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Fenoldopam Mesylate Injection

DEFINITION

Change to read:

Fenoldopam Mesylate Injection is a sterile solution of fenoldopam mesylate ($C_{16}H_{16}ClNO_3 \cdot CH_4SO_3$). It contains ▲an amount of fenoldopam mesylate, equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of fenoldopam ($C_{16}H_{16}ClNO_3$).▲ (USP 1-Dec-2019)

IDENTIFICATION

Delete the following:

▲• **A.** [Thin-Layer Chromatographic Identification Test ⟨201⟩]

Standard solution: 1 mg/mL in methanol

Sample solution: Pipet 1.0 mL of Injection into a 10-mL volumetric flask. Dilute to volume with methanol, and mix.

Application volume: 20 µL

Developing solvent system: Acetone, chloroform, acetic acid, and water (6:2:1:1)

Place the mixture in a paper-lined chromatographic chamber, and equilibrate for about 15 min before use.

Analysis: Proceed as directed in the chapter, and then dry the plate under a current of warm air until completely dry. Place the plate into a second chromatographic chamber containing iodine crystals, and examine the plate.

Acceptance criteria: Meets the requirements.▲ (USP 1-Dec-2019)

Add the following:

▲• **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ *(USP 1-Dec-2019)*

• **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

Change to read:

• **Procedure**

Solution A: 1.38 g/L of monobasic sodium phosphate monohydrate and 1.88 g/L of sodium hexanesulfonate in water. Adjust with a ▲10% v/v phosphoric acid▲ (USP 1-Dec-2019) solution to a pH of 2.5.

Mobile phase: Methanol and *Solution A* (33:67)

Diluent: 1.38 g/L of monobasic sodium phosphate monohydrate in water. Adjust with a ▲10% v/v phosphoric acid▲ (USP 1-Dec-2019) solution to a pH of 2.5.

▲▲ (USP 1-Dec-2019)

Standard solution: 0.263 mg/mL of USP Fenoldopam Mesylate RS▲▲ (USP 1-Dec-2019) in *Diluent*

Sample solution: ▲Nominally 0.2 mg/mL of fenoldopam in *Diluent* from Injection▲ (USP 1-Dec-2019)

Chromatographic system

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

▲▲ (USP 1-Dec-2019)

Mode: LC

Detector: UV 225 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Dec-2019)

Column: 4.6-mm × 25-cm; ▲5-µm▲ (USP 1-Dec-2019) packing L1

▲**Column temperature:** 33°▲ (USP 1-Dec-2019)

Flow rate: 1 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 2 times the retention time of fenoldopam▲ (USP 1-Dec-2019)

System suitability

Sample: ▲▲ (USP 1-Dec-2019) *Standard solution*

Suitability requirements

▲▲ (USP 1-Dec-2019)

Tailing factor: ▲▲ (USP 1-Dec-2019) NMT 2.0 for the fenoldopam peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fenoldopam ▲▲ (USP 1-Dec-2019) ($C_{16}H_{16}ClNO_3$ ▲▲ (USP 1-Dec-2019)) in the portion of Injection taken:

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

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

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

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

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

M_{r1} = molecular weight of fenoldopam, 305.76

M_{r2} = molecular weight of fenoldopam mesylate, 401.86

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

Change to read:

• **Content of Sodium Metabisulfite ▲(if present)▲** (USP 1-Dec-2019)

Sample: Transfer 10.0 mL of Injection to a glass-stoppered conical flask containing 5.0 mL of 0.1 N iodine VS, and swirl to dissolve. Allow to stand for exactly 5 min, protected from light.

▲Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Endpoint detection: Visual▲ (USP 1-Dec-2019)

Analysis: Add 0.5 mL of hydrochloric acid. Titrate the excess iodine with 0.05 N sodium thiosulfate VS ▲until the solution is pale yellow.▲ (USP 1-Dec-2019) Add 0.5 mL of starch TS▲as indicator and complete the titration to a colorless endpoint.▲ (USP 1-Dec-2019) Perform a blank determination ▲using 10 mL of water,▲ (USP 1-Dec-2019) and make any necessary correction. Each milliliter of 0.05 N sodium thiosulfate is equivalent to 2.3763 mg of sodium metabisulfite.

Acceptance criteria: NLT 0.25 mg/mL of Injection

IMPURITIES

Change to read:

• **Organic Impurities**

Solution A, Mobile phase, Diluent, ▲▲ (USP 1-Dec-2019) **Sample solution,** and **Chromatographic system:** Proceed as directed in the *Assay*.

▲Standard solution: 0.263 mg/mL of USP Fenoldopam Mesylate RS and 0.274 µg/mL of USP Fenoldopam Related Compound B RS in *Diluent*▲ (USP 1-Dec-2019)

System suitability

Sample: ▲▲ (USP 1-Dec-2019) *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5 for the fenoldopam related compound B peak; ▲▲ (USP 1-Dec-2019) NMT 2.0 for the fenoldopam peak

Relative standard deviation: NMT 2.0% ▲for the fenoldopam related compound B and fenoldopam peaks▲ (USP 1-Dec-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of fenoldopam related compound B ▲free base▲ (USP 1-Dec-2019) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times {}^{\blacktriangle}(M_{r1}/M_{r2})^{\blacktriangle}_{\text{(USP 1-Dec-2019)}} \times 100$$

r_U = peak response of fenoldopam related compound B from the *Sample solution*

r_S = peak response of fenoldopam related compound B from the *Standard solution*

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

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

▲M_{r1} = molecular weight of fenoldopam related compound B free base, 271.32

M_{r2} = molecular weight of fenoldopam related compound B, 367.42▲ (USP 1-Dec-2019)

Acceptance criteria: NMT 0.6%

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test ⟨85⟩:** ▲Meets the requirements▲ (USP 1-Dec-2019)

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **pH ⟨791⟩:** 2.8–3.8

• **Other Requirements:** Meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*, preferably of Type I glass. Store in a refrigerator or at controlled room temperature.

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Fenoldopam Mesylate RS

USP Fenoldopam Related Compound B RS

1*H*-3-Benzazepine-7,8-diol, 2,3,4,5-tetrahydro-1-(4-hydroxyphenyl)-, methanesulfonate (salt);

▲Also known as

1-(4-Hydroxyphenyl)-2,3,4,5-tetrahydro-1*H*-benzo[*d*]azepine-7,8-diol methanesulfonate.

$C_{16}H_{17}NO_3 \cdot CH_4SO_3$ 367.42▲ (USP 1-Dec-2019)

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

Topic/Question	Contact	Expert Committee
FENOLDOPAM MESYLATE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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