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

# Enrofloxacin Oral Solution

General Notices

**Action and use**

Fluoroquinolone antibacterial.

## DEFINITION

Enrofloxacin Oral Solution contains Enrofloxacin.

*The oral solution complies with the requirements stated under Oral Liquids 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 oral solution containing 0.1 g of Enrofloxacin, add 10 mL of *dichloromethane*, shake and allow to separate. Discard the upper aqueous layer and wash the lower dichloromethane layer 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

**Related substances**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in 0.1M *formic acid*.

(1) Dilute a quantity of the oral solution containing 50 mg of Enrofloxacin to 100 mL.
(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

(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.
(g) Allow 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*, 190 volumes of *acetonitrile* and 710 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.

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 9 minutes.

Relative retention: impurity B, about 0.8.

LIMITS

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

— total impurities: not more than 2.0%;

— reporting threshold: 0.3%.

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in 0.1M *formic acid*.

(1) Dilute an quantity of the oral solution containing 50 mg of Enrofloxacin to 100 mL.
(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

Determine the *weight per mL* of the oral solution, Appendix V G, and calculate the content of $C_{19}H_{22}FN_3O_3$ in the oral solution 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.