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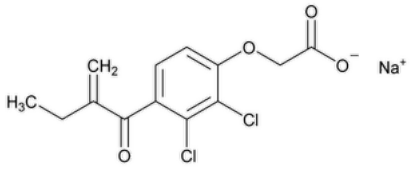
Ethacrynate Sodium for Injection



$C_{13}H_{11}Cl_2NaO_4$ 325.12

Acetic acid, [2,3-dichloro-4-(2-methylene-1-oxobutyl)phenoxy]-, sodium salt;

Sodium [2,3-dichloro-4-(2-methylenebutyryl)phenoxy]acetate CAS RN®: 6500-81-8; UNII: K41MYV7MPM.

DEFINITION

Ethacrynate Sodium for Injection is a sterile, freeze-dried powder prepared by the neutralization of Ethacrynic Acid with the aid of Sodium Hydroxide. It contains an amount of ethacrynate sodium equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of ethacrynic acid ($C_{13}H_{12}Cl_2O_4$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Diluent: Acidified methanol prepared by adding 9 mL of hydrochloric acid to 100 mL of methanol

Sample solution: 50 µg/mL in *Diluent*

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Buffer: Mix 10 mL of triethylamine and about 900 mL of water in a 1-L volumetric flask. Adjust with phosphoric acid to a pH of 6.8 ± 0.1, and dilute with water to volume.

Diluent: Acetonitrile and water (20:30)

Mobile phase: Acetonitrile and *Buffer* (400:600)

Standard solution: 0.5 mg/mL of USP Ethacrynic Acid RS in *Diluent*

Sample stock solution: Nominally equivalent to 2.5 mg/mL of ethacrynic acid from a suitable number of containers of Ethacrynate Sodium for Injection prepared as follows. Combine the contents of a suitable number of containers of Ethacrynate Sodium for Injection, equivalent to about 500 mg of ethacrynic acid, in a 200-mL volumetric flask. Add 5 mL of *Diluent* to each container, mix to dissolve the contents, and combine the resulting solutions in the volumetric flask taken. Rinse each container with two additional 5-mL portions of *Diluent*, add the rinsings to the solution in the volumetric flask, and dilute with *Diluent* to volume.

Sample solution: 0.5 mg/mL of ethacrynic acid in *Diluent* from *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1200 theoretical plates

Tailing factor: NMT 2

Capacity factor, *k'*: NLT 0.8

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ethacrynic acid ($C_{13}H_{12}Cl_2O_4$) in the portion of Ethacrynate Sodium for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Ethacrynic Acid RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ethacrynic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: Equivalent to 1 mg/mL of ethacrynic acid in Sterile Water for Injection

Acceptance criteria: 5.0–7.0

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 5.0 USP Endotoxin Units/mg of ethacrynate sodium

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution* .

• **Labeling:** Label it to indicate that it was prepared by freeze-drying, having been filled into its container in the form of a true solution.

• **USP Reference Standards ⟨11⟩**

USP Ethacrynic Acid RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ETHACRYNATE SODIUM FOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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