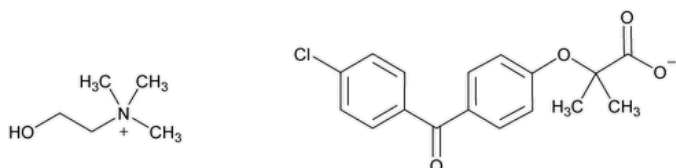


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Dec-2024
 Document Type: USP Monographs
 DocId: GUID-8BEFF1CF-6E38-47ED-8A42-19D3D470F56A_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M4254_02_01
 DOI Ref: v3713

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Add the following:

Choline Fenofibrate



$C_{17}H_{14}ClO_4^- \cdot C_5H_{14}NO^+$ 421.91

Ethanaminium, 2-hydroxy-*N,N,N*-trimethyl-, salt with 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoic acid (1:1);

2-Hydroxy-*N,N,N*-trimethylethanaminium 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoate CAS RN®: 856676-23-8; UNII: 4BMH7IZT98.

DEFINITION

Choline Fenofibrate contains NLT 97.0% and NMT 103.0% of choline fenofibrate ($C_{17}H_{14}ClO_4^- \cdot C_5H_{14}NO^+$), calculated on the anhydrous basis.

IDENTIFICATION

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A

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

• **C.**

Mobile phase: 18 mM [methanesulfonic acid](#) in [water](#)

Standard stock solution: Equivalent to 500 µg/mL of choline in [water](#) from [USP Choline Chloride RS](#)

Standard solution: Equivalent to 100 µg/mL of choline in *Mobile phase* from *Standard stock solution*

Sample stock solution: 2 mg/mL of Choline Fenofibrate in [water](#)

Sample solution: 0.4 mg/mL of Choline Fenofibrate in *Mobile phase* from *Sample stock solution*. [NOTE—This solution has an approximate concentration of 100 µg/mL of choline.]

Chromatographic system

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

Mode: Ion chromatography

Detector: Conductivity with a suitable suppressor

Column: 4.0-mm × 25-cm; 8-µm packing [L106](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The retention time of the choline peak of the *Sample solution* corresponds to the retention time of the choline peak of the *Standard solution*.

ASSAY

PROCEDURE

Protect solutions containing fenofibric acid or choline fenofibrate from light.

Solution A: [Water](#) adjusted with [phosphoric acid](#) to a pH of 2.5

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	50	50
5	50	50
25	20	80
35	20	80
36	50	50
50	50	50

Diluent: *Solution A and Solution B (50:50)*

Standard stock solution: 0.5 mg/mL of [USP Fenofibric Acid RS](#) in [acetonitrile](#)

Standard solution: 100 µg/mL of [USP Fenofibric Acid RS](#) in *Diluent* from the *Standard stock solution*

Sample solution: 130 µg/mL of Choline Fenofibrate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 286 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 40 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.10%

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of choline fenofibrate ($C_{17}H_{14}ClO_4^- \cdot C_5H_{14}NO^+$) in the portion of Choline Fenofibrate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of fenofibric acid from the *Sample solution*

r_S = peak response of fenofibric acid from the *Standard solution*

C_S = concentration of [USP Fenofibric Acid RS](#) in the *Standard solution* (µg/mL)

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

M_{r1} = molecular weight of choline fenofibrate, 421.91

M_{r2} = molecular weight of fenofibric acid, 318.75

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.15%

• **ORGANIC IMPURITIES**