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Ciprofloxacin Tablets

DEFINITION

Ciprofloxacin Tablets contain Ciprofloxacin Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of ciprofloxacin ($C_{17}H_{18}FN_3O_3$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Solution A: 0.025 M phosphoric acid. Adjust with triethylamine to a pH of 2.0 ± 0.1.

Solution B: Acetonitrile and *Solution A* (13:87)

Solution C: 0.025 M phosphoric acid. Adjust with triethylamine to a pH of 3.0 ± 0.1.

Mobile phase: Acetonitrile and *Solution C* (13:87)

Standard solution: 0.2 mg/mL of USP Ciprofloxacin Hydrochloride RS in *Solution B*

System suitability solution: 0.05 mg/mL of USP Ciprofloxacin Ethylenediamine Analog RS in the *Standard solution*

Sample solution: Transfer 5 Tablets to a 500-mL volumetric flask, add 400 mL of *Solution B*, and sonicate for about 20 min. Dilute with *Solution B* to volume and pass through a membrane filter of 0.45-µm pore size. Prepare the equivalent of 0.20 mg/mL of ciprofloxacin from the filtrate with *Solution B*.

Chromatographic system

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

Mode: LC

Detector: UV 278 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

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

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

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

[Note—The retention time for ciprofloxacin is 6.4–10.8 min. The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ciprofloxacin ($C_{17}H_{18}FN_3O_3$) 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 from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of ciprofloxacin, 331.34

M_{r2} = molecular weight of ciprofloxacin hydrochloride, 367.81

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: USP Ciprofloxacin Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: 276 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: An amount of ciprofloxacin hydrochloride ($C_{17}H_{18}FN_3O_3 \cdot HCl$) equivalent to NLT 80% (Q) of the labeled amount of ciprofloxacin ($C_{17}H_{18}FN_3O_3$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Solution C, Mobile phase, and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 0.5 mg/mL each of USP Ciprofloxacin Hydrochloride RS and USP Ciprofloxacin Ethylenediamine Analog RS in *Mobile phase*

Standard solution: 1.0 µg/mL of USP Ciprofloxacin Hydrochloride RS in *Mobile phase*

Sample solution: Nominally 0.45 mg/mL of ciprofloxacin prepared as follows. Finely powder NLT 20 Tablets and transfer a portion of the powder to an appropriate volumetric flask. Add *Mobile phase* to about 50% of the flask volume and sonicate as necessary to dissolve. Dilute with *Mobile phase* to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

System suitability

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

Suitability requirements

Resolution: NLT 6.0 between the ciprofloxacin ethylenediamine analog and ciprofloxacin, *System suitability solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each specified or unspecified impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria: See *Table 1*. Disregard any impurity peaks less than 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Ciprofloxacin ethylenediamine analog	0.68	0.5
Ciprofloxacin	1.0	—
7-Chloro-6-piperazinyl analog[a]	1.2	0.3
Chlorociprofloxacin[b]	2.0	0.3
Any individual unspecified impurity	—	0.2
Total impurities	—	1.0

[a] 7-Chloro-1-cyclopropyl-4-oxo-6-(piperazin-1-yl)-1,4-dihydroquinoline-3-carboxylic acid.

[b] 6-Chloro-1-cyclopropyl-4-oxo-7-(piperazin-1-yl)-1,4-dihydroquinoline-3-carboxylic acid.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Ciprofloxacin Ethylenediamine Analog RS

1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-[(2-aminoethyl)amino]-3-quinolinecarboxylic acid hydrochloride.

$C_{15}H_{16}FN_3O_3 \cdot HCl$ 341.77

USP Ciprofloxacin Hydrochloride RS

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

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

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