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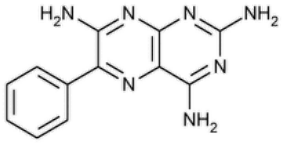
Triamterene



$C_{12}H_{11}N_7$ 253.26
2,4,7-Pteridinetriamine, 6-phenyl-;
2,4,7-Triamino-6-phenylpteridine;
6-Phenylpteridine-2,4,7-triamine CAS RN®: 396-01-0; UNII: WS821Z52LQ.

DEFINITION

Triamterene contains NLT 98.0% and NMT 102.0% of triamterene ($C_{12}H_{11}N_7$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197M▲ (CN 1-May-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: *Acetonitrile*, methanol, butylamine, and water (140:140:2:720). Sonicate to mix and adjust with acetic acid to a pH of 5.3.

Standard solution: 0.05 mg/mL of USP Triamterene RS in *Mobile phase*

Sample solution: 0.05 mg/mL of Triamterene in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 355 nm

Column: 4.0-mm × 25-cm; 5-µm packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 3 times the retention time of triamterene

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triamterene ($C_{12}H_{11}N_7$) in the portion of Triamterene taken:

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

r_U = peak response of triamterene from the *Sample solution*

r_S = peak response of triamterene from the *Standard solution*

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

C_U = concentration of Triamterene in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Organic Impurities**

Mobile phase and **Chromatographic system:** Proceed as directed in the *Assay*.

Diluent: To 50 mL of 0.1 N sodium hydroxide in a 500-mL volumetric flask, add 250 mL of acetonitrile and dilute with water to volume.

Standard stock solution 1: 0.25 mg/mL of USP Triamterene RS in *Mobile phase*

Standard stock solution 2: 0.1 mg/mL of USP Triamterene Related Compound A RS in *Diluent*. Sonication may be required for complete dissolution.

Standard stock solution 3: 0.1 mg/mL of USP Triamterene Related Compound B RS in *Diluent*. Sonication may be required for complete dissolution.

Standard stock solution 4: 0.1 mg/mL of USP Triamterene Related Compound C RS in *Diluent*. Sonication may be required for complete dissolution.

System suitability solution: 0.1 mg/mL of USP Triamterene RS from *Standard stock solution 1* and 0.01 mg/mL of USP Triamterene Related Compound B RS from *Standard stock solution 3* in *Mobile phase*

Sensitivity solution: 0.5 µg/mL of USP Triamterene RS in *Mobile phase* from *Standard stock solution 1*

Standard solution: 0.001 mg/mL each of USP Triamterene RS, USP Triamterene Related Compound A RS, USP Triamterene Related Compound B RS, and USP Triamterene Related Compound C RS from the respective *Standard stock solution* in *Mobile phase*

Sample solution: 1 mg/mL of Triamterene in *Mobile phase*. [Note—Sonication may be required to aid the dissolution.]

System suitability

Samples: *System suitability solution*, *Sensitivity solution*, and *Standard solution*

[Note—See *Table 1* for the relative retention times for triamterene related compound B and triamterene.]

Suitability requirements

Resolution: NLT 2.0 between triamterene related compound B and triamterene, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triamterene related compound A, triamterene related compound B, and triamterene related compound C in the portion of Triamterene taken:

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

r_U = peak response of each corresponding specified impurity from the *Sample solution*

r_S = peak response of each corresponding specified impurity from the *Standard solution*

C_S = concentration of each corresponding specified impurity in the *Standard solution* (mg/mL)

C_U = concentration of Triamterene in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Triamterene taken:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

r_S = peak response of triamterene from the *Standard solution*

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

C_U = concentration of Triamterene in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*. Reporting threshold: 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Triamterene related compound A	0.4	0.1
Triamterene related compound B	0.8	0.15
Triamterene	1.0	—
Triamterene related compound C	2.8	0.15
Any unspecified impurity	—	0.10
Total impurities	—	0.5

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry under vacuum at 105° for 2 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Triamterene RS

USP Triamterene Related Compound A RS

5-Nitrosopyrimidine-2,4,6-triamine.

$C_4H_6N_6O$ 154.13

USP Triamterene Related Compound B RS

2,7-Diamino-6-phenylpteridin-4-ol.

$C_{12}H_{10}N_6O$ 254.25

USP Triamterene Related Compound C RS

2,4-Diamino-6-phenylpteridin-7-ol.

$C_{12}H_{10}N_6O$ 254.25

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

Topic/Question	Contact	Expert Committee
TRIAMTERENE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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