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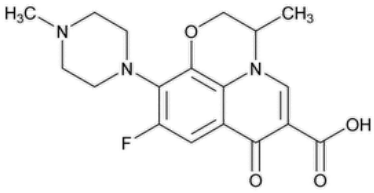
Ofloxacin



$C_{18}H_{20}FN_3O_4$ 361.37

7*H*-Pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-, (±)-;

(±)-9-Fluoro-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 CAS RN®: 82419-36-1; UNII: A4P49JAZ9H.

Change to read:

DEFINITION

Ofloxacin contains NLT ▲98.0%▲ (USP 1-Dec-2024) and NMT ▲102.0%▲ (USP 1-Dec-2024) of ofloxacin ($C_{18}H_{20}FN_3O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** ▲197A or▲ (USP 1-Dec-2024) 197K

Delete the following:

▲• **B.** **Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*.**▲ (USP 1-Dec-2024)

Add the following:

▲• **B.** The retention time 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**

▲**Diluent:** Acetonitrile and water (1:6)

Buffer: 3.1 g/L of ammonium acetate and 5.4 g/L of sodium perchlorate in water. Adjust with phosphoric acid to a pH of 2.2.

Mobile phase: Acetonitrile and *Buffer* (570:4430)

Standard solution: 0.2 mg/mL of USP Ofloxacin RS in *Diluent*

Sample solution: 0.2 mg/mL of Ofloxacin in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 294 nm

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

Column temperature: 45°

Flow rate: 0.5 mL/min

Injection volume: 10 µL

Run time: NLT 2.5 times the retention time of ofloxacin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ofloxacin ($C_{18}H_{20}FN_3O_4$) in the portion of Ofloxacin taken:

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

r_U = peak response of ofloxacin 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 = concentration of Ofloxacin in the *Sample solution* (mg/mL)

▲ (USP 1-Dec-2024)

Acceptance criteria: ▲98.0%–102.0%▲ (USP 1-Dec-2024) on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Delete the following:

▲• **Arsenic ⟨211⟩, *Procedures, Procedure 2*** ▲ (USP 1-Dec-2024)

Change to read:

• **Organic Impurities**

▲**Diluent, Buffer, Sample solution,** and **Chromatographic system:** Proceed as directed in the *Assay*.▲ (USP 1-Dec-2024)

Mobile phase: Acetonitrile and *Buffer* (240:1300)

System suitability solution: 0.4 µg/mL each of USP Ofloxacin RS and USP Ofloxacin Related Compound A RS in *Diluent*

▲**Sensitivity solution:** 0.04 µg/mL of USP Ofloxacin RS in *Diluent*▲ (USP 1-Dec-2024)

Standard solution: 0.4 µg/mL of USP Ofloxacin RS in *Diluent*

▲▲ (USP 1-Dec-2024)

System suitability

Samples: *System suitability solution*, ▲*Sensitivity solution*, and *Standard solution*

[Note—The relative retention times for ofloxacin related compound A and ofloxacin are 0.88 and 1.0, respectively.]

▲ (USP 1-Dec-2024)

Suitability requirements

Resolution: NLT 2.0 between ofloxacin and ofloxacin related compound A, *System suitability solution*

Relative standard deviation: NMT 3.0%, ▲*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 each impurity in the portion of Ofloxacin taken:

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

r_U = peak response ▲of each impurity▲ (USP 1-Dec-2024) 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)▲ (USP 1-Dec-2024)

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

Acceptance criteria: ▲The reporting threshold is 0.02%.▲ (USP 1-Dec-2024)

Individual impurities: NMT 0.3% ▲▲ (USP 1-Dec-2024)

Total impurities: NMT 0.5%

Delete the following:

▲• **Limit of Methanol and Ethanol**▲ (USP 1-Dec-2024)

SPECIFIC TESTS

• **Optical Rotation** ⟨781S⟩, *Procedures, Specific Rotation*

Sample solution: 10 mg/mL in chloroform

Acceptance criteria: +1° to −1°

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.2%

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in well-closed containers, protected from light. Store at ▲controlled room temperature.▲ (USP 1-Dec-2024)

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Ofloxacin RS

USP Ofloxacin Related Compound A RS

▲9-Fluoro-3-methyl-7-oxo-10-(piperazin-1-yl)-2,3-dihydro-7*H*-[1,4]oxazino[2,3,4-*ij*]quinoline-6-carboxylic acid;
Also known as▲ (USP 1-Dec-2024) 9-Fluoro-3-methyl-7-oxo-10-(piperazin-1-yl)-2,3-dihydro-7*H*-pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid.

$C_{17}H_{18}FN_3O_4$ ▲347.35▲ (USP 1-Dec-2024)

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(3)

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