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

Levofloxacin Infusion

General Notices

Action and use

Fluoroquinolone antibacterial.

DEFINITION

Levofloxacin Infusion is a sterile solution of Levofloxacin Hemihydrate in a suitable vehicle.

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

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

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, in the mobile phase.

(1) Shake a volume of the infusion containing the equivalent of 0.1 g of levofloxacin with 15 mL of 20% v/v of *acetonitrile*. Dilute with 20% v/v of *acetonitrile* to produce 50 mL and filter. Dilute 1 volume to 4 volumes.
(2) Dilute 1 volume of solution (1) to 200 volumes.
(3) Dissolve the contents of a vial of *levofloxacin for system suitability EPCRS* in 1 mL.
(4) Dilute 1 volume of solution (2) to 5 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *base-deactivated end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Inertsil ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 0.8 mL per minute.
(d) Use a column temperature of 45°.

(e) Use a detection wavelength of 360 nm.
(f) Inject 25 µL of each solution.
(g) Allow the chromatography to proceed for three times the retention time of levofloxacin.

MOBILE PHASE

0.0875% w/v of *copper sulphate pentahydrate*, 0.091% w/v of *isoleucine* and 0.595% w/v of *ammonium acetate* in 30% v/v of *methanol*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurities B and G is at least 1.5.

CALCULATION OF IMPURITIES

For all impurities, use the concentration of levofloxacin in solution (2).

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

For peak identification, use solution (3).

Levofloxacin retention time: about 20 minutes.

Relative retention: impurity E, about 0.4; impurity B, about 0.5; impurity G, about 0.56; impurity 1, about 0.63; impurity A, about 1.2.

Correction factors: impurity B, multiply by 1.3; impurity E, multiply by 1.7.

LIMITS

— impurity A: not more than 0.5%;

— unspecified impurities: for each impurity, not more than 0.2%;

— total impurities: not more than 0.8%;

— reporting threshold: 0.1%.

ASSAY

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

(1) Shake a volume of the infusion containing 0.1 g of levofloxacin with 15 mL of 20% v/v of *acetonitrile*. Dilute with 20% v/v of *acetonitrile* to produce 100 mL and filter. Dilute 1 volume to 5 volumes with the mobile phase.
(2) 0.2% w/v of *levofloxacin hemihydrate BPCRS* in 20% v/v of *acetonitrile*, dissolved with the aid of ultrasound if necessary. Dilute 1 volume to 10 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{18}H_{20}FN_3O_4$ in the infusion using the declared content of $C_{18}H_{20}FN_3O_4,½H_2O$ in *levofloxacin hemihydrate BPCRS*. Each mg of $C_{18}H_{20}FN_3O_4,½H_2O$ is equivalent to 0.9757 mg of $C_{18}H_{20}FN_3O_4$.

STORAGE

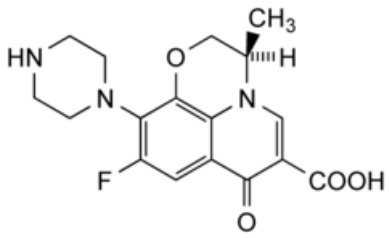
Levofloxacin Infusion should be protected from light.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of levofloxacin.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A, B, C, D, E, G, H and I listed under *Levofloxacin Hemihydrate* and:



1. (*S*)-4-(6-Carboxy-9-fluoro-2,3-dihydro-3-methyl-7-oxo-7*H*-pyrido-[1,2,3-*de*][1,4]benzoxazine-10-yl)-1-methylpiperazine 1-oxide (N-Oxide)