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Vancomycin Hydrochloride for Injection

DEFINITION
Vancomycin Hydrochloride for Injection is a sterile dry mixture of Vancomycin Hydrochloride and may contain a suitable stabilizing agent. It contains NLT 90.0% and NMT 115.0% of the labeled amount of vancomycin.

IDENTIFICATION
Change to read:

- ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

ASSAY

- [ANTIBIOTICS—MICROBIAL ASSAYS \(81\)](#)
Sample solution 1 (where it is represented as being in a single-dose container): Constitute a container of Vancomycin Hydrochloride for Injection in water corresponding to the volume of diluent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe. Dilute to an equivalent of 1 mg/mL of vancomycin with water.
Sample solution 2 (where it is packaged for dispensing): Dissolve the contents of 1 container of Vancomycin Hydrochloride for Injection in water, and dilute with water to obtain a solution having a concentration of 1 mg/mL of vancomycin.
Sample solution 3 (where the label states the quantity of vancomycin in a given volume of constituted solution): Constitute a container of Vancomycin Hydrochloride for Injection in water corresponding to the volume of diluent specified in the labeling. Dilute a portion to obtain a final concentration equivalent to 1 mg/mL of vancomycin in water.
Analysis: Proceed as directed in [Antibiotics—Microbial Assays \(81\)](#). [NOTE—Use a measured volume of the appropriate *Sample solution*, diluted quantitatively with *Buffer B.4* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.]
Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements

SPECIFIC TESTS

- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements under small-volume injections
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): NMT 0.33 USP Endotoxin Unit/mg of vancomycin
- [STERILITY TESTS \(71\)](#): It meets the requirements when tested as directed for [Test for Sterility of the Product to Be Examined, Membrane Filtration](#), except to dissolve the specimen in water instead of in *Fluid A*.
- [pH \(791\)](#): 2.5–4.5, 50 mg/mL in water
- [WATER DETERMINATION, Method I \(921\)](#): NMT 5.0%
- [INJECTIONS AND IMPLANTED DRUG PRODUCTS \(1\)](#), [Specific Tests, Completeness and clarity of solutions](#): Meets the requirements at the time of use.
- **CONTENT OF VANCOMYCIN**
Solution A: Triethylamine and water (1:500). Adjust with phosphoric acid to a pH of 3.2.
Solution B: Acetonitrile, tetrahydrofuran, and *Solution A* (7:1:92)
Solution C: Acetonitrile, tetrahydrofuran, and *Solution A* (29:1:70)
Mobile phase: See the gradient table below.
[NOTE—Make adjustments if necessary, changing the acetonitrile proportion in *Solution B* to obtain a retention time of 7.5–10.5 min for the main vancomycin peak.]

Time (min)	Solution B (%)	Solution C (%)
0	100	

Time (min)	Solution B (%)	Solution C (%)
12	100	0
20	0	100
22	0	100
23	100	0
30	100	0

System suitability solution: 0.5 mg/mL of [USP Vancomycin Hydrochloride RS](#). Heat at 65° for 48 h, and allow to cool.

Sample solution 1: Equivalent to 10 mg/mL of vancomycin from Vancomycin Hydrochloride for Injection in *Solution B*

Sample solution 2: 0.4 mg/mL of vancomycin from *Sample solution 1* in *Solution B*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Flow rate: 2 mL/min

Injection size: 20 μL

System suitability

Sample: *System suitability solution*

[NOTE—The elution order is compound 1, vancomycin B, and compound 2. Compound 2 elutes 3–6 min after the start of the period when the percentage of *Solution C* increases from 0% to 100%.]

Suitability requirements

Resolution: NLT 3.0 between compound 1 and vancomycin B

Column efficiency: NLT 1500 theoretical plates, calculated from the vancomycin B peak

Analysis

Samples: *Sample solution 1* and *Sample solution 2*

[NOTE—Where baseline separation is not achieved, peak areas are defined by vertical lines extended from the valleys between peaks to the baseline. The main component peak may include a fronting shoulder, which is attributed to monodechlorovancomycin. This shoulder should not be integrated separately.]

[NOTE—Correct any peak observed in the chromatograms obtained from *Sample solution 1* and *Sample solution 2* by subtracting the area response of any peak observed in the chromatogram of *Solution B* at the corresponding elution time.]

Measure the area responses for all of the peaks.

Calculate the percentage of vancomycin B in the specimen tested:

$$\text{Result} = [D \times r_B / ((D \times r_B) + r_A)] \times 100$$

D = dilution factor, *Sample solution 1* to *Sample solution 2*, 25

r_B = corrected area response of the main peak from *Sample solution 2*

r_A = sum of the corrected area responses of all the peaks, other than the main peak, from *Sample solution 1*

Calculate the percentage of each other peak taken:

$$\text{Result} = \{r_i / [(D \times r_B) + r_A]\} \times 100$$

r_i = corrected area response of any individual peak, other than the main peak, from *Sample solution 1*

D = dilution factor, *Sample solution 1* to *Sample solution 2*, 25

Acceptance criteria: NLT 80.0% of vancomycin B; NMT 9.0% of any peak other than the main peak

• **OTHER REQUIREMENTS:** It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).