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Oxybutynin Chloride Tablets

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DEFINITION

Oxybutynin Chloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of $C_{22}H_{31}NO_3 \cdot HCl$.

IDENTIFICATION

• THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST (201)

Sample solution: Add a portion of powdered Tablets, equivalent to about 50 mg of oxybutynin chloride, to 10 mL of [chloroform](#). Mix for two minutes, and centrifuge. Use the supernatant layer.

Developing solvent system: [Methanol](#)

Visualization: Iodine vapor

ASSAY

• PROCEDURE

Solution A: [Methanol](#), [water](#), and [triethylamine](#) (800: 3200: 0.9). Adjust with [phosphoric acid](#) to a pH of 3.5 ± 0.05 .

Mobile phase: [Acetonitrile](#) and *Solution A* (1:4)

Standard solution: 0.05 mg/mL of [USP Oxybutynin Chloride RS](#) in *Mobile phase*

Sample solution: Transfer an amount of powdered Tablets (from NLT 20 Tablets) nominally equivalent to 50 mg of oxybutynin chloride to a 1000-mL volumetric flask. Add about 400 mL of *Mobile phase*, sonicate for about 10 min, shake by mechanical means for about 45 min, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 203 nm

Column: 4-mm × 30-cm; packing [L10](#)

Flow rate: 2 mL/min

Injection size: 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 $C_{22}H_{31}NO_3 \cdot HCl$ in the portion of Tablets 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 Oxybutynin Chloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Sample solution: Pass a portion of the solution under test through a suitable 0.45-μm filter. Dilute with *Medium* if necessary.

Analysis: Determine the amount of $C_{22}H_{31}NO_3 \cdot HCl$ dissolved using the method set forth in the Assay, making any necessary modifications to the concentration of the *Standard solution* to correspond to that of the solution under test and injecting 100 μL of both solutions.

Tolerances: NLT 80% (Q) of the labeled amount of $C_{22}H_{31}NO_3 \cdot HCl$ is dissolved.

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

Medium: 0.01 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 5 μg/mL of [USP Oxybutynin Chloride RS](#) in *Medium*. This solution is stable for 5 days at ambient conditions.

Sample solution: Pass a portion of the solution under test through a suitable 0.45-μm filter, discarding the first few mL.

Mobile phase: [Water](#), [acetonitrile](#), and [phosphoric acid](#) (760:240:1)

Chromatographic system

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

Mode: LC

Detector: UV 203 nm

Column: 4.6-mm × 7.5-cm; 3.5-μm packing [L7](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection size: 100 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxybutynin chloride 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 oxybutynin chloride in the *Standard solution*

L = Tablet label claim (mg)

V = volume of *Medium* (mL), 900

Tolerances: NLT 80% (Q) of the labeled amount of oxybutynin 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, degassed

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 0.01 mg/mL of [USP Oxybutynin Chloride RS](#) in *Medium*. Sonicate to dissolve, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size, discarding the first 5 mL of the filtrate.

Solution A: 0.05% [Trifluoroacetic acid](#) in [water](#)