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Fenofibrate Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-fenofibrate-caps-notice-20210430>.

DEFINITION

Fenofibrate Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$).

IDENTIFICATION

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

ASSAY

Change to read:

• PROCEDURE

Use *Sample stock solution 2* for Capsules labeled to meet the requirements of *Dissolution Test 2*. For all other products, use *Sample stock solution 1*.

Solution A: 136 mg/L of [▲potassium phosphate, monobasic▲](#) (RB 1-May-2021) in [water](#). Adjust with dilute [phosphoric acid](#) (1 in 10) to a pH of 2.9 ± 0.05 .

Mobile phase: [Methanol](#) and *Solution A* (4:1)

Standard solution: 67 µg/mL of [USP Fenofibrate RS](#) in *Mobile phase*

Sample stock solution 1: Accurately weigh the contents of NLT 20 Capsules. Mix the contents, and transfer a weighed portion of the powder, equivalent to about 67 mg of fenofibrate, to a 100-mL volumetric flask. Add 80 mL of *Mobile phase*, sonicate for 10 min, stir for 15 min, and dilute with *Mobile phase* to volume.

Sample stock solution 2 (for Capsules labeled to meet the requirements of *Dissolution Test 2*): Weigh the contents of NLT 20 Capsules. Mix the contents, melt in an oven at 80° for NLT 30 min, and homogenize. Allow the sample to solidify. Transfer a weighed portion of the sample, equivalent to about 67 mg of fenofibrate, to a 100-mL volumetric flask, dissolve in 30 mL of [methanol](#) with the aid of a mechanical shaker for NLT 4 h, and dilute with *Mobile phase* to volume.

Sample solution: Nominally 67 µg/mL of fenofibrate from the designated *Sample stock solution*, in *Mobile phase*. Pass a portion of this solution through a polyvinylidene difluoride (PVDF) filter of 0.45-µm pore size, discarding the first 5 mL.

Chromatographic system

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

Mode: LC

Detector: UV 285 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 1.5 times the retention time of the fenofibrate peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) in the portion of Capsules taken:

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

r_U = peak response of fenofibrate from the *Sample solution*

r_S = peak response of fenofibrate from the *Standard solution*

C_s = concentration of the *Standard solution* (µg/mL)

C_u = nominal concentration of the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 0.05 M ▲[sodium dodecyl sulfate](#)▲ (RB 1-May-2021) in [water](#); 1000 mL, deaerated

Apparatus 2: 75 rpm

Time: 40 min

Solution A and Mobile phase: Prepare as directed in the Assay.

Standard solution: (0.001 × *L*) mg/mL of [USP Fenofibrate RS](#) in *Mobile phase*, where *L* is the label claim, in mg/Capsule

Sample solution: Pass a portion of the solution under test through a suitable PVDF filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 µL for Capsules labeled to contain 67 mg; 5 µL for Capsules labeled to contain 134 or 200 mg

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) dissolved:

$$\text{Result} = (r_u/r_s) \times C_s \times V \times (1/L) \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of the *Standard solution* (mg/mL)

V = volume of *Medium*, 1000 mL

L = label claim (mg/Capsule)

Tolerances: NLT 70% (*Q*) of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: Phosphate buffer pH 6.8 ± 0.1 containing 0.1% [pancreatin](#) and 2% [polysorbate 80](#); 900 mL, deaerated by vacuum

Apparatus 2: 75 rpm with sinkers (see [Dissolution \(711\)](#), [Figure 2a](#))

Time: 2 h

Standard solution: (*L*/1000) mg/mL of [USP Fenofibrate RS](#) in *Medium*, where *L* is the label claim in mg/Capsule. A volume of [methanol](#), not exceeding 10%, can be used in the first dilution to solubilize fenofibrate.

Sample solution: Pass 20 mL of the solution under test through a suitable PVDF filter of 0.45-µm pore size, discarding the first 2 mL.

Blank: *Medium*

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: Spectrophotometry

Detector: UV 288 nm

Path length: 0.1-cm flow cell

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) dissolved:

$$\text{Result} = (A_u/A_s) \times C_s \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Capsule)

Tolerances: NLT 80% (Q) of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) is dissolved.

Test 3: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 3*.

Medium: 0.72% ▲[sodium dodecyl sulfate](#)▲ (RB 1-May-2021) in [water](#); 1000 mL, deaerated

Apparatus 2: 75 rpm, with sinkers with three prongs

Time: 30 min

Standard solution: ($L/10$) mg/mL of [USP Fenofibrate RS](#) in [methanol](#), where L is the label claim in mg/Capsule. Transfer 10.0 mL of this solution to a 1000-mL volumetric flask, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable PVDF filter of 0.45-μm pore size. Dilute with *Medium*, if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: Spectrophotometry

Detector: UV 290 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 1000 mL

L = label claim (mg/Capsule)

Tolerances: NLT 80% (Q) of the labeled amount of fenofibrate ($C_{20}H_{21}ClO_4$) is dissolved.

Test 4: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: 0.05 M ▲[sodium dodecyl sulfate](#)▲ (RB 1-May-2021) in [water](#); 1000 mL

Apparatus 2: 75 rpm, with helix sinkers or hose clamp sinkers

Times: 30 min for products labeled to contain 67, 134, and 200 mg; 40 min for products labeled to contain 43 and 130 mg

Standard stock solution: 0.5 mg/mL of [USP Fenofibrate RS](#) in *Medium* prepared as follows. Dissolve a suitable quantity of [USP Fenofibrate RS](#), taken in a suitable volumetric flask, in about 6% of the total volume of [methanol](#), and dilute with *Medium* to volume.

Standard solution: Prepare solutions of [USP Fenofibrate RS](#) in *Medium* as per [Table 1](#) from *Standard stock solution*.

Table 1

Capsule Strength (mg)	Concentration (mg/mL)
67	0.065
130 and 134	0.13
200	0.2
43	0.045

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size, discarding the first 9 mL of the filtrate.