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Moxifloxacin Tablets

DEFINITION

Moxifloxacin Tablets contain an amount of Moxifloxacin Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$).

IDENTIFICATION

• **A.** The UV absorption spectrum of the *Sample solution* exhibits maxima at the same wavelength as that of the *Standard solution*, as obtained in the *Dissolution* test.

• **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: 1.36 g/L of monobasic potassium phosphate in water. Add 2 mL of triethylamine for each liter of the solution and adjust with phosphoric acid to a pH of 1.9.

Solution A: Methanol, *n*-propyl alcohol, and *Buffer* (300:34:666)

Mobile phase: Acetonitrile and *Solution A* (50:1000)

Diluent: Methanol and *Buffer* (20:80)

Standard solution: 0.09 mg/mL of USP Moxifloxacin Hydrochloride RS in *Diluent*. Sonicate, if necessary, to dissolve.

Sample stock solution: Nominally 4 mg/mL of moxifloxacin prepared as follows. Transfer NLT 5 Tablets to an appropriate volumetric flask. Add *Diluent* to about 40% of the final volume of the flask and sonicate for about 30 min with intermittent shaking. Dilute with *Diluent* to volume.

Sample solution: 0.08 mg/mL of moxifloxacin prepared as follows. Centrifuge a portion of the *Sample stock solution* and pipette 5 mL of the supernatant into a 250-mL volumetric flask. Dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 293 nm

Column: 4.6-mm × 25-cm; 5-µm packing L11

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: 10 min

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 percentage of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$) 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 moxifloxacin from the *Sample solution*

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

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

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

M_{r1} = molecular weight of moxifloxacin, 401.43

M_{r2} = molecular weight of moxifloxacin hydrochloride, 437.89

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 N hydrochloric acid; 900 mL, degassed

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 9 µg/mL of USP Moxifloxacin Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution through a suitable filter of 0.45-µm pore size. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Blank: *Medium*

Instrumental conditions

Mode: UV

Analytical wavelength: 296 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times (M_{r1}/M_{r2}) \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

M_{r1} = molecular weight of moxifloxacin, 401.43

M_{r2} = molecular weight of moxifloxacin hydrochloride, 437.89

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*, if applicable

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of moxifloxacin ($C_{21}H_{24}FN_3O_4$) is dissolved.

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

IMPURITIES

Change to read:

• **Organic Impurities**

Buffer: 1.5 g/L of ▲tetrabutylammonium▲ (ERR 1-Oct-2024) hydrogen sulfate and 1 g/L of potassium dihydrogen phosphate in water. Add 2 mL of phosphoric acid for each liter of the solution and adjust with triethylamine to a pH of 2.5. Pass through a suitable filter of 0.45-µm pore size.

Solution A: Methanol and *Buffer* (20:80)

Solution B: Methanol and *Buffer* (80:20)

Solution C: 0.5 g/L of ▲tetrabutylammonium▲ (ERR 1-Oct-2024) hydrogen sulfate and 1 g/L of monobasic potassium phosphate in water. Add 2 mL of phosphoric acid for each liter of the solution. Pass through a suitable filter of 0.45-µm pore size.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
22	95	5
39	30	70
52	30	70

Time (min)	Solution A (%)	Solution B (%)
53	0	100
58	0	100
58.1	95	5
70	95	5

Diluent: *Solution C* and 0.1 N sodium hydroxide (1000:10)

Impurity stock solution: 0.02 mg/mL each of USP Moxifloxacin Related Compound F RS and USP Moxifloxacin Related Compound A RS in acetonitrile

System suitability solution: 0.3 mg/mL of USP Moxifloxacin Hydrochloride RS and 0.3 µg/mL each of USP Moxifloxacin Related Compound F RS and USP Moxifloxacin Related Compound A RS in *Diluent* prepared as follows. Transfer 82 mg of USP Moxifloxacin Hydrochloride RS to a 250-mL volumetric flask and add 4.0 mL of *Impurity stock solution*. Dilute with *Diluent* to volume.

Standard solution: 3.3 µg/mL of USP Moxifloxacin Hydrochloride RS in *Diluent*

Sample solution: Nominally 0.33 mg/mL of moxifloxacin hydrochloride in *Diluent* prepared as follows. Transfer an amount equivalent to 82 mg of moxifloxacin hydrochloride from finely powdered Tablets (NLT 10) to a 250-mL volumetric flask. Add about 150 mL of *Diluent* and sonicate for 30 min with intermittent shaking. Dilute with *Diluent* to volume. Centrifuge a portion of the solution and pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 293 and 317 nm

Column: 4.0-mm × 25-cm; 5-µm packing L11

Column temperature: 50°

Flow rate: 1.1 mL/min

Injection volume: 25 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between moxifloxacin related compound F and moxifloxacin, *System suitability solution* at 293 nm

Peak-to-valley ratio: NLT 1.5 between moxifloxacin and moxifloxacin related compound A, *System suitability solution* at 293 nm

Tailing factor: NMT 2.0, *Standard solution* at 293 nm

Relative standard deviation: NMT 10.0%, *Standard solution* at 293 nm

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

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

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

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

F = relative response factor for each impurity (see *Table 2*)

Acceptance criteria: See *Table 2*. Disregard the peaks eluting before 3 min, after the 8-methoxy quinolonic ethyl ester peak, and any peak less than 0.05%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Wavelength (nm)	Acceptance Criteria, NMT (%)
Moxifloxacin related	0.82	1.0	293	[a]

Name	Relative Retention Time	Relative Response Factor	Wavelength (nm)	Acceptance Criteria, NMT (%)
compound F				
Moxifloxacin	1.0	—	293/317	—
Moxifloxacin related compound A	1.1	0.53	293	—[a]
Moxifloxacin related compound B[b]	1.26	0.77	317	—[a]
Moxifloxacin related compound C[c]	1.33	1.0	293	—[a]
Moxifloxacin related compound D[d]	1.38	0.76	293	—[a]
Moxifloxacin related compound E[e]	1.49	0.26	293	—[a]
8-Hydroxy quinolonic acid derivative[f]	1.72	1.3	293	—[a]
8-Methoxy quinolonic acid derivative[g]	1.89	1.9	317	—[a]
8-Methoxy quinolonic ethyl ester[h]	1.93	1.6	317	—[a]
Any other individual impurity	—	1.0	293	0.2
Total impurities	—	—	293/317	0.75

[a] For identification only. These are process related impurities monitored in the drug substance and not included in the total impurities calculation.

[b] 1-Cyclopropyl-6,8-dimethoxy-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.

[c] 1-Cyclopropyl-8-ethoxy-6-fluoro-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.

[d] 1-Cyclopropyl-8-fluoro-6-methoxy-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.

[e] 1-Cyclopropyl-6-fluoro-8-hydroxy-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.

[f] 1-Cyclopropyl-6,7-difluoro-8-hydroxy-4-oxo-3-quinolinecarboxylic acid.

[g] 1-Cyclopropyl-6,7-difluoro-8-methoxy-4-oxo-3-quinolinecarboxylic acid.

[h] Ethyl 1-cyclopropyl-6,7-difluoro-8-methoxy-4-oxo-3-quinolinecarboxylate.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers and store at controlled room temperature. Avoid high humidity.
- **USP Reference Standards** ⟨11⟩
  USP Moxifloxacin Hydrochloride RS

USP Moxifloxacin Related Compound A RS

1-Cyclopropyl-6,8-difluoro-1,4-dihydro-7-[(4a*S*,7a*S*)-octahydro-6*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid.

$C_{20}H_{21}F_2N_3O_3$ 389.40

USP Moxifloxacin Related Compound F RS

1-Cyclopropyl-6-fluoro-8-methoxy-7-[(4a*S*,7a*S*)-1-methylhexahydro-1*H*-pyrrolo[3,4-*b*]pyridin-6(2*H*)-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

$C_{22}H_{26}FN_3O_4$ 415.46

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

Topic/Question	Contact	Expert Committee
MOXIFLOXACIN TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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