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Verteporfin for Injection

DEFINITION

Verteporfin for Injection is a sterile mixture of verteporfin and lipids. It contains NLT 91.0% and NMT 110.0% of the labeled amount of verteporfin ($C_{41}H_{42}N_4O_8$).

IDENTIFICATION

Change to read:

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

Sample solution: 10 µg/mL in methanol

Acceptance criteria: Meets the requirements

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

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, tetrahydrofuran, 1% (w/v) ammonium sulfate solution, and acetic acid (11:9:20:2), adjusted with 3.6 M sulfuric acid to a pH of 3.0

Diluent 1: Acetonitrile and tetrahydrofuran (1:1)

Diluent 2: Acetonitrile, tetrahydrofuran, and water (3:3:4)

Standard solution: 0.1 mg/mL of USP Verteporfin RS prepared as follows. Prepare 0.167 mg/mL of USP Verteporfin RS in *Diluent 1*, then dilute this solution with water. Protect the solution from light.

Sample solution: Reconstitute 1 vial of Verteporfin for Injection in deionized water to obtain 2 mg/mL of verteporfin. Transfer the contents to a 200-mL volumetric flask, rinsing the vial with *Diluent 2*. Dilute with *Diluent 2* to volume. Protect the solution from light.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 410 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1.4 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.5 between the two verteporfin isomer peaks

Tailing factor: NMT 1.3

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of verteporfin ($C_{41}H_{42}N_4O_8$) in the portion of Verteporfin for Injection taken:

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

r_U = sum of two verteporfin isomer peak responses from the *Sample solution*

r_S = sum of two verteporfin isomer peak responses from the *Standard solution*

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

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

Acceptance criteria: 91.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

• **Limit of Verteporfin Related Compound A**

Mobile phase, Sample solution, Chromatographic system and **System suitability:** Proceed as directed in the *Assay*.

Diluent: Acetonitrile and tetrahydrofuran (1:1)

Standard stock solution: 0.167 mg/mL of USP Verteporfin RS and 6.67 µg/mL of USP Verteporfin Related Compound A RS in *Diluent*

Standard solution: 0.1 mg/mL of USP Verteporfin RS and 4 µg/mL of USP Verteporfin Related Compound A RS prepared as follows. Dissolve 3 parts of the *Standard stock solution* with 2 parts of water. Protect the solution from light.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 410 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1.4 mL/min

Injection volume: Equal volumes for *Standard solution* and *Sample solution*

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.5 between the two verteporfin isomer peaks

Tailing factor: NMT 1.3

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of verteporfin related compound A in the portion of Verteporfin for Injection taken:

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

r_U = peak response of verteporfin related compound A from the *Sample solution*

r_S = peak response of verteporfin related compound A from the *Standard solution*

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

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

Acceptance criteria: NMT 4.0%

SPECIFIC TESTS

• **Pyrogen Test ⟨151⟩**

Test dose: 4 mg/kg

Acceptance criteria: Meets the requirements

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

• **Water Determination, *Method Ic*⟨921⟩:** NMT 3.0%, use a mixture of methanol and formamide (7:3) as the solvent.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, and store at controlled room temperature, protected from light.

• **Labeling:** The label states that it is to be protected from light after constitution, indicates that it is intended for intravenous use only, and includes the name and amount of diluent for constitution.

• **USP Reference Standards ⟨11⟩**

USP Verteporfin RS

USP Verteporfin Related Compound A RS

trans-(±)-18-Ethenyl-4,4a-dihydro-3,4-bis(methoxycarbonyl)-4a,8,14,19-tetramethyl- 23*H*,25*H*-benzo[*b*]porphine-9,13-dipropionic acid.

$C_{40}H_{40}N_4O_8$ 704.77

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

Topic/Question	Contact	Expert Committee
VERTEPORFIN FOR INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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