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Vinorelbine Injection

DEFINITION

Vinorelbine Injection is a sterile solution of Vinorelbine Tartrate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of vinorelbine ($C_{45}H_{54}N_4O_8$).

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

IDENTIFICATION

• **A.** The retention time and UV spectrum of the major peak of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **PROCEDURE**

Buffer: Dissolve 6.9 g of monobasic sodium phosphate in 900 mL of water. Adjust with phosphoric acid to a pH of 4.2, and dilute with water to 1000 mL.

Mobile phase: Dissolve 1.22 g of sodium 1-decanesulfonate in 620 mL of methanol, and add 380 mL of *Buffer*.

System suitability solution: Prepare a solution containing 1.4 mg/mL of USP Vinorelbine Tartrate RS and 0.01 mg/mL of USP Vinorelbine Related Compound A RS in water. Expose a portion of this solution in a suitable xenon lamp apparatus capable of supplying a dose of 1600 KJ/m^2 between 310 and 800 nm at a power of 500 W/m^2 for 1 h to generate an additional photodegradation product, 3,6-epoxy vinorelbine.

Standard solution: 0.14 mg/mL of USP Vinorelbine Tartrate RS in water

Sample solution: Nominally equivalent to 0.1 mg/mL of vinorelbine in water, from Injection

Chromatographic system

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

Mode: LC

Detector: Diode array

Column: 3.9-mm × 15-cm; packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for 3,6-epoxy vinorelbine, vinorelbine, and vinorelbine related compound A are 0.8, 1.0, and 1.2, respectively.]

Suitability requirements

Resolution: NLT 1.5 between vinorelbine and vinorelbine related compound A, *System suitability solution*

Relative standard deviation: ▲NMT▲ (ERR 1-Nov-2018) 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of vinorelbine ($C_{45}H_{54}N_4O_8$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution* at 267 nm

r_S = peak response from the *Standard solution* at 267 nm

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

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

M_{r1} = molecular weight of vinorelbine, 778.93

M_{r2} = molecular weight of vinorelbine tartrate, 1079.11

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

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

Sample solution: Nominally equivalent to 1.0 mg/mL of vinorelbine in *Mobile phase*, from Injection

Chromatographic system

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

Mode: LC

Detector: UV 267 nm

Column: 3.9-mm × 15-cm; packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between vinorelbine and vinorelbine related compound A

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Injection taken:

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

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

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

Acceptance criteria: See *Table 1*. Disregard any peaks less than 0.1%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
3,6-Epoxy vinorelbine[a]	0.8	1.0
Vinorelbine	1.0	—
Vinorelbine related compound A[b]	1.2	0.3
Any unspecified impurity	—	0.2
Total impurities	—	2.0

[a] 3',4',7,8-Tetradehydro-3,4'-dideoxy-3,6-epoxy-6,7-dihydro-8'-norvincaleukoblastine.

[b] 4-*O*-Deacetylvinorelbine.

SPECIFIC TESTS

• **Clarity of Solution**

Sample solution: 10 mg/mL

Acceptance criteria: The solution is clear.

• **Color of Solution**

Sample solution: 10 mg/mL

Analysis: Determine the absorbance of the *Sample solution* in a 1-cm cell at 420 nm in a suitable spectrophotometer, using water as the blank.

Acceptance criteria: NMT 0.060

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 3.0 USP Endotoxin Units/mg of vinorelbine.

• **Sterility Tests ⟨71⟩:** Meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*

• **pH ⟨791⟩:** 3.3–3.8

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose containers as described in *Packaging and Storage Requirements* ⟨659⟩, preferably of Type I glass, protected from light. Store in a refrigerator.

• **USP Reference Standards** ⟨11⟩

USP Vinorelbine Related Compound A RS

4-*O*-Deacetylvinorelbine tartrate.

$C_{43}H_{52}N_4O_7 \cdot 2C_4H_6O_6$ 1037.07

USP Vinorelbine Tartrate RS

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

Topic/Question	Contact	Expert Committee
VINORELBINE 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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