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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- μ m pore size, and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Flow rate: 1.0 mL/min

Column temperature: 40°

Injection volume: 20 μ L

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 Trosipium 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 trosipium 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 trosipium 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 Trosipium 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 x 4-cm; 5-µm packing [L7](#)

Analytical: 4.0-mm x 12.5-cm; 4-µm packing [L7](#)

Flow rate: 1.0 mL/min

Column temperature: 40°