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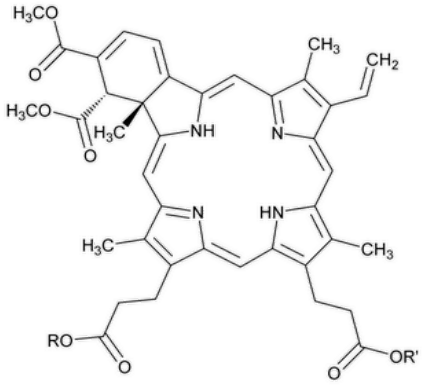
Verteporfin



R	R'
H	CH_3
CH_3	H

$C_{41}H_{42}N_4O_8$ 718.79

23*H*,25*H*-Benzo[*b*]porphine-9,13-dipropanoic acid, 18-ethenyl-4,4a-dihydro-3,4-bis(methoxycarbonyl)-4a,8,14,19-tetramethyl-, monomethyl ester, *trans*-;
(±)-*trans*-3,4-Dicarboxy-4,4a-dihydro-4a,8,14,19-tetramethyl-18-vinyl-23*H*,25*H*-benzo[*b*]porphine-9,13-dipropanoic acid, 3,4,9-trimethyl ester mixture with (±)-*trans*-3,4-dicarboxy-4,4a-dihydro-4a,8,14,19-tetramethyl-18-vinyl-23*H*,25*H*-benzo[*b*]porphine-9,13-dipropionic acid, 3,4,13-trimethyl ester CAS RN®: 129497-78-5; UNII: 0X9PA28K43.

DEFINITION

Verteporfin contains NLT 94.0% and NMT 102.0% of verteporfin ($C_{41}H_{42}N_4O_8$), calculated on the anhydrous basis.

[**Caution—**Verteporfin is a light-activated drug used in photodynamic therapy. Care should be taken to avoid contact with eyes and skin.]

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (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**

Solution A: Acetonitrile, 1% (w/v) aqueous ammonium sulfate, glacial acetic acid, and 3.6 M sulfuric acid (10:10:1:0.027)

Solution B: Tetrahydrofuran, 1% (w/v) aqueous ammonium sulfate, glacial acetic acid, and 3.6 M sulfuric acid (10:10:1:0.034)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
60	80	20
90	60	40

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Time (min)	Solution A (%)	Solution B (%)
91	60	40
120	30	70
121	30	70
125	0	100
137	0	100
140	80	20
150	80	20

Diluent: Acetonitrile and tetrahydrofuran (1:1)

Standard solution: 0.25 mg/mL of USP Verteporfin RS prepared as follows. Transfer USP Verteporfin RS to a suitable volumetric flask, add *Diluent* equivalent to 60% of the flask volume and dissolve, then dilute with water to volume. Protect this solution from light.

Sample solution: Equivalent to 0.25 mg/mL of Verteporfin prepared as follows. Transfer 25 mg of Verteporfin to a 100-mL volumetric flask, add 60 mL of *Diluent* and dissolve, then dilute with water to volume. Protect this solution from light.

Chromatographic system

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

Mode: LC

Detector: Vis 410 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.5 between the two verteporfin regioisomer peaks

Tailing factor: NMT 1.3

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

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

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

Calculate the ratio for the two verteporfin regioisomer peaks from the *Sample solution*.

Acceptance criteria

Assay: 94.0%–102.0% on the anhydrous basis

Peak ratio: 0.9–1.1

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**

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Procedure

Solution A, Solution B, Mobile phase, Standard solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.25 µg/mL of USP Verteporfin RS in water from the *Standard solution*

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Resolution: NLT 2.5 between the two verteporfin peaks, *Standard solution*

Tailing factor: NMT 1.3, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual impurity in the portion of Verteporfin taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity from the *Sample solution*

r_T = sum of the responses of all the peaks from the *Sample solution*

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Impurity	0.56	0.6
Verteporfin (first regioisomer peak)	1.0	—
Any other individual impurity	—	0.8
Total impurities	—	4.0

SPECIFIC TESTS

- **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^2 cfu/g.
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.5 USP Endotoxin Unit/mg of verteporfin
- **Water Determination, *Method Ic*⟨921⟩:** NMT 1.4%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store in a freezer.
- **USP Reference Standards ⟨11⟩**

  USP Verteporfin RS

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

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

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Chromatographic Database Information: Chromatographic Database

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