



Edition: BP 2025 (Ph. Eur. 11.6 update)

Vindesine Injection

[General Notices](#)

Vindesine Sulphate for Injection

Action and use

Vinca alkaloid cytotoxic.

DEFINITION

Vindesine Injection is a sterile solution of Vindesine Sulfate in a suitable liquid. It is prepared by dissolving Vindesine Sulfate for Injection in the requisite volume of a suitable diluent in accordance with the manufacturer's instructions.

The injection complies with the requirements stated under Parenteral Preparations.

STORAGE

Vindesine Injection should be used immediately after preparation but, in any case, within the period recommended by the manufacturer when prepared and stored strictly in accordance with the manufacturer's instructions.

VINDESINE SULFATE FOR INJECTION

DEFINITION

Vindesine Sulfate for Injection is a sterile material consisting of a mixture of one part by weight of Vindesine Sulfate and five parts by weight of a suitable carrier with or without other [excipients](#). It is supplied in a sealed container.

The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements.

Content of vindesine sulfate, $C_{43}H_{55}N_5O_7 \cdot H_2SO_4$

90.0 to 105.0% of the stated amount of anhydrous vindesine sulfate.

IDENTIFICATION

A. Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions in [methanol](#).

(1) Dissolve a quantity of the contents of the injection in sufficient [methanol](#) to produce a solution containing the equivalent of 0.20% w/v of anhydrous vindesine sulfate.

(2) 0.20% w/v of [vindesine sulfate EPCRS](#).

(3) 0.20% w/v each of [vinblastine sulfate EPCRS](#), [vincristine sulfate EPCRS](#) and [vindesine sulfate EPCRS](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel GF₂₅₄](#).
- (b) Use the mobile phase as described below.
- (c) Apply 10 µL of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#).

MOBILE PHASE

5 volumes of [diethylamine](#), 5 volumes of [methanol](#) and 90 volumes of [chloroform](#).

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows three clearly separated spots.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2).

- B. In the Assay, the principal peak in the chromatogram obtained with solution (1) has the same retention time as the principal peak in the chromatogram obtained with solution (2).
- C. Yields the reactions characteristic of [sulfates](#), [Appendix VI](#).

TESTS

[Clarity of solution](#)

Dissolve the contents of a sealed container in 10 mL of [carbon dioxide-free water](#). The solution is *clear*, [Appendix IV A](#).

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions in [water](#). Keep the solutions in ice before use.

- (1) To a quantity of injection add sufficient water to produce a solution expected to contain 0.10% w/v of anhydrous Vindesine Sulfate.
- (2) Dilute 1 volume of solution (1) to 50 volumes.
- (3) Dissolve 1 mg of [desacetylvindesine EPCRS](#) in [water](#); add 1 mL of solution (1) and dilute to 50 mL.
- (4) Dilute 1 volume of solution (2) to 20 volumes.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Jones Apex ODS is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 2 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 270 nm.
- (f) Inject 200 µL of each solution.
- (g) Maintain the final concentration of the mobile phase until the total run time is twice the retention time of the principal peak in the chromatogram obtained with solution (1).

MOBILE PHASE

Mobile phase A A 1.5% v/v solution of [diethylamine](#) adjusted to pH 7.4 with [orthophosphoric acid](#).

Mobile phase B [methanol](#).

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)	Comment
	49	51	Equilibration
0–40	49	51	Isocratic
40–49	49→30	51→70	Linear gradient
49–end	30	70	Isocratic

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3):

the retention time of vindesine is less than 40 minutes;

the [symmetry factor](#) of the vindesine peak is not more than 2.0;

the [resolution factor](#) between the peaks due to vindesine and desacetylvinblastine is at least 2.0.

LIMITS

In the chromatogram obtained with the solution (1):

the area of any [secondary peak](#) is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (3%);

the sum of the areas of any such peaks is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (5%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

[Uniformity of content](#)

The content of anhydrous vindesine sulfate in each of 10 individual containers as determined in the Assay is not less than 90.0% and not more than 110.0% of the average except that in one container the content may be not less than 80.0% and not more than 120.0% of the average.

ASSAY

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions. Keep the solutions in ice before use.

- (1) Dissolve the contents of a sealed container in [water](#) and add sufficient [water](#) to produce a solution containing the equivalent of 0.05% w/v of anhydrous vindesine sulfate.
- (2) Dissolve and dilute the entire contents of a vial of [vindesine sulfate EPCRS](#) with [water](#) to yield a concentration of approximately 0.05% w/v.
- (3) Add 2 mL of solution (2) to 1 mg of [desacetylvinblastine EPCRS](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Jones Apex ODS is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 270 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

38 volumes of a 1.5% v/v solution of [diethylamine](#), previously adjusted to pH 7.4 with [orthophosphoric acid](#), and 62 volumes of [methanol](#).

SYSTEM SUITABILITY

The assay is not valid unless:

the [*resolution factor*](#) between the peaks corresponding to vindesine sulfate and desacetylvinblastine sulfate is greater than 1.5;

the [*symmetry factor*](#) of the vindesine peak is not more than 2.0.

DETERMINATION OF CONTENT

Calculate the content of vindesine sulfate, $C_{43}H_{55}N_5O_7 \cdot H_2SO_4$, in the container using the declared content of $C_{43}H_{55}N_5O_7 \cdot H_2SO_4$ in [*vindesine sulfate EP CRS*](#). Repeat the procedure with a further nine containers. Calculate the average content of $C_{43}H_{55}N_5O_7 \cdot H_2SO_4$ per container from the 10 individual results obtained.

STORAGE

Vindesine Sulfate for Injection should be stored at a temperature of 2° to 8°.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed in the monograph for Vindesine Sulfate.