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Vinblastine Sulfate for Injection

DEFINITION

Change to read:

Vinblastine Sulfate for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of vinblastine sulfate ($C_{46}H_{58}N_4O_9 \cdot H_2SO_4$).

[Caution—Handle ▲vinblastine sulfate▲ (USP 1-Aug-2022) with great care because it is a potent cytotoxic agent.]

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K

  Sample: Use material previously dried in a vacuum at 60° for 16 h.

  Acceptance criteria: Meets the requirements of 197K

- **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. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sulfate***

  Sample solution: 100 mg/mL in water

  Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

  Solution A: Diethylamine and water (14:986). Adjust with phosphoric acid to a pH of 7.5.

  Solution B: Acetonitrile and methanol (20:80)

  Mobile phase: *Solution A* and *Solution B* (38:62)

  Standard solution: 0.4 mg/mL of USP Vinblastine Sulfate RS in water

  System suitability solution: 0.4 mg/mL of USP Vincristine Sulfate RS in *Standard solution*. [Note—No loss on drying determination is needed for USP Vincristine Sulfate RS.]

  Sample stock solution: Pipet a suitable volume of water into each of five containers of Vinblastine Sulfate for Injection to obtain a solution in each having a nominal concentration of 1 mg/mL of vinblastine sulfate. Insert the stopper, shake to mix, and combine the solutions from the five containers.

  Sample solution: Nominally equivalent to 0.4 mg/mL of vinblastine sulfate in water, from the *Sample stock solution*

  Chromatographic system

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

  Mode: LC

  Detector: UV 262 nm

  Columns

  Precolumn: Packed with porous silica gel; installed between the pump and the injector

  Analytical: 4.6-mm × 15-cm; 5-µm packing L1

  Flow rate: 2 mL/min

  Injection volume: 20 µL

  System suitability

  Samples: *Standard solution* and *System suitability solution*

  Suitability requirements

  Resolution: NLT 4.0 between vincristine and vinblastine, *System suitability solution*

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

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Calculate the percentage of the labeled amount of vinblastine sulfate ($C_{46}H_{58}N_4O_9 \cdot H_2SO_4$) in the portion of Vinblastine Sulfate for Injection taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

Change to read:

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meets the requirements▲ (USP 1-Aug-2022)

IMPURITIES

Change to read:

• **Organic Impurities**

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

Sample solution A: Use the *Sample solution*, prepared as directed in the *Assay*.

Sample solution B: 16 µg/mL of vinblastine sulfate in water, from *Sample solution A*

Chromatographic system

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

Mode: LC

Detector: UV 262 nm

Columns

Precolumn: Packed with porous silica gel; installed between the pump and the injector

Analytical: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 2 mL/min

Injection volume: 200 µL (20 µL for *System suitability*)

Analysis

Samples: *Sample solution A* and *Sample solution B*

Calculate the percentage of each ▲individual▲ (USP 1-Aug-2022) impurity in the portion of Vinblastine Sulfate for Injection taken:

$$\text{Result} = [r_{UA}/(\Sigma r_{UA} + 25r_{UB})] \times 100$$

r_{UA} = peak response of each ▲individual▲ (USP 1-Aug-2022) impurity appearing after the solvent peak from *Sample solution A*

r_{UB} = peak response of vinblastine from *Sample solution B*

Calculate the percentage of total impurities:

$$\text{Result} = [\Sigma r_{UA}/(\Sigma r_{UA} + 25r_{UB})] \times 100$$

r_{UA} = peak response of each ▲individual▲ (USP 1-Aug-2022) impurity appearing after the solvent peak from *Sample solution A*

r_{UB} = peak response of vinblastine from *Sample solution B*

Acceptance criteria

Individual impurities: NMT 2.0%

Total impurities: NMT 5.0%

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test ⟨85⟩:** ▲Meets the requirements▲ (USP 1-Aug-2022)

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

• **Injections and Implanted Drug Products ⟨1⟩,** *Product Quality Tests Common to Parenteral Dosage Forms, Specific Tests, Completeness and Clarity of Solutions*: At the time of use, it meets the requirements.

• **Other Requirements:** It meets the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for Constitution*, and store in a refrigerator.

Change to read:

• **Labeling:** ▲Label to indicate:▲ (USP 1-Aug-2022) "For Intravenous Use Only—Fatal If Given By Other Routes." When dispensed, the container ▲▲ (USP 1-Aug-2022) (holding the individual dose prepared for administration to the patient) must ▲bear▲ (USP 1-Aug-2022) the statement: "▲▲ (USP 1-Aug-2022) For Intravenous Use Only—Fatal If Given By Other Routes."

• **USP Reference Standards ⟨11⟩**

USP Vinblastine Sulfate RS

USP Vincristine Sulfate RS

[Note—No loss on drying determination is needed for USP Vincristine Sulfate RS.]

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

Topic/Question	Contact	Expert Committee
VINBLASTINE SULFATE 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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