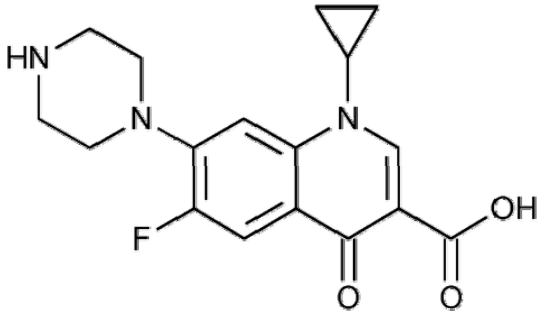
Ciprofloxacin

USP Method Ciprofloxacin Assay



Original Manufacturer:	Bayer A.G (patent expired)
Original Brand Name:	Ciloxan, Cipro,
Generic Names:	Baycip, Ciprex, Cetraxal, Ciflox, Cipro XR, Cipro XL, Ciproxin, Prociflor, Proquin

Ciprofloxacin is a synthetic chemotherapeutic antibiotic of the fluoroquinolone drug class. It kills bacteria by interfering with the enzymes that cause DNA to rewind after being copied, which stops synthesis of DNA and of protein.

Ciprofloxacin is marketed worldwide with over three hundred different brand names.

Merck Millipore is a division of Merck KGaA, Darmstadt, Germany
www.merck-chemicals.com/chromatography
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Ciprofloxacin

USP34 – NF29 S1

USP Columns:

Prodigy ODS (3) Assay and Chromatographic purity 4.6 mm x 25 cm, 5 µm, Phenomenex

Equivalent Column:

Purospher®STAR RP-18 endcapped (5 µm) 250x4.6 mm (1.51456.0001)

Recommended Solvents and Reagents:

Acetonitrile isocratic grade for liquid chromatography LiChrosolv® (1.14291)

Water Water for chromatography LiChrosolv® (1.15333)
or freshly purified water from Milli-Q water purification system

Phosphoric Acid Use ACS reagent grade

Triethylamine Use a suitable grade with a content of not less than 99.5%. (8.45061)

USP Standards

Ciprofloxacin (200 mg)	USP Product Number:1134313
Ciprofloxacin Ethylenediamine Analog (25 mg)	USP Product Number:1134324

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Buffer solution A: 0.025 M phosphoric acid. Adjust with triethylamine to a pH of 3.0 ± 0.1.

Mobile phase (v/v): Acetonitrile and Solution A (13:87)

Standard solution
Transfer 12.5 mg of USP Ciprofloxacin RS to a 25-mL volumetric flask.
Add 0.1 mL of 7% phosphoric acid, and dilute with Mobile phase to volume.

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 the Standard solution to volume.

Sample solution
Transfer 25 mg of Ciprofloxacin to a 50-mL volumetric flask. Add 0.2 mL of 7% phosphoric acid, and dilute with Mobile phase to volume.

Chromatographic system *(See Chromatography 621, System Suitability.)*
Detector: UV 278 nm
Column temperature: 30 ± 1
Injection size: 10 µL
Column: 4.6-mm × 25-cm; packing L1
Flow rate: 1.5 mL/min

System suitability
Samples: Standard solution and System suitability solution
[Note—The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are about 0.7 and 1.0, respectively.]

Suitability requirements
Resolution: Not less then (NLT) 6 between ciprofloxacin ethylenediamine analog and ciprofloxacin

Column efficiency: NLT 2500 theoretical plates from the ciprofloxacin peak

Tailing factor: Not more than (NMT) 2.5 for the ciprofloxacin peak

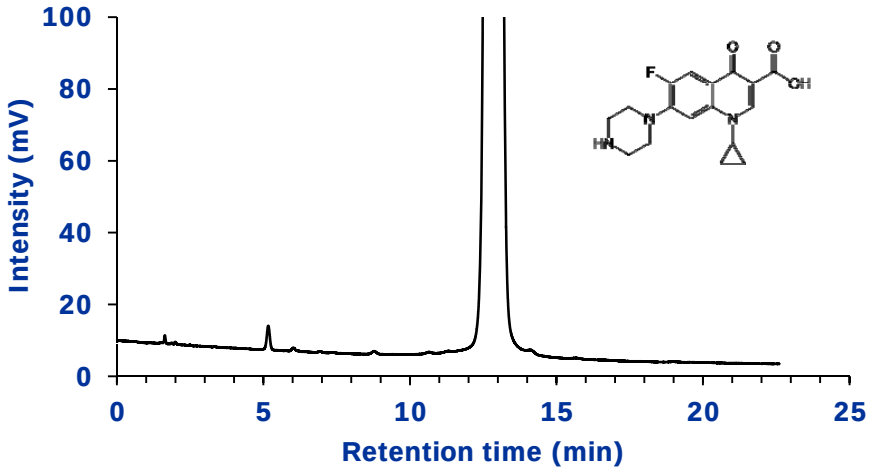
Relative standard deviation: NMT 1.5%

USP Method for Ciprofloxacin Assay

Purospher®STAR RP-18 endcapped

Chromatographic Conditions

Column:	Purospher®STAR RP-18 endcapped (5 µm) 250x4.6 mm	1.51456.0001
Injection:	10 µL	
Detection:	Shimadzu Prominence 2010, UV 278 nm	
Cell:	8 µL	
Flow Rate:	1.5 mL/min	
Mobile Phase (v/v):	Buffer: 0.025 M phosphoric acid, previously adjusted (with triethylamine) to a pH of 3.0 ± 0.1 Mix buffer and acetonitrile: 87:13	
Temperature:	30° Celsius	
Diluent	mobile phase	
Sample:	500 ppm of Ciprofloxacin	
Pressure Drop:	158 Bar (2290 psi)	



Chromatographic Data

No.	Compound	Time (min)	Tailing Factor (TUSP)	Relative Retention Time (RRT)	Plates (N)
1	Impurity 1	5.2	1.0	-	
2	Impurity 2	6.0	1.4	-	
3	Ciprofloxacin ethylenediamine	8.8	1.0	0.7	13454
4	Ciprofloxacin	12.7	1.8	1.0	8105
5	Impurity 3	14.1	1.2	-	
6	Impurity 4	15.7	1.0	-	

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