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

Enrofloxacin Tablets

General Notices

Action and use

Fluoroquinolone antibacterial.

DEFINITION

Enrofloxacin Tablets contain Enrofloxacin.

The tablets complies with the requirements stated under Tablets and with the following requirements.

Content of enrofloxacin, $C_{19}H_{22}FN_3O_3$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. To a quantity of the powdered tablets containing 0.1 g of Enrofloxacin, add 10 mL of *dichloromethane*, shake and filter. Wash the filtrate with three 20-mL quantities of *water*. Dry the washed dichloromethane with *sodium sulfate*, filter and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the dried residue, Appendix II A, is concordant with the reference spectrum of enrofloxacin *(RSV 55)*.
B. In the Assay, 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

Dissolution

Comply with the *dissolution test for tablets and capsules*, *Appendix XII B1*.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 100 revolutions per minute.
(b) Use 900 mL of a solution containing 2.1% w/v *citric acid monohydrate* in 0.2M *sodium hydroxide*, adjusted to pH 4.0 with 0.1M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

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

(1) After 30 minutes withdraw a sample of the medium and filter (a 0.45-µm cellulose filter is suitable). Dilute the filtrate with dissolution medium, if necessary, to produce a solution expected to contain 0.0015% w/v of Enrofloxacin.
(2) 0.0015% w/v of *enrofloxacin BPCRS* in 0.1M *formic acid*.
(3) 0.05% w/v of *enrofloxacin BPCRS* and 0.0005% w/v of *ciprofloxacin hydrochloride BPCRS* (impurity B).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.0 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Nucleosil RP18 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 a column temperature of 40°.
(e) Use a detection wavelength of 278 nm.
(f) Inject 5 µL of each solution.

MOBILE PHASE

100 volumes of a solution containing 1.1% w/v of *sodium heptanesulfonate monohydrate* and 2.72% w/v of *potassium dihydrogen orthophosphate*, 240 volumes of *acetonitrile* and 660 volumes of *water*, adjust the pH of the mixture to 2.1 with *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks corresponding to impurity B and enrofloxacin is at least 2.0.

DETERMINATION OF CONTENT

Calculate the total content of enrofloxacin, $C_{19}H_{22}FN_3O_3$, in the medium from the chromatograms obtained and using the declared content of $C_{19}H_{22}FN_3O_3$ in *enrofloxacin BPCRS*.

LIMITS

The amount of enrofloxacin released is not less than 75% (Q) of the stated amount.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in a solution containing 1 volume of *acetonitrile* and 3 volumes of 0.1M *formic acid*.

(1) Dissolve a quantity of the powdered tablets containing 50 mg of Enrofloxacin in the solvent mixture, dilute to 100 mL and filter (a 0.45-µm cellulose filter is suitable).
(2) Dilute 1 volume of solution (1) to 100 volumes.
(3) 0.05% w/v of *enrofloxacin BPCRS* and 0.0005% w/v of *ciprofloxacin hydrochloride BPCRS* (impurity B).
(4) Dilute 3 volumes of solution (2) to 10 volumes.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under dissolution may be used with the following mobile phase and allowing the chromatography to proceed for twice the retention time of enrofloxacin.

MOBILE PHASE

100 volumes of a solution containing 1.1% w/v of *sodium heptanesulfonate monohydrate* and 2.72% w/v of *potassium dihydrogen orthophosphate*, 230 volumes of *acetonitrile* and 670 volumes of *water* adjusted to pH 2.1 with *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks corresponding to impurity B and enrofloxacin is at least 2.0.

CALCULATION OF IMPURITIES

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

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

For peak identification, use solution (3).

Enrofloxacin retention time: about 6 minutes.

Relative retention: impurity B, about 0.7.

LIMITS

— unspecified impurities: for each impurity, not more than 1.0%;

— total impurities: not more than 2.0%;

— reporting threshold: 0.3%.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in a solution containing 1 volume of *acetonitrile* and 3 volumes of 0.1M *formic acid*.

(1) Disperse a quantity of the powdered tablets containing 50 mg of Enrofloxacin in the solvent mixture, dilute to 100 mL and filter (a 0.45-µm cellulose filter is suitable).
(2) 0.05% w/v of *enrofloxacin BPCRS*.
(3) 0.05% w/v of *enrofloxacin BPCRS* and 0.0005% w/v of *ciprofloxacin hydrochloride BPCRS* (impurity B).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks corresponding to impurity B and enrofloxacin is at least 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{19}H_{22}FN_3O_3$ in the tablets from the chromatograms obtained and using the declared content of $C_{19}H_{22}FN_3O_3$ in *enrofloxacin BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurity B listed under Enrofloxacin.