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Alfuzosin Hydrochloride Extended-Release Tablets

DEFINITION

Alfuzosin Hydrochloride Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of alfuzosin hydrochloride ($C_{19}H_{27}N_5O_4 \cdot HCl$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K.

Sample: Grind 4 Tablets, and add 20 mL of [water](#). [NOTE—When analyzing multi-layer Tablets, isolate the layer containing alfuzosin hydrochloride using a suitable tool.] Add 20 mL of [strong ammonia solution](#). Extract with 20 mL of [methylene chloride](#), and separate the organic layer. Repeat the extraction successively with 20 mL, then with 10 mL of [methylene chloride](#). Wash the combined organic layers with 20 mL of [water](#). Dry the organic solution using a phase separation filter. Take 2.0 mL of the dried organic solution, and mix with 200 mg of finely ground [potassium bromide](#). Evaporate the [methylene chloride](#) at 60°, then at 105° for 30 min. Make a disk. Alternatively, evaporate [methylene chloride](#) from the dried organic solution at 60°, then at 105° for 30 min. Perform the IR spectrum.

Acceptance criteria: The maxima of the spectrum obtained from the *Sample* correspond in position and relative intensity to those obtained from [USP Alfuzosin Hydrochloride RS](#), treated in the same manner as the *Sample*, beginning with “add 20 mL of [water](#).”

- **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

Solution A: 5.0 mL of [perchloric acid](#) in 900 mL of [water](#). Adjust with 2 M sodium hydroxide to a pH of 3.5, and dilute with [water](#) to 1000 mL.

Mobile phase: [Acetonitrile](#), [tetrahydrofuran](#), and *Solution A* (20:1:80)

Diluent: [0.01 N hydrochloric acid](#)

Standard stock solution: 0.15 mg/mL of [USP Alfuzosin Hydrochloride RS](#) in [methanol](#)

Standard solution: 0.03 mg/mL of [USP Alfuzosin Hydrochloride RS](#) in *Diluent* from the *Standard stock solution*

Sample stock solution: Place a suitable number of Tablets into a suitable volumetric flask to obtain a solution having a concentration of 0.16 mg/mL of alfuzosin hydrochloride. Add 80% of the flask volume of [methanol](#), and stir for at least 1 h using a magnetic stirrer. Add 10% of the flask volume of *Diluent*, mix, and allow it to cool to room temperature. Dilute the resulting suspension with [methanol](#) to volume, stir, and allow to settle for 30 min.

Sample solution: 0.03 mg/mL of alfuzosin hydrochloride in *Diluent* from the *Sample stock solution* supernatant. Pass through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–1.5 for alfuzosin

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of alfuzosin hydrochloride ($C_{19}H_{27}N_5O_4 \cdot HCl$) 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 Alfuzosin Hydrochloride 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

• [DISSOLUTION \(711\)](#).

Test 1

Medium: [0.01 N hydrochloric acid](#); 500 mL

Apparatus 2: 100 rpm, with Tablet holder (see [Figure 1](#))

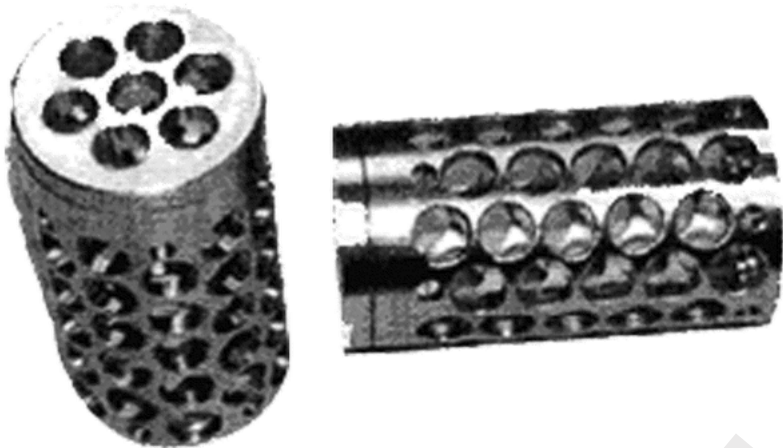


Figure 1. 37.5-mm (l) × 20-mm (d) stainless steel cylinders are used as sample holders. The cylinders contain screw caps drilled with seven 4.5-mm holes. Seven 4.5-mm holes are drilled in the bottom, and 12 longitudinal series of five 5-mm holes are drilled on the cylinders, alternatively starting and ending with one 1.7-mm hole.

Times: 1, 6, 12, and 20 h

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

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

Detector: UV 330 nm

Blank: *Medium*

Path length: 1 cm

Tolerances: See [Table 1](#).

Table 1

Level	Time (h)	Amount Dissolved (%)
L1		Each Tablet:
	1	10–20
	6	40–55
	12	65–85
	20	NLT 85
L2		Average of 12 Tablets complies with L1 and each Tablet:
	1	9–22
	6	36–61

Level	Time (h)	Amount Dissolved (%)
	12	59–94
	20	NLT 77
L3		Average of 24 Tablets complies with L1, NMT 2 Tablets outside L2, and all Tablets within:
	1	8–24
	6	32–66
	12	52–102
	20	NLT 68

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: 100 rpm

Times: 1, 3, 12, and 24 h

Buffer: Dilute 5.0 mL of [perchloric acid](#) in 900 mL of [water](#), adjust with diluted sodium hydroxide (0.1 g/mL) to a pH of 3.5 ± 0.5 , and dilute with [water](#) to 1 L.

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

Standard stock solution: 0.28 mg/mL of [USP Alfuzosin Hydrochloride RS](#), prepared as follows. In a 200-mL volumetric flask dissolve 55.5 mg of [USP Alfuzosin Hydrochloride RS](#) in 5 mL of [methanol](#), sonicate to dissolve, and dilute with *Medium* to volume.

Standard solution: 0.011 mg/mL of [USP Alfuzosin Hydrochloride RS](#) in *Medium* from the *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter. Replace the portion of solution withdrawn with an equal volume of *Medium*.

Chromatographic system

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

Mode: LC

Detector: UV 244 nm

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

Column temperature: 30°

Flow rate: 1.2 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 3000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of alfuzosin hydrochloride ($C_{19}H_{27}N_5O_4 \cdot HCl$) in the sample withdrawn from the vessel at each time point (i):

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

Calculate the percentage of the labeled amount of alfuzosin hydrochloride ($C_{19}H_{27}N_5O_4 \cdot HCl$) dissolved at each time point (i):

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

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