

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-Aug-2022
 Document Type: USP Monographs
 DocId: GUID-86D0BFD3-9FB6-4EC0-A8B9-632F6A28CF04_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M88259_05_01
 DOI Ref: t0klv

© 2025 USPC
 Do not distribute

Vincristine Sulfate Injection

DEFINITION

Change to read:

Vincristine Sulfate Injection is a sterile solution of Vincristine Sulfate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of vincristine sulfate ($C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$).

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

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Standard solution: 10 mg/mL of [USP Vincristine Sulfate RS](#) in [methylene chloride](#) and [methanol](#) (3:1)

Sample solution: Transfer a volume of Injection, equivalent to 2 mg of vincristine sulfate, to a small centrifuge tube. For each milliliter of solution add 1 drop of [ammonium hydroxide](#). Add 0.2 mL of [methylene chloride](#). Place the cap on the tube, shake it vigorously for NLT 1 min, and centrifuge for 1 min. Carefully withdraw the [methylene chloride](#) layer, and transfer to a small stoppered vial.

Chromatographic system

(See [Chromatography \(621\)](#), [General Procedures](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 20 µL

Developing solvent system: Fresh [ether](#), [methanol](#), and methylamine solution (2 in 5) (19:2:1)

Spray reagent: Dissolve 2.0 g of [ceric ammonium sulfate](#) in 100 mL of [water](#) with heating and stirring, and slowly add 100 mL of [phosphoric acid](#). Filter if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatographic plate in a [methanol](#) prewash tank; for maximum sensitivity, dry NMT 2 h before use. Score the plate about 15 cm above the points of application. Apply the *Standard solution* and the *Sample solution* about 2.5 cm from the lower edge of the plate, and dry thoroughly (a current of cool air may be used to help dry the spots). Place the plate in the nonequilibrated developing chamber that contains a paper liner around the back and sides and *Developing solvent system* to a depth of about 2 cm. Remove the plate when the solvent moves to the scored line (about 80 min), and discard the solvent system. Dry the plate in a fume hood at room temperature, heat on a metal plate on a steam bath for 15 min, and spray the plate while still hot with *Spray reagent*. Continue heating the plate for 15 min to stabilize the spots.

Acceptance criteria: The R_f value and the color of the principal spot from the *Sample solution* correspond to those from the *Standard solution*.

• 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

▲**Buffer:**▲ (USP 1-Aug-2022) [Diethylamine](#) and [water](#) (1:59). Adjust with [phosphoric acid](#) to a pH of 7.5.

Mobile phase: [Methanol](#) and ▲*Buffer*▲ (USP 1-Aug-2022) (70:30)

Standard solution: 1.2 mg/mL of [USP Vincristine Sulfate RS](#) 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: Nominally 1.0 mg/mL of vincristine sulfate in [water](#) from Injection

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 vincristine^{▲▲} (USP 1-Aug-2022) and vinblastine, ^{▲▲} (USP 1-Aug-2022) *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 vincristine sulfate ($C_{46}H_{56}N_4O_{10} \cdot H_2SO_4$) in the portion of Injection taken:

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

 r_U = peak response of vincristine from the *Sample solution* r_S = peak response of vincristine from the *Standard solution* C_S = concentration of [USP Vincristine Sulfate RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of vincristine sulfate in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**IMPURITIES****Change to read:**• **ORGANIC IMPURITIES****Solution A:** [Diethylamine](#) and [water](#) (3:197). Adjust with [phosphoric acid](#) to a pH of 7.5.**Solution B:** [Methanol](#)**Solution C:** Prepare a suitable dilution of any preservative present in the Injection, as identified in the labeling.**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: Nominally 1 mg/mL of vincristine sulfate in [water](#), from Injection**Sample solution B:** Nominally 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**