Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Nov-2021
Document Type: USP Monographs
DocId: GUID-3D905D14-737A-40D4-8D1A-454DBF0DBC33_3_en-US
DOI: https://doi.org/10.31003/USPNF_M892_03_01
DOI Ref: s799y

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*)

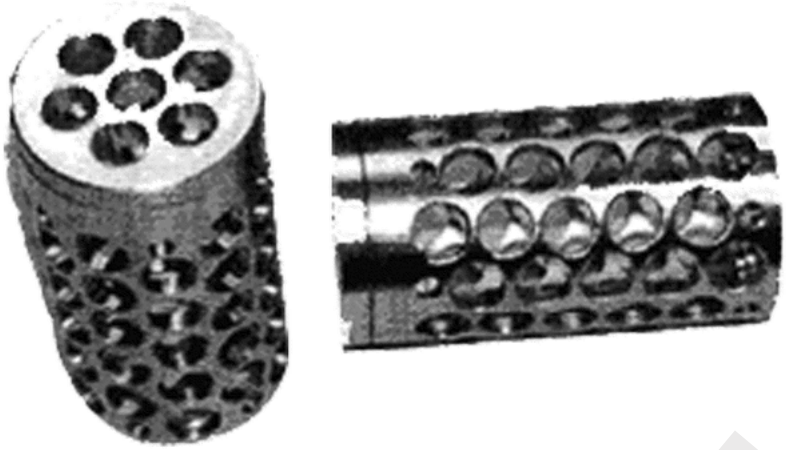

Figure 1. 37.5-mm (l) × 20-mm (d) stainless steel cylinders are used as sample holders. The cylinders contain screw caps drilled with seven 4.5-mm holes. Seven 4.5-mm holes are drilled in the bottom, and 12 longitudinal series of five 5-mm holes are drilled on the cylinders, alternatively starting and 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 (%)
		Each Tablet:
	1	10–20
	6	40–55
	12	65–85
L1	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):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

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

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

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

C_i = concentration of alfuzosin hydrochloride in the portion of sample withdrawn at the specified time point (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 and replaced with *Medium* (mL)

Tolerances: See *Table 2*.

Table 2

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 20
2	3	15–35
3	12	50–70
4	24	NLT 80

The percentages of the labeled amount of alfuzosin hydrochloride dissolved at the times specified conform to *Dissolution ⟨711⟩, Acceptance Table 2*.

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: 0.25% sodium dodecyl sulfate in 0.05 M sodium phosphate buffer, pH 6.8 (2.5 g/L of sodium dodecyl sulfate, 6.9 g/L of monobasic sodium phosphate monohydrate, and 0.83 g/L of sodium hydroxide in water previously degassed with helium. Adjust with either phosphoric acid or 1 N sodium hydroxide to a pH of 6.8 ± 0.05); 900 mL

Apparatus 1: 100 rpm

Times: 1, 6, 12, and 24 h

Standard stock solution: 1.1 mg/mL of USP Alfuzosin Hydrochloride RS in methanol

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.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV-Vis

Analytical wavelength: 331 nm, background correction at 490 nm

Blank: *Medium*

Cell: 1.0 cm

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result}_i = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium* (mL)

L = label claim (mg/Tablet)

Tolerances: See *Table 3*.

Table 3

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 15
2	6	20–40
3	12	45–70
4	24	NLT 80

The percentages of the labeled amount of alfuzosin hydrochloride dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

Test 4: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 100 rpm

Times: 1, 6, 12, and 20 h

Standard solution: 0.01 mg/mL of USP Alfuzosin Hydrochloride RS in *Medium*

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

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 245 nm

Blank: *Medium*

Path length: 0.2 cm

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*):

$$\text{Result}_i = (A_U/A_S) \times C_S$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of 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*):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

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

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

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

C_i = concentration of alfuzosin hydrochloride in the portion of sample withdrawn at the specified time point (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 4*.

Table 4

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 30
2	6	40–60
3	12	65–85
4	20	NLT 80

The percentages of the labeled amount of alfuzosin hydrochloride dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

Test 5: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 5*.

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 100 rpm

Times: 1, 3, 6, 12, and 20 h

Buffer: Add 1 mL of triethylamine in 1000 mL of water. Adjust with phosphoric acid to a pH of 2.5 ± 0.05. Pass through a suitable filter of 0.45-µm pore size.

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

Standard stock solution: 0.55 mg/mL of USP Alfuzosin Hydrochloride RS. Prepare by transferring a portion of USP Alfuzosin Hydrochloride RS to a suitable flask. Add methanol to 20% of the flask volume, and sonicate at room temperature to dissolve. Dilute with *Medium* to volume.

Standard solution: 0.011 mg/mL of USP Alfuzosin Hydrochloride RS in *Medium* from the *Standard stock solution.* Pass through a suitable filter of 0.45-µm pore size.

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 245 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 2000 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*):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

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

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

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

$$Result_5 = (\{C_5 \times [V - (4 \times V_S)]\} + [(C_4 + C_3 + C_2 + C_1) \times V_S]) \times (1/L) \times 100$$

C_i = concentration of alfuzosin hydrochloride in the portion of sample withdrawn at the specified time point (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 5*.

Table 5

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 20
2	3	20–40
3	6	35–55
4	12	60–80
5	20	NLT 80

The percentages of the labeled amount of alfuzosin hydrochloride dissolved at the times specified conform to *Dissolution ⟨711⟩, Acceptance Table 2*.

Test 6: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 6*.

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 100 rpm. Adjust the paddle height to 4.5 cm above the bottom of the vessel and use a 10# mesh basket as sinker.

Times: 1, 6, 12, and 20 h

Buffer: 2.3 g/L of anhydrous dibasic sodium phosphate and 1.75 g/L of monobasic potassium phosphate

Mobile phase: Acetonitrile and *Buffer* (50:50)

Standard stock solution: 0.45 mg/mL of USP Alfuzosin Hydrochloride RS. Prepare by transferring a portion of USP Alfuzosin Hydrochloride RS to a suitable flask. Add 20% of the flask volume of water. 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 with the same volume of *Medium*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 3500 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*):

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

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*):

$$Result_1 = C_1 \times V \times (1/L) \times 100$$

$$Result_2 = [(C_2 \times V) + (C_1 \times V_S)] \times (1/L) \times 100$$

$$Result_3 = \{(C_3 \times V) + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$$Result_4 = \{(C_4 \times V) + [(C_3 + C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

C_i = concentration of alfuzosin hydrochloride in the portion of sample withdrawn at the specified time point (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 and replaced with *Medium* (mL)

Tolerances: See *Table 6*.

Table 6

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 30
2	6	45–65
3	12	70–90
4	20	NLT 85

The percentages of the labeled amount of alfuzosin hydrochloride dissolved at the times specified conform to *Dissolution ⟨711⟩, Acceptance Table 2*.

Test 7: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 7*.

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 100 rpm with sinker; see *Dissolution ⟨711⟩, Figure 2a*.

Times: 1, 6, 12, and 20 h

Solution A: 500 g/L of sodium hydroxide

Solution B: 100 g/L of sodium hydroxide

Buffer: Add 5 mL of perchloric acid in 1000 mL of water. Adjust with *Solution A* to a pH of 2.5, then adjust with *Solution B* to a pH of 3.50 ± 0.05. Pass through a suitable filter of 0.45-µm pore size.

Mobile phase: Acetonitrile and *Buffer* (24:76)

Standard solution: 0.01 mg/mL of USP Alfuzosin Hydrochloride RS in *Medium*

Sample solution: Centrifuge or pass a portion of the solution under test through a suitable filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm × 5-cm; 3-µm packing L7

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: NLT 1.5 times the retention time of alfuzosin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

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):

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

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):

$$Result_1 = C_1 \times V \times (1/L) \times 100$$

$$Result_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

$$Result_3 = (\{C_3 \times [V - (2 \times V_S)]\} + [(C_2 + C_1) \times V_S]) \times (1/L) \times 100$$

$$Result_4 = (\{C_4 \times [V - (3 \times V_S)]\} + [(C_3 + C_2 + C_1) \times V_S]) \times (1/L) \times 100$$

C_i = concentration of alfuzosin hydrochloride in the portion of sample withdrawn at the specified time point (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 7*.

Table 7

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 25
2	6	40–60
3	12	65–85
4	20	NLT 85

The percentages of the labeled amount of alfuzosin hydrochloride dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

Change to read:

• **Organic Impurities**

Solution A, Mobile phase, Diluent, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability stock solution: 0.4 mg/mL of USP Alfuzosin System Suitability Mixture A RS in methanol

System suitability solution: 0.03 mg/mL of USP Alfuzosin System Suitability Mixture A RS in *Diluent* from the *System suitability stock solution*

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*

System suitability

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

Suitability requirements

Resolution: NLT 1.0 between alfuzosin and the furamide analog; NLT 1.0 between deacylated alfuzosin and the *N*-formyl analog, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

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

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of alfuzosin from the ▲*Standard*▲ *(ERR 1-Nov-2021)* *solution*

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

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

Acceptance criteria: See *Table 8.*

Table 8

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Deacylated alfuzosin[a]	0.46	0.40
N-Formyl analog[b]	0.50	0.30
Alfuzosin	1.0	—
Furamide analog[c]	1.18	—[d]
Any individual unspecified impurity	—	0.20
Total impurities	—	0.80

[a] N^2-(3-Aminopropyl)-6,7-dimethoxy-N^2-methylquinazoline-2,4-diamine.

[b] *N*-[3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl]formamide.

[c] *N*-{3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl}furan-2-carboxamide.

[d] Furamide analog, a component of USP Alfuzosin System Suitability Mixture A RS, is not a specified impurity.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Protect from light and moisture. Store at controlled room temperature.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩

USP Alfuzosin Hydrochloride RS

USP Alfuzosin System Suitability Mixture A RS

Furamide analog: *N*-{3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl}furan-2-carboxamide. $C_{19}H_{23}N_5O_4$ 385.42

Deacylated alfuzosin: N^2-(3-Aminopropyl)-6,7-dimethoxy-N^2-methylquinazoline-2,4-diamine. $C_{14}H_{21}N_5O_2$ 291.35

N-Formyl analog: *N*-[3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl]formamide. $C_{15}H_{21}N_5O_3$ 319.36

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ALFUZOSIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(1)

Current DocID: GUID-3D905D14-737A-40D4-8D1A-454DBF0DBC33_3_en-US

DOI: https://doi.org/10.31003/USPNF_M892_03_01

DOI ref: s799y