



## Ciprofloxacin Hydrochloride

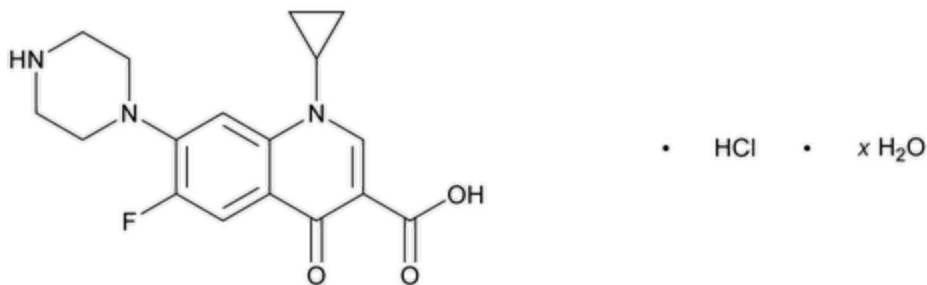
<b>Type of Posting</b>	Revision Bulletin
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<b>Expert Committee</b>	Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 1 Expert Committee has revised the Ciprofloxacin Hydrochloride monograph. The purpose of this revision is to widen the criterion of the *Water Determination* test from 4.7%–6.7% to 3.7%–6.7% to accommodate FDA-approved products with wider specifications.

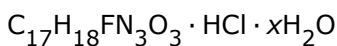
The Ciprofloxacin Hydrochloride Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please Jasmine Lawrence, Scientist IV (301-230-6363 or [jasmine.lawrence@usp.org](mailto:jasmine.lawrence@usp.org)).

## Ciprofloxacin Hydrochloride



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Sesquihydrate 394.83

Monohydrate 385.82

Anhydrous 367.81

3-Quinolinecarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-, monohydrochloride;

1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, monohydrochloride

Monohydrate CAS RN<sup>®</sup>: 86393-32-0; UNII: 4BA73M5E37.

### DEFINITION

Ciprofloxacin Hydrochloride contains NLT 98.0% and NMT 102.0% of ciprofloxacin hydrochloride ( $\text{C}_{17}\text{H}_{18}\text{FN}_3\text{O}_3 \cdot \text{HCl}$ ), calculated on the anhydrous basis. It contains a variable quantity of water.

### IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS](#) (197), [Infrared Spectroscopy: 197K](#)**
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **C. [IDENTIFICATION TESTS—GENERAL](#) (191), [Chloride](#)**

### ASSAY

#### • PROCEDURE

**Buffer:** 0.025 M phosphoric acid. Adjust with triethylamine to a pH of  $3.0 \pm 0.1$ .

**Mobile phase:** Acetonitrile and *Buffer* (13:87)

**Standard solution:** 0.5 mg/mL of [USP Ciprofloxacin Hydrochloride RS](#) in *Mobile phase*

**System suitability stock solution:** 0.025 mg/mL of [USP Ciprofloxacin Ethylenediamine Analog RS](#) in *Mobile phase*

**System suitability solution:** Transfer 1.0 mL of the *System suitability stock solution* to a 10-mL volumetric flask, and dilute with *Standard solution* to volume.

**Sample solution:** 0.5 mg/mL of Ciprofloxacin Hydrochloride in *Mobile phase*

#### **Chromatographic system**

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

**Mode:** LC

**Detector:** UV 278 nm

**Column:** 4.6-mm × 25-cm; packing L1

**Column temperature:** 30 ± 1°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

### System suitability

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

[NOTE—The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively.]

### Suitability requirements

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

**Tailing factor:** NMT 2.5, *Standard solution*

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

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of ciprofloxacin hydrochloride ( $C_{17}H_{18}FN_3O_3 \cdot HCl$ ) in the portion of Ciprofloxacin Hydrochloride taken:

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

$r_U$  = peak area from the *Sample solution*

$r_S$  = peak area from the *Standard solution*

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

$C_U$  = concentration of Ciprofloxacin Hydrochloride in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis

### IMPURITIES

• **RESIDUE ON IGNITION** (281): NMT 0.1%

#### • ORGANIC IMPURITIES

**Buffer:** Dilute 3.4 mL of phosphoric acid with water to 2000 mL. Adjust with triethylamine to a pH of 3.0 ± 0.1.

**Solution A:** Acetonitrile

**Mobile phase:** See [Table 1](#).

**Table 1**

Time (min)	Buffer (%)	Solution A (%)
0	87	13
10	87	13
11	50	50
16	50	50

Time (min)	Buffer (%)	Solution A (%)
16.1	87	13
20	87	13

**Diluent:** *Solution A and Buffer (13:87)*

**System suitability solution:** 7.5 µg/mL each of [USP Ciprofloxacin Ethylenediamine Analog RS](#) and [USP Ciprofloxacin Hydrochloride RS](#) in *Diluent*

**Standard stock solution:** 0.1 mg/mL each of [USP Fluoroquinolonic Acid RS](#) and [USP Ciprofloxacin Hydrochloride RS](#) prepared as follows. Add suitable amounts of [USP Fluoroquinolonic Acid RS](#) and [USP Ciprofloxacin Hydrochloride RS](#) to a suitable volumetric flask. Add 0.1% of the flask volume of 6 M ammonium hydroxide and dilute with water to volume.

**Standard solution:** 0.7 µg/mL each of [USP Fluoroquinolonic Acid RS](#) and [USP Ciprofloxacin Hydrochloride RS](#) from *Standard stock solution* in *Diluent*

**Sample solution:** 0.35 mg/mL of Ciprofloxacin Hydrochloride in *Diluent*

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 263 and 278 nm

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

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume:** 30 µL

### System suitability

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

[NOTE—The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively.]

### Suitability requirements

**Resolution:** NLT 6.0 between ciprofloxacin ethylenediamine analog and ciprofloxacin at 278 nm, *System suitability solution*

**Tailing factor:** NMT 2.0 for the ciprofloxacin peak at 278 nm, *Standard solution*

**Relative standard deviation:** NMT 5.0% for ciprofloxacin at 278 nm; NMT 5.0% for fluoroquinolonic acid at 263 nm, *Standard solution*

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of fluoroquinolonic acid in the portion of Ciprofloxacin Hydrochloride taken:

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

$r_U$  = peak response of fluoroquinolonic acid at 263 nm from the *Sample solution*

$r_S$  = peak response of fluoroquinolonic acid at 263 nm from the *Standard solution*

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

$C_U$  = concentration of Ciprofloxacin Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of ciprofloxacin ethylenediamine analog and any individual unspecified impurity in the portion of Ciprofloxacin Hydrochloride taken:

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

$r_U$  = peak response of each impurity at 278 nm from the *Sample solution*

$r_S$  = peak response of ciprofloxacin at 278 nm from the *Standard solution*

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

$C_U$  = concentration of Ciprofloxacin Hydrochloride in the *Sample solution* (mg/mL)

**Acceptance criteria:** See [Table 2](#). Disregard peaks less than 0.05%.

**Table 2**

Name	Relative Retention Time	Wavelength (nm)	Acceptance Criteria, NMT (%)
Ciprofloxacin ethylenediamine analog	0.70	278	0.2
Ciprofloxacin	1.00	278	—
Fluoroquinolonic acid	1.89	263	0.2
Any individual unspecified impurity	—	278	0.2
Total impurities <sup>a</sup>	—	—	0.5

<sup>a</sup> Total impurities does not include fluoroquinolonic acid impurity.

## SPECIFIC TESTS

- **pH** [\(791\)](#).

**Sample solution:** 25-mg/mL solution in water

**Acceptance criteria:** 3.0–4.5

### Change to read:

- **WATER DETERMINATION** [\(921\)](#), *Method I*: ▲3.7%–6.7%▲ (RB 1-Apr-2026)

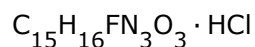
## ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

- **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.



341.77

[USP Ciprofloxacin Hydrochloride RS](#)

[USP Fluoroquinolonic Acid RS](#)

7-Chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

$C_{13}H_9ClFNO_3$             281.67

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**Page Information:**

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