

Amlodipine Besylate Suspension 1 mg/mL— Formulation 1

INGREDIENTS:

Amlodipine besylate 5 mg tablet	24 tablets
Ora-Plus/Ora-Sweet*	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, mortar and pestle, graduated cylinder

PREPARATION DETAILS:

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

Special Instructions — *Mix 60 mL of Ora-Plus with 60 mL of Ora-Sweet. Use mixture as vehicle or use Ora-Blend.

Alternatives — May substitute vehicle with 60 mL of methylcellulose 1% (see page 107 for preparation directions) mixed with 60 mL of 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. Shake well before use.

Storage Conditions/Stability — Store at room temperature or refrigerate. Stable for 91 days when refrigerated and 56 days when stored at room temperature.

STABILITY STUDY DETAILS:

Study Container Type — Amber plastic prescription bottle

Referenced Manufacturers — Amlodipine besylate tablets (Norvasc, Pfizer); Ora-Plus, Ora-Sweet (Paddock Laboratories, LLC); methylcellulose (not specified); simple syrup (Humco).

Stability-Indicating Study — Yes

Commercially available — Use extemporaneously prepared formulation only when commercial product is unavailable.

REFERENCE

1. Nahata MC, Morosco RS, Hipple TF. Stability of amlodipine besylate in two liquid dosage forms. *J Am Pharm Assoc (Wash)*. 1999;39(3):375-377.