

Enalapril Maleate Suspension 1 mg/mL—Formulation 1

INGREDIENTS:

Enalapril maleate 20 mg tablet	6 tablets
Citric acid 1 M solution	QS to pH 3
Methyl hydroxybenzoate powder	240 mg
Hydroxyethylcellulose 0.5% solution	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

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

PREPARATION DETAILS:

1. Triturate tablets to a fine powder with a mortar and pestle.
2. Weigh out methyl hydroxybenzoate powder, add to mortar, and mix well.
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. Add adequate amount of citric acid 1 M to adjust for a pH of 3.
9. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
10. Shake well to mix.

Alternatives — May substitute vehicle with 1:10 raspberry syrup and hydroxyethylcellulose 0.5% solution.

Quality-Control Procedures — Conduct pH testing to adjust for a pH of 3. 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 30 days.

STABILITY STUDY DETAILS:

Study Container Type — Orange glass bottle

Referenced Manufacturers — Enalapril maleate tablets (Enarenal, Polpharma SA); hydroxyethylcellulose solution (Natrosol HR, ACEF Spa); methyl hydroxybenzoate powder (Caesar & Loretz GmbH); citric acid solution (ChemPUR); raspberry syrup (Gemi).

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

Stability-Indicating Study — No

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

REFERENCE

1. Sosnowska K, Winnicka K, Czajkowska-Kośnik A. Stability of extemporaneous enalapril maleate suspensions for pediatric use prepared from commercially available tablets. *Acta Pol Pharm.* 2009;66(3):321-326.