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Ethacrynic Acid Tablets

DEFINITION

Ethacrynic Acid Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of ethacrynic acid ($C_{13}H_{12}Cl_2O_4$).

IDENTIFICATION

Delete the following:

▲ **A. ULTRAVIOLET ABSORPTION** ▲ (USP 1-Dec-2024)

Add the following:

▲ **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Dec-2024)

Change to read:

• **B.** ▲ The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Dec-2024)

ASSAY

Change to read:

PROCEDURE

▲ **Buffer:** 1% (v/v) [triethylamine](#) solution in [water](#) prepared as follows. Transfer a suitable aliquot of [triethylamine](#) to an appropriate volumetric flask containing 90% of the flask volume of [water](#). ▲ (USP 1-Dec-2024) Adjust with [phosphoric acid](#) to a pH of 6.8 ▲ (USP 1-Dec-2024) and dilute with [water](#) to volume. ▲ (USP 1-Dec-2024)

Mobile phase: [Acetonitrile](#) and *Buffer* (40:60). ▲ (USP 1-Dec-2024)

Diluent: [Acetonitrile](#) and [water](#) (40:60)

Standard solution: 0.5 mg/mL of [USP Ethacrynic Acid RS](#) in *Diluent*

Sample solution: Nominally 0.5 mg/mL of ethacrynic acid in *Diluent* prepared as follows. Transfer a portion of the powder from NLT 20 finely powdered Tablets, equivalent to about 50 mg of ethacrynic acid, to a 100-mL volumetric flask, add about 80 mL of *Diluent*, and shake or sonicate as necessary. Dilute with *Diluent* to volume, and mix.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm. ▲ For *Identification B*, use a diode array detector in the range of 200–400 nm. ▲ (USP 1-Dec-2024)

Column: 3.9-mm × 30-cm; ▲ 10-μm ▲ (USP 1-Dec-2024) packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

▲ **Run time:** NLT 2 times the retention time of ethacrynic acid ▲ (USP 1-Dec-2024)

System suitability

Sample: *Standard solution*

Suitability requirements

▲ ▲ (USP 1-Dec-2024)

Tailing factor: NMT ▲ 2.0 ▲ (USP 1-Dec-2024)

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 Tablets taken:

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

r_U = peak response of ethacrynic acid from the *Sample solution*

r_S = peak response of ethacrynic acid 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

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 0.1 M phosphate buffer, Δ pH 8.0 (dissolve 13.6 g of [monobasic potassium phosphate](#) in [water](#), adjust with 92.2 mL of [1 N sodium hydroxide VS](#) to a pH of 8.0, and dilute with [water](#) to 1000 mL); Δ (USP 1-Dec-2024) 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of [USP Ethacrynic Acid RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute suitably with *Medium*.

Instrumental conditions

Δ (See [Ultraviolet-Visible Spectroscopy \(857\)](#).) Δ (USP 1-Dec-2024)

Mode: UV

Analytical wavelength: 277 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ethacrynic acid ($C_{13}H_{12}Cl_2O_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of ethacrynic acid ($C_{13}H_{12}Cl_2O_4$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: Citrate buffer, pH 3.0 (dissolve 17.2 g of [citric acid](#) and 5.3 g of [sodium citrate dihydrate](#) in 1 L of [water](#), and adjust with Δ [1 N sodium hydroxide VS](#) Δ (USP 1-Dec-2024) or [1 M acetic acid TS](#) to a pH of 3.0 Δ Δ (USP 1-Dec-2024)); 900 mL, deaerated

Apparatus 2: 50 rpm

Time: 30 min

Δ Determine the percentage of the labeled amount of ethacrynic acid by using either the *Chromatographic procedure* or the *Spectrophotometric procedure*.

Chromatographic procedure

Buffer: Δ (USP 1-Dec-2024) 1% (v/v) [triethylamine](#) solution in [water](#) prepared as follows. Transfer a suitable aliquot of [triethylamine](#) to an appropriate volumetric flask containing 90% of the flask volume of [water](#). Adjust with [phosphoric acid](#) to a pH of 6.8. Δ Δ (USP 1-Dec-2024) Dilute with [water](#) to volume.

Mobile phase: [Acetonitrile](#) and *Buffer* (40:60)

Standard stock solution: Δ 0.3 Δ (USP 1-Dec-2024) mg/mL of [USP Ethacrynic Acid RS](#) prepared as follows. Transfer a portion of [USP Ethacrynic Acid RS](#) to a suitable volumetric flask and add [methanol](#) to 10% of the flask volume. Dilute with *Medium* to volume.

Standard solution: Δ (L/900) Δ (USP 1-Dec-2024) mg/mL of [USP Ethacrynic Acid RS](#) from the *Standard stock solution* in *Medium*, Δ where L is the label claim in mg/Tablet Δ (USP 1-Dec-2024)

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)