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Trospium Chloride Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-trospium-chloride-tabs-20241227.

DEFINITION

Trospium Chloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of trospium chloride ($C_{25}H_{30}ClNO_3$).

IDENTIFICATION

• **A.** The retention time and UV spectrum of the major peak of the *Sample solution* correspond to those of the major peak of the *Standard solution,* as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, triethylamine, phosphoric acid, and water (350:1:3:650)

Standard solution: 0.1 mg/mL of USP Trospium Chloride RS in *Mobile phase*

Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 100 mg of trospium chloride, to a 100-mL volumetric flask. Add 75 mL of *Mobile phase*, and sonicate for about 30 min. Dilute with *Mobile phase* to volume. Further dilute with *Mobile phase* to obtain a solution having a nominal concentration of 0.1 mg/mL of trospium chloride. Pass through a suitable filter of 0.45-µm pore size, and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Column temperature: 40°

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of trospium chloride ($C_{25}H_{30}ClNO_3$) in the portion of Tablets taken:

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

r_U = peak response of trospium chloride from the *Sample solution*

r_S = peak response of trospium chloride from the *Standard solution*

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

C_U = nominal concentration of trospium chloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Test 1

Medium: 0.1 N hydrochloric acid; 1000 mL

Apparatus 2: 50 rpm

Time: 30 min

Mobile phase: Acetonitrile, triethylamine, phosphoric acid, and water (350:1:3:650)

Standard stock solution: 0.5 mg/mL of USP Trospium Chloride RS in *Mobile phase*

Standard solution: 0.02 mg/mL in *Medium* from the *Standard stock solution*

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

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm x 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Column temperature: 40°

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of trospium chloride ($C_{25}H_{30}ClNO_3$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 1000 mL

Tolerances: NLT 80% (Q) of the labeled amount of trospium chloride is dissolved.

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

Medium: 0.1 N hydrochloric acid; 1000 mL

Apparatus 2: 50 rpm

Time: 30 min

Mobile phase: Acetonitrile, triethylamine, phosphoric acid, and water (300:1:3:700)

Standard stock solution: 0.2 mg/mL of USP Trospium Chloride RS in *Medium*

Standard solution: 0.02 mg/mL in *Medium* from the *Standard stock solution*

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

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Columns

Guard: 4.0-mm × 4-cm; 5-µm packing L7

Analytical: 4.0-mm × 12.5-cm; 4-µm packing L7

Flow rate: 1.0 mL/min

Column temperature: 40°

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of trospium chloride ($C_{25}H_{30}ClNO_3$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 1000 mL

Tolerances: NLT 75% (Q) of the labeled amount of trospium chloride is dissolved.

▲**Test 3:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Mobile phase: Acetonitrile, triethylamine, phosphoric acid, and water (35: 0.1: 0.3: 65)

Standard stock solution: 0.5 mg/mL of USP Trospium Chloride RS in *Medium*. Sonicate to dissolve, if necessary.

Standard solution: 0.04 mg/mL of USP Trospium Chloride RS from the *Standard stock solution* in *Medium*

Sample solution: Pass the portion of the solution under test through a suitable filter of 0.45-µm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 50 µL

Run time: NLT 1.8 times the retention time of trospium

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of trospium chloride ($C_{25}H_{30}ClNO_3$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times (1/L) \times V \times 100$$

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

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

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

Tolerances: NLT 80% (Q) of the labeled amount of trospium chloride is dissolved.▲ (RB 1-Jan-2025)

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

IMPURITIES

• **Organic Impurities**

Mobile phase: Acetonitrile, triethylamine, phosphoric acid, and water (300:1:3:700)

System suitability solution: 0.01 mg/mL of USP Trospium Chloride RS, 0.003 mg/mL of USP Trospium Chloride Related Compound A RS, and 0.015 mg/mL of USP Trospium Chloride Related Compound B RS in *Mobile phase*

Standard solution: 0.003 mg/mL of USP Trospium Chloride RS in *Mobile phase*

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 150 mg of trospium chloride, to a 50-mL volumetric flask. Add 30 mL of *Mobile phase*, and sonicate for about 30 min. Dilute with *Mobile phase* to volume. Pass through a suitable filter of 0.45-µm pore size, and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 1.0 mL/min

Column temperature: 40°

Injection volume: 20 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 5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

r_S = peak response of trospium chloride from the *Standard solution*

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

C_U = nominal concentration of trospium chloride in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Nortropane benzilate (trospium chloride related compound B)	0.7	1.0	0.2
Trospium	1.0	—	—
Benzilic acid (trospium chloride related compound A)	1.9	1.7	0.2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Any other individual impurity	—	1.0	0.1
Total impurities	—	—	0.5

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, protected from light. Store at controlled room temperature.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩

USP Trospium Chloride RS

USP Trospium Chloride Related Compound A RS

Benzilic acid.

$C_{14}H_{12}O_3$ 228.24 CAS RN®: 76-93-7..

USP Trospium Chloride Related Compound B RS

Nortropane benzilate; (1*R*,3*r*,5*S*)-8-azabicyclo [3.2.1]octan-3-yl hydroxydiphenylacetate.

$C_{21}H_{23}NO_3$ 337.41

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

Topic/Question	Contact	Expert Committee
TROSPIUM CHLORIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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