Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-13CCB116-B0BC-406F-AFBB-CD03DA5E0914_2_en-US
DOI: https://doi.org/10.31003/USPNF_M32730_02_01
DOI Ref: v31qd

Fenoprofen Calcium Capsules

» Fenoprofen Calcium Capsules 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—

A: Transfer a portion of Capsule contents, equivalent to about 85 mg of fenoprofen, to a 125-mL separator containing 5 mL of acetone and 2 mL of 6 N hydrochloric acid. Swirl to dissolve, add 15 mL of water, and extract with three 15-mL portions of chloroform, draining each chloroform extract through a layer of about 2 g of anhydrous sodium sulfate, supported on glass wool and previously washed with chloroform, into a 50-mL volumetric flask. Rinse the sodium sulfate filter with about 2 mL of chloroform, collect the rinsing with the combined chloroform extracts, dilute with chloroform to volume, and mix. Transfer this solution to a suitable flask, and evaporate on a water bath with the aid of a current of air to dryness: the IR absorption spectrum of a film of the liquid residue thus obtained between sodium chloride plates exhibits maxima only at the same wavelengths as that of a similar preparation of USP Fenoprofen Calcium RS.

B: Place an amount of Capsule contents, equivalent to about 300 mg of fenoprofen, in a suitable container, and dissolve in 10 mL of acetone. Filter the solution through paper, and collect the filtrate in a crucible. Carefully evaporate to dryness, and ignite the crucible and its contents. Dissolve the residue in 10 mL of 1 N hydrochloric acid, transfer the solution to a beaker, add 2 drops of methyl red TS, neutralize with 6 N ammonium hydroxide, and add 3 N hydrochloric acid dropwise until the solution is acid to the indicator. Upon the addition of ammonium oxalate TS, a white precipitate is formed. The residue so obtained is insoluble in acetic acid but dissolves in hydrochloric acid.

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 5.0 mL of the filtrate to a 25-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:

$$(242.28/264.26)(5C)(A_U/A_S)$$

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 the contents of not fewer than 20 Capsules, and calculate the average weight per Capsule. Mix the combined contents of the Capsules, and transfer an accurately weighed portion, equivalent to about 150 mg of fenoprofen, to a 250-mL volumetric flask. Add about 200 mL of *Diluting solution*, and sonicate for about 15 minutes. Allow to cool, dilute with *Diluting solution* to volume, mix, and pass through a suitable filter, discarding the first 10 mL of the filtrate. 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 Capsules taken by the formula:

$$(484.55/522.61)(1000C)(r_U/r_S)$$

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.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(4)

Current DocID: GUID-13CCB116-B0BC-406F-AFBB-CD03DA5E0914_2_en-US
Previous DocID: GUID-13CCB116-B0BC-406F-AFBB-CD03DA5E0914_1_en-US
DOI: https://doi.org/10.31003/USPNF_M32730_02_01
DOI ref: v31qd