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Orphenadrine Citrate Extended-Release Tablets

DEFINITION

Orphenadrine Citrate Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of orphenadrine citrate ($C_{18}H_{23}NO \cdot C_6H_8O_7$).

IDENTIFICATION

- **A.** 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: 5.8 g/L of monobasic ammonium phosphate. Adjust with phosphoric acid to a pH of 3.2.

Mobile phase: Acetonitrile and *Buffer* (40:60)

System suitability solution: 0.1 mg/mL of [USP Orphenadrine Citrate RS](#) and 0.01 mg/mL each of [USP Orphenadrine Related Compound B RS](#) and [USP Orphenadrine Related Compound C RS](#), in *Mobile phase*

Standard solution: 0.1 mg/mL of [USP Orphenadrine Citrate RS](#)

Sample stock solution: Nominally 0.5 mg/mL of orphenadrine citrate prepared as follows. Transfer a quantity of powder equivalent to NLT 100 mg of orphenadrine citrate, from finely powdered Tablets (NLT 20), to a suitable volumetric flask. Add 50% of the flask volume of *Mobile phase*. Sonicate for 5 min and shake for 15 min. Dilute with *Mobile phase* to volume. Pass through a suitable filter.

Sample solution: Nominally 0.1 mg/mL of orphenadrine citrate in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 3.9-mm × 30-cm; 10-μm L1 packing

Flow rate: 2 mL/min

Injection volume: 20 μL

System suitability

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

Suitability requirements

Resolution: NLT 1.2 between orphenadrine and orphenadrine related compound C; NLT 2.0 between orphenadrine citrate and orphenadrine related compound B, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of orphenadrine citrate ($C_{18}H_{23}NO \cdot C_6H_8O_7$) 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 Orphenadrine Citrate RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS• [DISSOLUTION \(711\)](#)**Test 1****Medium:** Water; 900 mL, deaerated**Apparatus 2:** 50 rpm**Times:** 1, 2, 6, and 12 h**Buffer:** 5.8 g/L of monobasic ammonium phosphate in water**Mobile phase:** Acetonitrile and *Buffer* (40:60). Adjust with phosphoric acid to a pH of 3.2 ± 0.1 .**Standard stock solution:** 1 mg/mL of [USP Orphenadrine Citrate RS](#) in *Mobile phase*. Sonication may be used to promote dissolution.**Standard solution** 0.1 mg/mL of [USP Orphenadrine Citrate RS](#) in *Medium* from a suitable volume of *Standard stock solution* and *Medium***Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size and discard the first few mL of the filtrate.**Chromatographic system**(See [Chromatography \(621\)](#), *System Suitability*.)**Mode:** LC**Detector:** UV 225 nm**Column:** 3.9-mm $\times$ 30-cm; 10- μ m packing L1**Flow rate:** 2 mL/min**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 concentration (C_i) of orphenadrine citrate ($C_{18}H_{23}NO \cdot C_6H_8O_7$) dissolved in the portion of the sample withdrawn at each time point (i) (mg/mL):

$$C_i = (r_U/r_S) \times C_S$$

 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)Calculate the percentage of the labeled amount of orphenadrine citrate ($C_{18}H_{23}NO \cdot C_6H_8O_7$) dissolved at each time point (i):

$$\text{Result}_1 = C_i \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

$$\text{Result}_3 = \{C_3 \times [V - (2 \times V_S)] + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$$\text{Result}_4 = \{C_4 \times [V - (3 \times V_S)] + [(C_3 + C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

 C_i = concentration of orphenadrine citrate in the portion of the sample withdrawn at time point (i) (mg/mL) V = volume of *Medium*, 900 mL L = label claim (mg/Tablet) V_S = volume of the *Sample solution* withdrawn at each time point (mL)**Tolerances:** See [Table 1](#).**Table 1**