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Ofloxacin Ophthalmic Solution

DEFINITION

Ofloxacin Ophthalmic Solution is a sterile aqueous solution of Ofloxacin. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ofloxacin ($C_{18}H_{20}FN_3O_4$).

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard stock solution: 3.0 mg/mL of USP Ofloxacin RS in a mixture of chloroform and methanol (1:1)

Standard solution: 0.3 mg/mL of USP Ofloxacin RS from *Standard stock solution* prepared as follows. Transfer 5.0 mL of *Standard stock solution* to a 50-mL volumetric flask, add 5 mL of water, and dilute with a mixture of chloroform and methanol (1:1) to volume.

Sample solution: 0.3 mg/mL of ofloxacin from a portion of Ophthalmic Solution in a mixture of chloroform and methanol (1:1)

Application volume: 2 µL

Developing solvent system: Chloroform, methanol, and a solution (1 in 30) of ammonium hydroxide (150:75:15). Saturate a paper-lined chromatographic chamber with this mixture.

• **B.** The retention time of the ofloxacin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, 0.24% sodium dodecyl sulfate, and glacial acetic acid (400:580:20)

0.05 N hydrochloric acid: Add 4.0 mL of hydrochloric acid to 500 mL of water, dilute with water to 1000 mL, and mix.

System suitability solution: 0.1 mg/mL of USP Ofloxacin RS and 2.4 mg/mL of propylparaben in acetonitrile

Standard solution: 0.06 mg/mL of USP Ofloxacin RS in *0.05 N hydrochloric acid*

Sample solution: 0.06 mg/mL of ofloxacin from Ophthalmic Solution in *0.05 N hydrochloric acid*

Chromatographic system

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

Mode: LC

Detector: UV 294 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 2 between the propylparaben and ofloxacin peaks, *System suitability solution*

Tailing factor: NMT 3, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ofloxacin ($C_{18}H_{20}FN_3O_4$) in the portion of Ophthalmic Solution taken:

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

r_U = peak area of ofloxacin from the *Sample solution*

r_S = peak area 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)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed for *Membrane Filtration* in the test for *Sterility of the Product to Be Examined*.

• **pH ⟨791⟩:** 6.0–6.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers 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 OPHTHALMIC SOLUTION	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

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