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Prazosin Hydrochloride Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-prazosin-hcl-caps-20230526>.

DEFINITION

Prazosin Hydrochloride Capsules contain an amount of prazosin hydrochloride ($C_{19}H_{21}N_5O_4 \cdot HCl$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$).

[**CAUTION**—Care should be taken to prevent inhaling particles of prazosin hydrochloride and to prevent it contacting any part of the body.]

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

ASSAY

• PROCEDURE

Mobile phase: [Methanol](#), [glacial acetic acid](#), and [water](#) (70:1:30). Add 0.2 mL of [diethylamine](#) to 1 L of *Mobile phase*, such that the retention time of prazosin is 6–10 min.

Solution A: To 300 mL of water add 0.85 mL of [hydrochloric acid](#) in a 1000-mL volumetric flask. Dilute with [methanol](#) to volume, and mix.

Transfer 300 mL of this solution to a 500-mL volumetric flask, and dilute with [methanol](#) to volume.

Standard stock solution: 0.2 mg/mL of [USP Prazosin Hydrochloride RS](#) in *Solution A*

Standard solution: 0.01 mg/mL of [USP Prazosin Hydrochloride RS](#), prepared as follows. Transfer 5 mL of *Standard stock solution* to a 100-mL volumetric flask, add 45.0 mL of *Solution A*, diluted with [methanol](#) to volume, and mix.

Sample stock solution: Nominally 0.02 mg/mL of prazosin in *Solution A*, prepared as follows. Transfer a portion of the contents of NLT 20 Capsules, equivalent to about 1 mg of prazosin, to a glass-stoppered flask containing 50.0 mL of *Solution A*, and shake by mechanical means for 30 min. Place the flask in an ultrasonic bath for 30 min, cool to room temperature, and pass the contents through a suitable filter of 5-µm or finer pore size.

Sample solution: Nominally 0.01 mg/mL of prazosin prepared as follows. Transfer 25.0 mL of *Sample stock solution* to a 50-mL volumetric flask, and dilute with [methanol](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing [L3](#)

Flow rate: 0.6 mL/min

Injection volume: 5 µL

Run time: NLT 2 times the retention time of prazosin

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$) in the portion of Capsules taken:

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

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

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

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

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

M_{r1} = molecular weight of prazosin, 383.41

M_{r2} = molecular weight of prazosin hydrochloride, 419.87

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

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

Test 1

Medium: 0.1 N [hydrochloric acid](#) containing 3% ▲[sodium dodecyl sulfate](#)▲ (RB 9-May-2023) ; 900 mL

Apparatus 1: 100 rpm

Time: 60 min

Standard solution: Known concentration of [USP Prazosin Hydrochloride RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$) dissolved, using the procedure in the Assay.

Tolerances: NLT 75% (Q) of the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$) is dissolved.

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

Medium: Prepare as directed in *Test 1*.

Apparatus 1: 10-mesh basket; 100 rpm

Time: 30 min

Buffer: 3.4 g/L of [sodium dihydrogen phosphate](#). Adjust with 10% [sodium hydroxide](#) solution to a pH of 7.5.

Mobile phase: [Methanol](#) and *Buffer* (50:50)

Standard stock solution: 120 µg/mL of [USP Prazosin Hydrochloride RS](#), prepared as follows. In a suitable volumetric flask, dissolve a suitable amount of [USP Prazosin Hydrochloride RS](#) in 20% of the total volume of [methanol](#). Dilute with *Medium* to volume.

Standard solution: ($L/900$) mg/mL of [USP Prazosin Hydrochloride RS](#) in *Medium*, where L is the label claim in mg/Capsule, from *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 254 nm

Column: 4.6-mm × 10-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 60 µL

Run time: NLT 2 times the retention time of prazosin

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 the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$) dissolved:

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