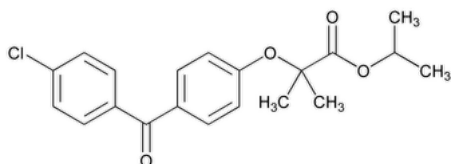


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-E5B7CDED-79F5-42D4-A6F4-D03AA8A937F2_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M32710_04_01
 DOI Ref: q438u

© 2025 USPC
 Do not distribute

Fenofibrate



$C_{20}H_{21}ClO_4$ 360.83

Isopropyl 2-[p-(p-chlorobenzoyl)phenoxy]-2-methylpropanoate CAS RN®: 49562-28-9; UNII: U202363UOS.

DEFINITION

Fenofibrate contains NLT 98.0% and NMT 102.0% of $C_{20}H_{21}ClO_4$, calculated on the dried basis.

IDENTIFICATION

Change to read:

- ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

ASSAY

PROCEDURE

Mobile phase: Acetonitrile and water acidified with phosphoric acid to a pH of 2.5 (7:3)

Standard solution: 1 mg/mL of [USP Fenofibrate RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Fenofibrate in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 286 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1.0 mL/min

Injection size: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0% for six replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{20}H_{21}ClO_4$ in the portion of Fenofibrate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Fenofibrate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Fenofibrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

INORGANIC IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%, determined on 1.0 g
- [CHLORIDE AND SULFATE, Chloride \(221\)](#)

Sample solution: Add 25 mL of water to 5.0 g of Fenofibrate, and heat at 50° for 10 min. Cool, dilute with water to 50.0 mL, filter, and use the filtrate. [NOTE—Retain the remaining portion of the *Sample solution* for the test for *Chloride and Sulfate, Sulfate*.]

Analysis: Use 10 mL of the *Sample solution*.

Acceptance criteria: It shows no more chloride than corresponds to 0.15 mL of 0.020 N hydrochloric acid (0.01%).

• [CHLORIDE AND SULFATE, Sulfate\(221\)](#)

Sample: Use the *Sample solution* prepared in the test for *Chloride and Sulfate, Chloride*.

Analysis: Use 10 mL of the *Sample*.

Acceptance criteria: It shows no more sulfate than corresponds to 0.15 mL of 0.020 N sulfuric acid (0.01%).

ORGANIC IMPURITIES

• PROCEDURE

Mobile phase: Acetonitrile and water acidified with phosphoric acid to a pH of 2.5 (7:3)

Impurity standard solution: 1 µg/mL each of [USP Fenofibrate RS](#), [USP Fenofibrate Related Compound A RS](#), and [USP Fenofibrate Related Compound B RS](#), and 2 µg/mL of [USP Fenofibrate Related Compound C RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Fenofibrate in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 286 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1.0 mL/min

Injection size: 20 µL

System suitability

Sample: *Impurity standard solution*

Suitability requirements

Resolution: NLT 1.5 between fenofibrate related compound A and fenofibrate related compound B

Analysis

Samples: *Impurity standard solution* and *Sample solution*

Identify the fenofibrate peak and the peaks due to the impurities and degradation products listed in [Impurity Table 1](#).

Measure the responses for the major peaks, and calculate the percentage of each of fenofibrate related compound A, fenofibrate related compound B, and fenofibrate related compound C in the portion of Fenofibrate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of appropriate fenofibrate related compound from the *Sample solution*

r_S = peak response of appropriate fenofibrate related compound from the *Impurity standard solution*

C_S = concentration of the appropriate fenofibrate related compound in the *Impurity standard solution* (µg/mL)

C_U = concentration of Fenofibrate in the *Sample solution* (µg/mL)

Calculate the percentage of any other impurity in the portion of Fenofibrate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of fenofibrate from the *Impurity standard solution*

C_S = concentration of fenofibrate in the *Impurity standard solution* (µg/mL)

C_U = concentration of Fenofibrate in the *Sample solution* (µg/mL)

Acceptance criteria

Individual impurities: See [Impurity Table 1](#).

Total impurities: NMT 0.5%

Impurity Table 1