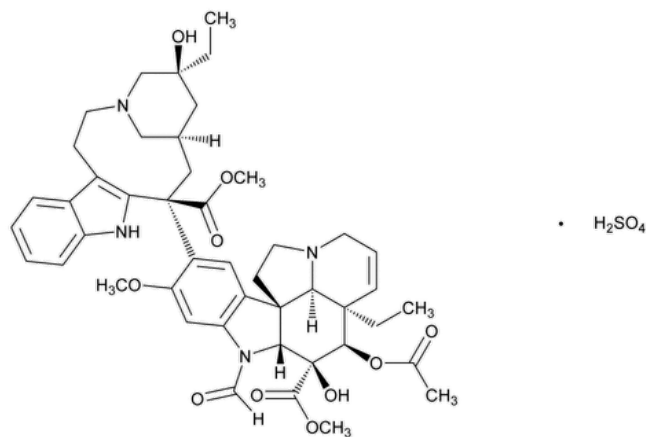


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Vincristine Sulfate



$C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$ 923.04

Vincalukoblastine, 22-oxo-, sulfate (1:1) (salt);

Leurocristine sulfate (1:1) (salt) CAS RN®: 2068-78-2; UNII: T5IRO3534A.

DEFINITION

Vincristine Sulfate contains NLT 95.0% and NMT 105.0% of vincristine sulfate ($C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$), calculated on the dried basis.

[CAUTION—Handle vincristine sulfate with great care because it is a potent cytotoxic agent.]

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), *Infrared Spectroscopy*:** 197A or 197K

▲ (USP 1-Dec-2020)

- **B. IDENTIFICATION TESTS—GENERAL (191), *Chemical Identification Tests, Sulfate***

Sample solution: 100 mg/mL

Acceptance criteria: Meets the requirements

- **C.** 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: [Diethylamine](#) and [water](#) (1:59). Adjust with [phosphoric acid](#) to a pH of 7.5.

Mobile phase: [Methanol](#) and *Solution A* (70:30)

Standard solution: 1.2 mg/mL of [USP Vincristine Sulfate RS](#)▲ (USP 1-Dec-2020) in [water](#)

System suitability solution: 1 mg/mL of [USP Vinblastine Sulfate RS](#) in the *Standard solution*. [NOTE—No loss on drying determination is needed for [USP Vinblastine Sulfate RS](#).]

Sample solution: 1.2 mg/mL of Vincristine Sulfate in [water](#). Equilibrate a portion of Vincristine Sulfate for 30 min in ambient humidity. Using another portion of the equilibrated specimen, determine the loss on drying.

Chromatographic system

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

Mode: LC

Detector: UV 297 nm

Columns**Precolumn:** Porous silica gel packing**Guard:** 2- to 5-cm; packing [L1](#)**Analytical:** 4.6-mm × 25-cm; 5-μm packing [L7](#)**Flow rate:** 1.5 mL/min**Injection volume:** 10 μL**System suitability****Samples:** *Standard solution* and *System suitability solution***Suitability requirements****Resolution:** NLT 4.0 between the vincristine sulfate and vinblastine sulfate peaks, *System suitability solution* ▲ (USP 1-Dec-2020)**Relative standard deviation:** NMT 2.0%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of vincristine sulfate ($C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$) in the portion of Vincristine Sulfate taken:

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

 r_U = peak response of vincristine sulfate from the *Sample solution* r_S = peak response of vincristine sulfate from the *Standard solution* C_S = concentration of [USP Vincristine Sulfate RS](#) ▲ (USP 1-Dec-2020) in the *Standard solution* (mg/mL) C_U = concentration of Vincristine Sulfate in the *Sample solution* (mg/mL)**Acceptance criteria:** 95.0%–105.0% on the dried basis**IMPURITIES****• ORGANIC IMPURITIES****Solution A:** [Diethylamine](#) and [water](#) (3:197). Adjust with [phosphoric acid](#) to a pH of 7.5.**Solution B:** [Methanol](#)**Mobile phase:** See [Table 1](#).**Table 1**

Time (min)	Solution A (%)	Solution B (%)
0	38	62
12	38	62
27	8	92
29	38	62
34	38	62

Sample solution A: Prepare as directed for the *Sample solution* in the Assay.**Sample solution B:** 0.04 mg/mL of Vincristine Sulfate in [water](#), from *Sample solution A***Chromatographic system:** Proceed as directed in the Assay, except for the *Flow rate* and *Injection volume*.**Flow rate:** 2 mL/min**Injection volume:** 200 μL**Analysis****Samples:** *Sample solution A* and *Sample solution B*

Calculate the percentage of each impurity in the portion of Vincristine Sulfate taken:

$$\text{Result} = [r_{UA}/(\sum r_{UA} + 30r_{UB})] \times 100$$