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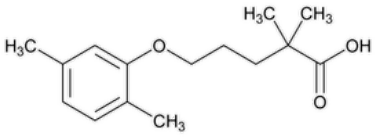
Gemfibrozil



$C_{15}H_{22}O_3$ 250.33

Pentanoic acid, 5-(2,5-dimethylphenoxy)-2,2-dimethyl-;

2,2-Dimethyl-5-(2,5-xylyloxy)valeric acid CAS RN®: 25812-30-0; UNII: Q8X02027X3.

DEFINITION

Gemfibrozil contains NLT 98.0% and NMT 102.0% of gemfibrozil ($C_{15}H_{22}O_3$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Add 10 mL of glacial acetic acid to 800 mL of methanol in a 1000-mL volumetric flask, dilute with water to volume, and pass through a membrane filter.

System suitability solution: 0.2 mg/mL of gemfibrozil and 0.05 mg/mL of 2,5-dimethylphenol in *Mobile phase*

Standard stock solution: 1 mg/mL of USP Gemfibrozil RS in methanol

Standard solution: 0.2 mg/mL of USP Gemfibrozil RS in *Mobile phase* from the *Standard stock solution*

Sample stock solution: 1 mg/mL of Gemfibrozil in methanol

Sample solution: 0.2 mg/mL of Gemfibrozil in *Mobile phase* from the *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 276 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

[Note—The elution order is 2,5-dimethylphenol, followed by gemfibrozil.]

Resolution: NLT 8.0 between gemfibrozil and 2,5-dimethylphenol, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of gemfibrozil ($C_{15}H_{22}O_3$) in the portion of Gemfibrozil 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 Gemfibrozil RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• **Organic Impurities**

Mobile phase: Add 10 mL of glacial acetic acid to 750 mL of methanol in a 1000-mL volumetric flask, dilute with water to volume, and pass through a membrane filter.

Peak identification solution: 0.2 mg/mL of USP Gemfibrozil RS, 0.05 mg/mL of USP Gemfibrozil Related Compound A RS, and 0.05 mg/mL of 2,5-dimethylphenol in *Mobile phase*

Standard stock solution: 0.1 mg/mL each of USP Gemfibrozil RS and USP Gemfibrozil Related Compound A RS in methanol

Standard solution: 0.01 mg/mL each of USP Gemfibrozil RS and USP Gemfibrozil Related Compound A RS in *Mobile phase* from the *Standard stock solution*

Sample solution: 10 mg/mL of Gemfibrozil in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 276 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0% for each peak

Analysis

Chromatograph the *Peak identification solution*, and identify the components on the basis of their relative retention times. The relative retention times for 2,5-dimethylphenol, gemfibrozil, and gemfibrozil related compound A are 0.35, 1.0, and 2.1, respectively.

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of gemfibrozil related compound A in the portion of Gemfibrozil taken:

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

r_U = peak area of gemfibrozil related compound A from the *Sample solution*

r_S = peak area of gemfibrozil related compound A from the *Standard solution*

C_S = concentration of USP Gemfibrozil Related Compound A RS in the *Standard solution* (mg/mL)

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

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

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

r_U = peak area of each individual impurity from the *Sample solution*

r_S = peak area for gemfibrozil from the *Standard solution*

C_S = concentration of USP Gemfibrozil RS in the *Standard solution* (mg/mL)

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

Acceptance criteria

Gemfibrozil related compound A: NMT 0.1%

Any other impurity: NMT 0.1%

Total impurities: NMT 0.5%

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.25%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Gemfibrozil RS

USP Gemfibrozil Related Compound A RS

(*E,Z*)-2,2-Dimethyl-5-[2,5-dimethyl-4-(propene-1-yl)phenoxy]valeric acid.

$C_{18}H_{26}O_3$ 290.40

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

Topic/Question	Contact	Expert Committee
GEMFIBROZIL	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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