

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Oct-2024
Document Type: USP Monographs
DocId: GUID-0C7776B8-FCDB-4943-9F2F-49BE8E1790A6_2_en-US
DOI: https://doi.org/10.31003/USPNF_M54945_02_01
DOI Ref: 1cr94

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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