

Enalapril Maleate Suspension 1 mg/mL—Formulation 2

INGREDIENTS:

Enalapril maleate 20 mg tablet	6 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 cherry syrup (cherry syrup concentrate diluted 1:4 with simple syrup) or 60 mL of Ora-Plus mixed with 60 mL of Ora-Sweet SF or Ora-Blend SF. Stable for 60 days when refrigerated or stored at 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. Store at room temperature or refrigerate. Shake well before use.

Storage Conditions/Stability — Store at room temperature or refrigerate. Stable for 91 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber clear polyethylene terephthalate (PET) prescription oval with low-density polyethylene foam cap lining¹; plastic prescription bottle²

Referenced Manufacturers — Enalapril maleate 20 mg tablets (Merck Sharp & Dohme Corp); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC); cherry syrup concentrate (Robinson Laboratories, Inc); simple syrup (not specified).¹ Enalapril maleate 10 mg tablets (Merck Sharp & Dohme Corp); Ora-Plus, Ora-Sweet, Ora-Sweet SF (Paddock Laboratories, LLC).²

Stability-Indicating Study — Yes

Enalapril Maleate Suspension 1 mg/mL—Formulation 2 (continued)

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

REFERENCES

1. Allen LV Jr, Erickson MA 3rd. Stability of alprazolam, chloroquine phosphate, cisapride, enalapril maleate, and hydralazine hydrochloride in extemporaneously compounded oral liquids. *Am J Health Syst Pharm.* 1998;55(18):1915-1920.
2. Nahata MC, Morosco RD, Hipple TF. Stability of enalapril maleate in three extemporaneously prepared oral liquids. *Am J Health Syst Pharm.* 1998;55:1155-1157.