Nifedipine Suspension 4 mg/mL—Formulation 1*

INGREDIENTS:

Nifedipine 10 mg capsule	24 capsules
Ora-Plus/Ora-Sweet*	QSAD: 60 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, 2 × 18–G needles, 1 × 10-mL syringe, graduated cylinder

PREPARATION DETAILS:

1. Puncture the top of each capsule with a needle to create a vent.
2. Puncture the bottom of each capsule and extract the liquid using a syringe. Keep the bevel of the needle close to the bottom wall of the capsule and rotate the capsule on the needle just after the first bubble appears in the syringe.
3. After pausing for 5 seconds, withdraw the liquid again and repeat this step twice for each capsule.
4. Transfer contents of the syringe to a graduated cylinder.
5. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
6. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
7. Shake well to mix.

Special Instructions — *Mix 30 mL of Ora-Plus with 30 mL of Ora-Sweet. Use mixture as vehicle or use Ora-Blend.

Alternatives — May substitute vehicle with 4.3 mL methylcellulose 1% (see page 107 for preparation directions) mixed with 55.7 mL simple syrup NF.

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 91 days.**

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle

Referenced Manufacturers — Nifedipine capsules (Novopharm USA Inc); Ora-Plus, Ora-Sweet (Paddock Laboratories, LLC); methylcellulose (not specified); simple syrup NF (Humco).

Stability-Indicating Study — Yes

REFERENCE

1. Nahata MC, Morosco RS, Willhite EA. Stability of nifedipine in two oral suspensions stored at two temperatures. *J Am Pharm Assoc (Wash)*. 2002;42(6):865-867.

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