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Fenoprofen Calcium Tablets

» Fenoprofen Calcium Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fenoprofen ($C_{15}H_{14}O_3$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Fenoprofen Calcium RS
USP Fenoprofen Sodium RS

Identification—An amount of finely powdered Tablets responds to the *Identification* tests under *Fenoprofen Calcium Capsules*.

Dissolution ⟨711⟩—

Medium: pH 7.0 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 1000 mL.

Apparatus 1: 10-mesh basket; 100 rpm.

Time: 60 minutes.

Procedure—Filter 20 mL of the solution under test, and transfer 10.0 mL of the filtrate to a 100-mL volumetric flask. Dilute with *Dissolution Medium* to volume, and mix. Determine the absorbances of this solution and a Standard solution prepared from USP Fenoprofen Sodium RS, in the same medium having a known concentration of about 60 µg per mL at the wavelength of maximum absorbance at about 270 nm, using *Dissolution Medium* as the blank. Calculate the amount of $C_{15}H_{14}O_3$ dissolved, in mg, by the formula:

$$(242.28/264.26)(10C)(A_U/A_S)$$

in which 242.28 is the molecular weight of fenoprofen; 264.26 is the molecular weight of anhydrous fenoprofen sodium; C is the concentration of anhydrous fenoprofen sodium in the Standard solution, as determined from the concentration of USP Fenoprofen Sodium RS corrected for moisture content by a titrimetric water determination; and A_U and A_S are the absorbances of the solutions obtained from the substance under test and the USP Reference Standard, respectively.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{15}H_{14}O_3$ is dissolved in 60 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase, Diluting solution, Resolution solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Fenoprofen Calcium*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 6000 mg of fenoprofen, to a 250-mL volumetric flask, add 50 mL of 0.5 N hydrochloric acid, and sonicate for 10 minutes, shaking the solution occasionally. Dilute with acetone to volume, sonicate for 10 minutes, and stir for an additional 30 minutes. Transfer 5.0 mL of this solution to a 200-mL volumetric flask, dilute with *Diluting solution* to volume, and mix. Pass a portion of this solution through a suitable filter having a 0.5-µm or finer porosity, discarding the first 8 mL of the filtrate, and use the clear filtrate as the *Assay preparation*.

Procedure—Proceed as directed in the *Assay* under *Fenoprofen Calcium*. Calculate the quantity, in mg, of fenoprofen ($C_{15}H_{14}O_3$) in the portion of Tablets taken by the formula:

$$(484.55/522.61)(10{,}000C)(r_U/r_S)$$

in which 484.55 is two times the molecular weight of fenoprofen; 522.61 is the molecular weight of fenoprofen calcium; and the other terms are as defined therein.

Topic/Question	Contact	Expert Committee
FENOPROFEN CALCIUM TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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