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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

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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**

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▲**Buffer:**▲ (USP 1-Dec-2024) 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)

Solution A: Acetonitrile and ▲*Buffer* (12:88)▲ (USP 1-Dec-2024)

Solution B: Acetonitrile and ▲*Buffer* (60:40)▲ (USP 1-Dec-2024)

Mobile phase: See ▲*Table 1*.

Table 1▲ (USP 1-Dec-2024)

Time (min)	Solution A (%)	Solution B (%)
0	100	0
8	100	0
25	40	60
26	100	0
40	100	0

▲**Sensitivity solution:** 1 µg/mL of USP Ofloxacin RS in methanol▲ (USP 1-Dec-2024)

Standard solution: ▲0.002 mg/mL▲ (USP 1-Dec-2024) of USP Ofloxacin RS in methanol

Sample 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▲ (USP 1-Dec-2024) of methanol and sonicate for 20 min. Dilute with methanol to volume. Pass a portion of this solution through a filter having a 0.45-µm ▲pore size,▲ (USP 1-Dec-2024) discarding the first 5 mL.▲▲ (USP 1-Dec-2024)

Chromatographic system

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

Mode: LC

Detector: UV 294 nm

Column: 4.6-mm × 10-cm; ▲3-µm▲ (USP 1-Dec-2024) packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: ▲*Sensitivity solution* and▲ (USP 1-Dec-2024) *Standard solution*

▲[NOTE—The relative retention times in *Table 2* are provided as information that could aid in peak assignment.]

Table 2▲ (USP 1-Dec-2024)

Name	Relative Retention Time
▲Desfluorooofloxacin▲ (USP 1-Dec-2024) [a]	0.5
▲Ofloxacin	1.0▲ (USP 1-Dec-2024)
▲Despiperazineofloxacin▲ (USP 1-Dec-2024) [b]	3.6

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[a] ▲(USP 1-Dec-2024) 2,3-Dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7*H*-pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid▲(USP 1-Dec-2024) .

[b] ▲(USP 1-Dec-2024) 9,10-Difluoro-3-methyl-7-oxo-2,3-dihydro-7*H*-pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid▲(USP 1-Dec-2024) .

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

▲**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲(USP 1-Dec-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲any▲(USP 1-Dec-2024) 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▲(USP 1-Dec-2024) impurity from the *Sample solution*

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

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

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

F = relative response factor ▲(USP 1-Dec-2024) (see ▲*Table 3*▲(USP 1-Dec-2024))

Acceptance criteria: See ▲*Table 3*. The reporting threshold is 0.1%.

Table 3▲(USP 1-Dec-2024)

Name	Relative Response Factor	Acceptance Criteria, NMT (%)
▲Desfluoroofloxacin▲(USP 1-Dec-2024)	1	0.3
▲Despiperazineofloxacin▲(USP 1-Dec-2024)	0.22	0.3
▲Any unspecified degradation product▲(USP 1-Dec-2024)	1	0.2
▲Total degradation products▲(USP 1-Dec-2024)	—	1.0

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ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Ofloxacin RS

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

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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