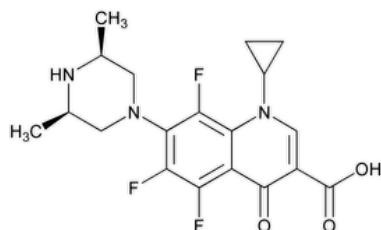


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Orbifloxacin



$C_{19}H_{20}F_3N_3O_3$ 395.38

1-Cyclopropyl-7-(*cis*-3,5-dimethyl-1-piperazinyl)-5,6,8-trifluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid CAS RN®: 113617-63-3; UNII: 660932TPY6.

» Orbifloxacin contains not less than 98.5 percent and not more than 101.5 percent of $C_{19}H_{20}F_3N_3O_3$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers. Store at room temperature.

USP REFERENCE STANDARDS (11)—

[USP Orbifloxacin RS](#)

Identification—

A: [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#)

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Change to read:

C: ▲ [X-Ray Powder Diffraction \(941\)](#)—▲ (CN 1-May-2022) The X-ray diffraction pattern conforms to that of [USP Orbifloxacin RS](#), similarly determined.

MICROBIAL ENUMERATION TESTS (61)—The total combined molds and yeasts count does not exceed 100 cfu per g.

pH (791): between 6.5 and 7.8, in a solution containing 10 mg per mL.

WATER DETERMINATION, Method 1c (921): between 1.5% and 2.9%.

RESIDUE ON IGNITION (281): not more than 0.1%.

Related compounds—

Buffer, Mobile phase, System suitability preparation, Standard preparation, and Chromatographic system— Prepare as directed in the *Assay*.

Standard solution—Dilute, quantitatively with *Buffer*, the *Standard preparation* to obtain a solution having a known concentration of about 0.00004 mg per mL.

Test solution—Transfer about 40 mg of Orbifloxacin, accurately weighed, to a 200-mL volumetric flask, dissolve in and dilute with *Buffer* to volume, and mix.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—Inject the *Buffer* as directed for *Procedure* to verify that there are no interfering peaks.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the area responses for the major peaks. Calculate the percentage of related compounds in the portion of Orbifloxacin taken by the formula:

$$20,000(C_s)(r_i/r_s)(1/F)(1/W)$$

in which C_s is the concentration, in mg per mL, of orbifloxacin in the *Standard solution*; r_i is the peak area response for each impurity obtained from the *Test solution*; r_s is the peak area response for the orbifloxacin peak obtained from the *Standard solution*; F is the relative response factor for each impurity, as presented in [Table 1](#); and W is the sample weight taken to prepare the *Test solution* (mg).

Table 1

Component/Impurity	Approximate Relative Retention Time	Relative Response Factor (F)	Limit %
<i>cis</i> , <i>cis</i> -1-Cyclopropyl-5,7-bis(3,5-dimethyl-1-piperazinyl)-6,8-difluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid	0.5	0.36	NMT 0.2
<i>cis</i> -1-Cyclopropyl-7-(3,5-dimethyl-1-piperazinyl)-5,6,8-trifluoro-4(1 <i>H</i>)-quinolinone	0.65	0.27	NMT 0.2
7-[(2-Aminopropyl)amino]-1-cyclopropyl-5,6-difluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid	0.75	0.49	NMT 0.2
Orbifloxacin	1.0	1.00	—
1-Cyclopropyl-7-(3,5-dimethyl-1-piperazinyl)-6,8-difluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid	1.4	0.84	NMT 0.2
<i>cis</i> -1-Cyclopropyl-7-(3,5-dimethyl-1-piperazinyl)-6,8-difluoro-1,4-dihydro-5-hydroxy-4-oxo-3-quinolinecarboxylic acid	2.7	0.73	NMT 0.2
<i>cis</i> -1-Cyclopropyl-5-(3,5-dimethyl-1-piperazinyl)-6,7,8-trifluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid	3.6	0.11	NMT 0.2
1-Cyclopropyl-5,6,7,8-tetrafluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid	6.8	0.16	NMT 0.2
Unknown	—	1.0	—
Total known and unknown	—	—	NMT 0.4

Assay—

Buffer—In a 2-L flask, dissolve about 11.8 g of sodium citrate in 1600 mL of water, and mix. Add 180 mL of acetic acid, and mix. Adjust with 6 N sodium hydroxide to a pH of 3.5, dilute with water to about 2 L, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *Buffer*, methanol, and dioxane (86:11:4). Make adjustments if necessary (see *System Suitability* under [Chromatography \(621\)](#)).

Standard stock preparation—Dissolve in *Buffer* an accurately weighed quantity of [USP Orbifloxacin RS](#) to obtain a solution having a known concentration of about 0.2 mg per mL.

Standard preparation—Accurately transfer a quantity of *Standard stock preparation*, and dilute with *Buffer* to obtain a solution having a known concentration of about 0.02 mg per mL.

System suitability preparation—Dissolve about 40 mg of methyl 4-aminobenzoate in 2 mL of methanol, and dilute with *Buffer* to 200 mL. Pipet 10.0 mL of this solution and 10.0 mL of *Standard stock preparation* into a 100-mL volumetric flask. Dilute with *Buffer* to volume, and mix.