suspension 1 mg/mL.

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.

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