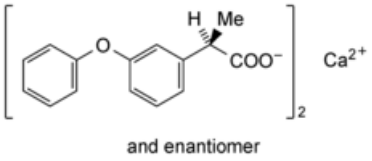
Edition: BP 2025 (Ph. Eur. 11.6 update)

Fenoprofen Calcium

General Notices



and enantiomer

$(C_{15}H_{13}O_3)_2Ca,2H_2O$ 558.6 *34957-40-5*

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

Preparation

Fenoprofen Tablets

DEFINITION

Fenoprofen Calcium is calcium (*RS*)-2-(3-phenoxyphenyl)propionate dihydrate. It contains not less than 97.5% and not more than 101.0% of $(C_{15}H_{13}O_3)_2Ca$, calculated with reference to the anhydrous substance.

CHARACTERISTICS

A white or almost white, crystalline powder.

Slightly soluble in *water*; soluble in *ethanol (96%)*.

IDENTIFICATION

A. Dissolve 0.1 g in 5 mL of *glacial acetic acid* and add sufficient *methanol* to produce 100 mL. Dilute 5 mL of this solution to 50 mL with *methanol*. The *light absorption* of the resulting solution, Appendix II B, in the range 230 to 350 nm exhibits two maxima, at 272 nm and 278 nm, and a shoulder at 266 nm. The *absorbance* at the maximum at 272 nm is about 0.70 and at the maximum at 278 nm is about 0.65.
B. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of fenoprofen calcium *(RS 142)*.
C. The residue on ignition yields the reactions characteristic of *calcium salts*, Appendix VI.

TESTS

Related substances

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

(1) 0.50% w/v of the substance being examined.
(2) 0.0025% w/v of the substance being examined.
(3) 0.04% w/v of *fenoprofen calcium* and 0.0015% w/v of *4,4'-dimethoxybenzophenone*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (7 to 8 µm) (Zorbax ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 270 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 3 times the retention time of the peak due to fenoprofen.

MOBILE PHASE

2 volumes of *glacial acetic acid*, 7 volumes of *tetrahydrofuran*, 30 volumes of *acetonitrile* and 61 volumes of *water*.

SYSTEM SUITABILITY

The test is valid if the *resolution factor* between the peaks corresponding to fenoprofen and 4,4′-dimethoxybenzophenone in the chromatogram obtained with solution (3) is at least 3.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than twice the area of the peak in the chromatogram obtained with solution (2) (1%);

not more than one *secondary peak* has an area greater than the area of the peak in the chromatogram obtained with solution (2) (0.5%);

the sum of the areas of all *secondary peaks* is not greater than four times the area of the peak in the chromatogram obtained with solution (2) (2%).

Water

5.0 to 8.0% w/w, Appendix IX C. Use 0.2 g.

ASSAY

Carry out Method I for *non-aqueous titration*, Appendix VIII A, using 0.5 g and determining the end point potentiometrically. Each mL of *0.1M perchloric acid VS* is equivalent to 26.13 mg of $(C_{15}H_{13}O_3)_2Ca$.