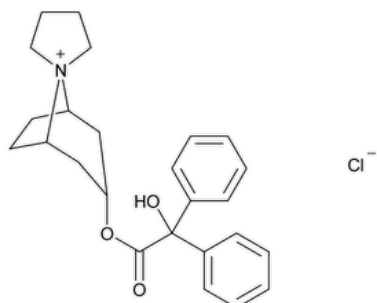


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Trospium Chloride



$C_{25}H_{30}ClNO_3$ 427.96

Spiro [8-azoniabicyclo[3.2.1]octane-8,1'-pyrrolidinium], 3-[(hydroxydiphenylacetyl)oxy]-, chloride, (1*R*,3*r*,5*S*);

(1*R*,3*r*,5*S*)-3-[(Hydroxydiphenylacetyl)oxy]spiro[8-azoniabicyclo[3.2.1]octane-8,1'-pyrrolidinium] chloride CAS RN®: 10405-02-4; UNII: 1E6682427E.

DEFINITION

Trospium Chloride contains NLT 98.0% and NMT 102.0% of trospium chloride ($C_{25}H_{30}ClNO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride \(191\)](#): Meets the requirements
- **C.** 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, triethylamine, phosphoric acid, and water (300:1:3:700)

System suitability solution: 0.01 mg/mL of [USP Trospium Chloride RS](#) and 0.003 mg/mL each of [USP Trospium Chloride Related Compound A RS](#) and [USP Trospium Chloride Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.6 mg/mL of [USP Trospium Chloride RS](#) in *Mobile phase*

Sample solution: 0.6 mg/mL of Trospium Chloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1. (Alternatively, a 4.6-mm × 25-cm column that contains 5-μm packing L7 may be used.)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

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

Suitability requirements

Resolution: NLT 3 between trospium chloride related compound B and trospium, *System suitability solution*

Relative standard deviation: NMT 0.85% for six replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trosipium chloride ($C_{25}H_{30}ClNO_3$) in the portion of Trosipium Chloride 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 Trosipium Chloride RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 1 g

Acceptance criteria: NMT 0.1%

• ORGANIC IMPURITIES

Mobile phase: Proceed as directed in the Assay.

Standard solution: 0.01 mg/mL of [USP Trosipium Chloride RS](#) and 0.003 mg/mL each of [USP Trosipium Chloride Related Compound A RS](#) and [USP Trosipium Chloride Related Compound B RS](#) in *Mobile phase*

Sample solution: 3.0 mg/mL of Trosipium Chloride in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay, except for the following parameters.

Injection volume: 20 μ L

Run time: NLT 3 times the retention time of trosipium

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3 between trosipium chloride related compound B and trosipium

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trosipium chloride related compound A and trosipium chloride related compound B in the portion of Trosipium Chloride taken:

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

r_U = peak response of trosipium chloride related compound A or trosipium chloride related compound B from the *Sample solution*

r_S = peak response of trosipium chloride related compound A or trosipium chloride related compound B from the *Standard solution*

C_S = concentration of trosipium chloride related compound A or trosipium chloride related compound B in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other individual impurity in the portion of Trosipium Chloride taken:

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

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

r_S = peak response of trosipium chloride related compound B from the *Standard solution*

C_S = concentration of [USP Trosipium Chloride Related Compound B RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: See [Table 1](#). The reporting level for impurities is 0.05%.

Table 1