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Ropinirole Extended-Release Tablets

DEFINITION

Ropinirole Extended-Release Tablets contain ropinirole hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of ropinirole free base ($C_{16}H_{24}N_2O$).

IDENTIFICATION

- A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- 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

Buffer: Dissolve 4.5 g of [dibasic sodium phosphate dihydrate](#) in 900 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 7.0. Dilute with [water](#) to 1 L.

Mobile phase: [Methanol](#) and *Buffer* (75:25)

Dilute phosphoric acid: Dissolve 0.7 mL of [phosphoric acid](#) in 1 L of [water](#).

Diluent: [Acetonitrile](#) and *Dilute phosphoric acid* (80:20)

System suitability solution: 0.1 mg/mL of [USP Ropinirole Hydrochloride RS](#) and 0.003 mg/mL of [USP Ropinirole Related Compound B RS](#) in *Diluent*. Sonication may be used to aid dissolution.

Standard solution: 0.11 mg/mL of [USP Ropinirole Hydrochloride RS](#) in *Diluent*. Sonication may be used to aid dissolution.

Sample solution: Nominally 0.05–0.2 mg/mL of ropinirole prepared as follows. Transfer NLT 5 Tablets to a suitable volumetric flask containing 75% of the flask volume of *Diluent*. Sonicate for NLT 30 min. Allow to cool to room temperature. Dilute with *Diluent* to volume. Pass a portion of the solution through a nylon filter of 0.45-μm pore size and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 12.5-cm; 5-μm packing [L7](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 1.5 times the retention time of ropinirole

System suitability

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

Suitability requirements

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

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ropinirole ($C_{16}H_{24}N_2O$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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

C_s = concentration of [USP Ropinirole Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of ropinirole in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of ropinirole free base, 260.37

M_{r2} = molecular weight of ropinirole hydrochloride, 296.84

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Solution A: 121.2 g/L of [trishydroxymethylaminomethane](#) in [water](#)

Buffer 1: Dissolve 2.1 g of [citric acid monohydrate](#) in 900 mL of [water](#). Adjust with *Solution A* to a pH of 4.0. Dilute with [water](#) to 1 L.

Buffer 2: Dissolve 3.9 g of [ammonium acetate](#) in 900 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5. Dilute with [water](#) to 1 L.

Medium: *Buffer 1*; 500 mL. Deaerate as appropriate.

Apparatus 2: 100 rpm with tablet holder. See [Figure 1](#).

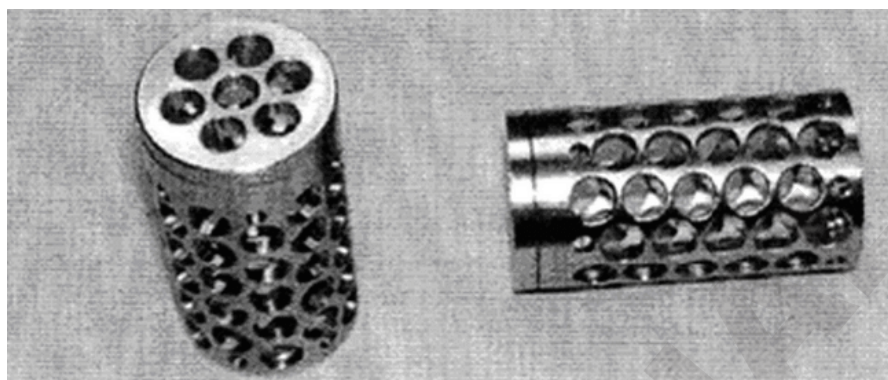


Figure 1. A 37-mm (length) × 19-mm (diameter) stainless steel sinker with screw cap drilled with seven 4-mm holes, bottom drilled with seven 5-mm holes, 12 longitudinal series of 5-mm holes alternately starting and ending with one 3-mm hole, polished electrochemically or with a suitably validated alternative.

Times: 2, 12, and 24 h

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer 2* (14:6:80)

Standard solution: ($L/400$) mg/mL of [USP Ropinirole Hydrochloride RS](#) in *Medium*, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 10- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.6-mm × 12.5-cm; 5- μ m packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 20 μ L for 12-mg Tablets; 100 μ L for all other strengths

Run time: NLT 2 times the retention time of ropinirole

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ropinirole ($C_{16}H_{24}N_2O$) dissolved at each time point (i):

$$\text{Result} = (r_u/r_s) \times C_s \times V \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Ropinirole Hydrochloride RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

M_{r1} = molecular weight of ropinirole free base, 260.37

M_{r2} = molecular weight of ropinirole hydrochloride, 296.84

Tolerances: See [Table 1](#).

Table 1

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 20
2	12	45–65
3	24	NLT 80

The percentages of the labeled amount of ropinirole ($C_{16}H_{24}N_2O$) dissolved at the times specified conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

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

Solution A: 121.2 g/L of [trishydroxymethylaminomethane](#) in [water](#)

Buffer 1: Dissolve 2.1 g of [citric acid monohydrate](#) and 11.7 mL of *Solution A* in 1000 mL of [water](#). Adjust with *Solution A* to a pH of 4.0.

Buffer 2: Dissolve 4.2 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [sodium hydroxide](#) to a pH of 6.5.

Medium: *Buffer 1*; 500 mL

Apparatus 2: 100 rpm

Times: 2, 6, 12, and 24 h

Mobile phase: [Acetonitrile](#) and *Buffer 2* (20:80)

Standard solution: ($L/500$) mg/mL of [USP Ropinirole Hydrochloride RS](#) in *Medium*, where L is the label claim in mg/Tablet

Sample solution: Centrifuge a portion of the solution under test.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 50 μL

Run time: NLT 2 times the retention time of ropinirole

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_p) of ropinirole ($C_{16}H_{24}N_2O$) in the sample withdrawn from the vessel at each time point (i):

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