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

Fenoprofen Tablets

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Fenoprofen Tablets contain Fenoprofen Calcium. They are coated.

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

Content of fenoprofen, $C_{15}H_{14}O_3$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 230 to 350 nm of the final solution obtained in the Assay exhibits two maxima, at 272 nm and 278 nm, and a shoulder at 266 nm.
B. Suspend a quantity of the powdered tablets containing the equivalent of 0.3 g of fenoprofen in 10 mL of 0.1M *hydrochloric acid*. Extract with 20 mL of *chloroform*, filter the extract through *anhydrous sodium sulfate* and evaporate the filtrate to dryness. The *infrared absorption spectrum* of a thin film of the residue, Appendix II A, is concordant with the *reference spectrum* of fenoprofen *(RS 141)*.
C. Ignite a quantity of the powdered tablets. The residue yields the reactions characteristic *of calcium salts*, Appendix VI.

Related substances

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

(1) To a quantity of the powdered tablets containing the equivalent of 0.5 g of fenoprofen add 80 mL of the mobile phase, mix with the aid of ultrasound, allow to cool, add sufficient mobile phase to produce 100 mL and filter.
(2) Dilute 1 volume of solution (1) to 200 volumes with the mobile phase.
(3) 0.04% w/v of *fenoprofen calcium* and 0.0015% w/v of *4,4'-dimethoxybenzophenone* in the mobile phase.
(4) Dilute 1 volume of solution (2) to 5 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped 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) For solution (1) 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 not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peaks corresponding to fenoprofen calcium and 4′,4′-dimethoxybenzophenone 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) (1.0%);

not more than one such 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 such peaks is not greater than four times the area of the peak in the chromatogram obtained with solution (2) (2%).

Disregard any peak with an area less than that of the principal peak in the chromatogram obtained with solution (4) (0.1%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing the equivalent of 0.2 g of fenoprofen add 5 mL of *glacial acetic acid* and shake for 1 minute. Add 100 mL of *methanol*, shake for 5 minutes, dilute to 200 mL with *methanol* and filter. Dilute 10 mL of the filtrate to 200 mL with *methanol* and measure the *absorbance* of the resulting solution at the maximum at 272 nm, Appendix II B. Calculate the content of $C_{15}H_{14}O_3$ taking 80.7 as the value of A (1%, 1 cm) at the maximum at 272 nm.

LABELLING

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