Edition: BP 2025 (Ph. Eur. 11.6 update)

Ofloxacin Infusion

General Notices

Action and use

Fluoroquinolone antibacterial.

DEFINITION

Ofloxacin Infusion is a sterile solution of Ofloxacin in a suitable vehicle.

The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of ofloxacin, $C_{18}H_{20}FN_3O_4$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in solution A.

Solution A 10 volumes of *acetonitrile* and 90 volumes of 0.01M *hydrochloric acid*.

Solution B 0.308% w/v of *ammonium acetate* and 0.538% w/v of *sodium perchlorate*, adjusted to pH 2.2 using *orthophosphoric acid*.

(1) Dilute a suitable volume of the infusion to produce a solution containing 0.04% w/v of Ofloxacin
(2) Dilute 1 volume of solution (1) to 200 volumes.
(3) 0.00008% w/v each of *ofloxacin impurity D EPCRS* and *ofloxacin impurity E EPCRS* and 0.0002% w/v of *ofloxacin BPCRS*.
(4) Dilute 1 volume of solution (2) to 5 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (3 µm) (YMC Pack Pro C18 is suitable).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 1.0 mL per minute.
(d) Use a column temperature of 38°.
(e) Use a detection wavelength of 294 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

Mobile phase A 16 volumes of *acetonitrile* and 84 volumes of solution B.

Mobile phase B 20 volumes of *methanol*, 30 volumes of *acetonitrile* and 50 volumes of solution B.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-5	100	0	isocratic
5-10	100→82	0→18	linear gradient
10-15	82→40	18→60	linear gradient
15-30	40	60	isocractic
30-32	40→100	60→0	linear gradient
32-40	100	0	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless:

in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity E and ofloxacin is at least 2.0 and;

in the chromatogram obtained with solution (4), the *signal-to-noise ratio* of the peak due to ofloxacin is at least 90.

CALCULATION OF IMPURITIES

For each impurity, use the concentration of ofloxacin in solution (2).

For the reporting threshold, use the concentration of ofloxacin in solution (4).

For peak identification, use solution (3).

Ofloxacin retention time: about 10 minutes.

Relative retention: impurity D, about 0.7; impurity E, about 0.9.

Correction factors: impurity D, multiply by 4.5.

LIMITS

— impurity D: not more than 0.2%;

— any other impurities: not more than 0.2%;

— total impurities: not more than 0.5%;

— reporting threshold: 0.1%.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute a suitable volume of the infusion with 10% v/v of *acetonitrile* to produce a solution containing 0.001% w/v of Ofloxacin.

(2) Prepare a 0.1% w/v solution of *ofloxacin BPCRS* in *methanol* and dilute 1 volume of this solution to 100 volumes with 10% v/v of *acetonitrile*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (3.5 µm) (Symmetry C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2.0 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 294 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

10 volumes of *acetonitrile* and 90 volumes of a solution containing 2.72% w/v of *potassium dihydrogen orthophosphate*, previously adjusted to pH 3.3 with *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *symmetry factor* of the principal peak is not greater than 2.0.

DETERMINATION OF CONTENT

Calculate the content of ofloxacin, $C_{18}H_{20}FN_3O_4$, in the infusion from the chromatograms obtained and using the declared content of $C_{18}H_{20}FN_3O_4$ in *ofloxacin BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities B, C, D, E and F listed under *Ofloxacin*.