

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2024
 Document Type: USP Monographs
 DocId: GUID-481D2DA5-A464-4292-A908-D7116375F210_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M58360_02_01
 DOI Ref: 33ckb

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Ofloxacin Tablets

DEFINITION

Ofloxacin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of ofloxacin ($C_{18}H_{20}FN_3O_4$).

IDENTIFICATION

Change to read:

• **A.** (USP 1-Dec-2024) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. (USP 1-Dec-2024)

ASSAY

Change to read:

PROCEDURE

Buffer: (USP 1-Dec-2024) Dissolve 2.72 g/L (USP 1-Dec-2024) of [monobasic potassium phosphate](#) in [water](#). Adjust with diluted [phosphoric acid](#) to a pH of 3.3. (USP 1-Dec-2024)

Mobile phase: [Acetonitrile](#) and **Buffer** (12:88) (USP 1-Dec-2024)

Diluent 1: [Methanol](#) and [glacial acetic acid](#) (75:25) (USP 1-Dec-2024)

Diluent 2: [Acetonitrile](#) and [water](#) (10:90) (USP 1-Dec-2024)

Standard stock solution: 1 mg/mL of [USP Ofloxacin RS](#) in *Diluent 1*

Standard solution: 0.02 mg/mL (USP 1-Dec-2024) of [USP Ofloxacin RS](#) from the *Standard stock solution* in *Diluent 2*

Sample stock solution: Nominally 1 mg/mL of ofloxacin from Tablets prepared as follows. Transfer a suitable portion of ofloxacin from powdered Tablets to a suitable volumetric flask. Add 70% of the flask volume of *Diluent 1*, sonicate for 20 min, and dilute with *Diluent 1* to volume. Pass the solution through a suitable filter of 0.45-μm pore size, and collect the filtrate. (USP 1-Dec-2024)

Sample solution: Nominally 0.02 mg/mL of ofloxacin from the *Sample stock solution* in *Diluent 2*. (USP 1-Dec-2024)

Chromatographic system

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

Mode: LC

Detector: UV 294 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm. (USP 1-Dec-2024)

Column: 4.6-mm × 10-cm; 3.5-μm (USP 1-Dec-2024) packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 1.5 times the retention time of the ofloxacin peak (USP 1-Dec-2024)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0% (USP 1-Dec-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲the labeled amount of ▲(USP 1-Dec-2024) ofloxacin ($C_{18}H_{20}FN_3O_4$) in the portion of Tablets taken:

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

r_U = peak response ▲of ofloxacin ▲(USP 1-Dec-2024) from the *Sample solution*

r_S = peak response ▲of ofloxacin ▲(USP 1-Dec-2024) from the *Standard solution*

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

C_U = nominal concentration of ▲ofloxacin in ▲(USP 1-Dec-2024) the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

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

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard stock solution: 0.44 mg/mL of [USP Ofloxacin RS](#) in [methanol](#)

Standard solution: ▲0.0088 mg/mL ▲(USP 1-Dec-2024) of [USP Ofloxacin RS](#) from the *Standard stock solution* ▲in ▲(USP 1-Dec-2024) *Medium*

Sample solution: Pass a portion of the solution under test through a suitable ▲filter of ▲(USP 1-Dec-2024) 0.45-μm ▲pore size. ▲(USP 1-Dec-2024)

Dilute a portion of the filtrate with *Medium* to obtain a final theoretical concentration of ▲0.0088 mg/mL ▲(USP 1-Dec-2024) assuming complete dissolution of the label claim.

Spectrometric conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV-Vis

Analytical wavelength: 294 nm

▲**Path length:** ▲(USP 1-Dec-2024) 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲the labeled amount of ▲(USP 1-Dec-2024) ofloxacin ($C_{18}H_{20}FN_3O_4$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

C_S = concentration of ofloxacin in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of ofloxacin ($C_{18}H_{20}FN_3O_4$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

Change to read:

- **ORGANIC IMPURITIES**