Ethacrynic Acid Solution 1 mg/mL

INGREDIENTS:

Ethacrynic acid powder	100 mg
Ethyl alcohol USP	10 mL
Sodium hydroxide 0.1 N	QS to pH 7
Sorbitol solution 50%	QSAD: 100 mL

EQUIPMENT AND SUPPLIES:

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

PREPARATION DETAILS:

1. Weigh out powder and add to a mortar.
2. Triturate contents to a fine powder.
3. Levigate powder with alcohol 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 sodium hydroxide 0.1 N to adjust for a pH of 7.
9. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
10. Shake well to mix.

Quality-Control Procedures — Conduct pH testing to adjust for a pH of 7. 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. Shake well before use.

Storage Conditions/Stability — **Store at room temperature. Stable for 220 days.**

STABILITY STUDY DETAILS:

Study Container Type — Amber bottle

Referenced Manufacturer — Ethacrynic acid powder (Merck & Co); sorbitol solution, alcohol, sodium hydroxide (not specified).

Stability-Indicating Study — No

Footnote — Sorbitol solution contained 0.005% methylparaben and 0.002% propylparaben as preservatives.

REFERENCE

1. Das Gupta V, Gibbs CW Jr, Ghanekar AG. Stability of pediatric liquid dosage forms of ethacrynic acid, indomethacin, methyldopate hydrochloride, prednisone and spironolactone. *Am J Hosp Pharm*. 1978;35(11):1382-1385.

DOI 10.37573/9781585286522.061