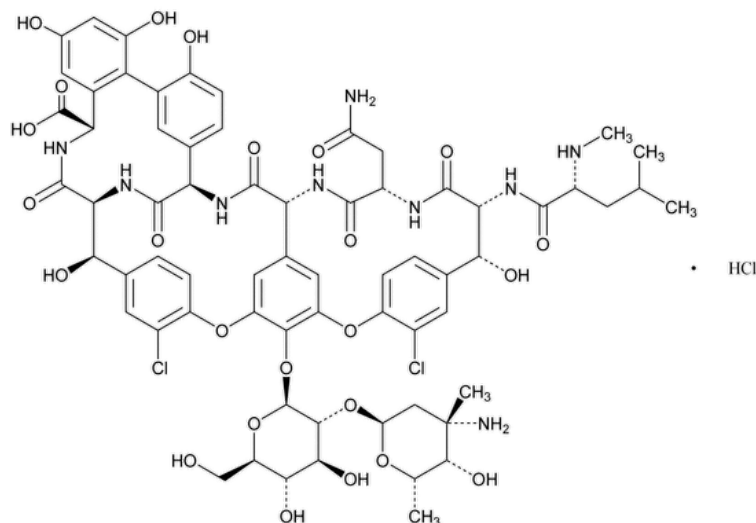


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-1FEE2E6F-D1D6-4E11-835D-2637361D4BB2_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M87760_04_01
 DOI Ref: 80698

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Vancomycin Hydrochloride



$C_{66}H_{75}Cl_2N_9O_{24} \cdot HCl$ 1485.71

Vancomycin, monohydrochloride;

Vancomycin monohydrochloride;

(S_a)-(3S,6R,7R,22R,23S,26S,36R,38aR)-44-[[2-O-(3-Amino-2,3,6-trideoxy-3-C-methyl-α-L-lyxo-hexopyranosyl)-β-D-glucopyranosyl]oxy]-3-(carbamoylmethyl)-10,19-dichloro-2,3,4,5,6,7,23,24,25,26,36,37,38,38a-tetradecahydro-7,22,28,30,32-pentahydroxy-6-[(2R)-4-methyl-2-(methylamino)]valeramido]-2,5,24,38,39-pentaoxo-22H-8,11:18,21-dietheno-23,36-(iminomethano)-13,16:31,35-dimetheno-1H,16H-[1,6,9]oxadiazacyclohexadecino[4,5-m][10,2,16]benzoxadiazacyclotetracosine-26-carboxylic acid, monohydrochloride;
 [3S-[3R*,6S*(S*),7S*,22S*,23R*,26R*,36S*,38aS*]]-3-(2-Amino-2-oxoethyl)-44-[[2-O-(3-amino-2,3,6-trideoxy-3-C-methyl-α-L-lyxo-hexopyranosyl)-β-D-glucopyranosyl]oxy]-10,19-dichloro-2,3,4,5,6,7,23,24,25,26,36,37,38,38a-tetradecahydro-7,22,28,30,32-pentahydroxy-6-[[4-methyl-2-(methylamino)-1-oxopentyl]amino]-2,5,24,38,39-pentaoxo-22H-8,11:18,21-dietheno-23,36-(iminomethano)-13,16:31,35-dimetheno-1H,16H-[1,6,9]oxadiazacyclohexadecino[4,5-m][10,2,16]benzoxadiazacyclotetracosine-26-carboxylic acid, monohydrochloride CAS RN[®]: 1404-93-9;
 UNII: 71W0621TJD.

DEFINITION

Vancomycin Hydrochloride is the hydrochloride salt of a kind of vancomycin, a substance produced by the growth of *Streptomyces orientalis* (Fam. Streptomycetaceae), or a mixture of two or more such salts. It has a potency equivalent to NLT 900 µg/mg of vancomycin, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K** (CN 1-MAY-2020)

ASSAY

- **PROCEDURE:** Proceed with Vancomycin Hydrochloride as directed under [Antibiotics—Microbial Assays \(81\)](#).

Acceptance criteria: NLT 900 µg/mg on the anhydrous basis

IMPURITIES

ORGANIC IMPURITIES

- **PROCEDURE: LIMIT OF MONOCHLOROVANCOMYCIN**

[NOTE—The System suitability solution, Standard solution, and Sample solution should be refrigerated immediately after preparation and during analysis. The solutions are stable for 4 days when refrigerated.]

Mobile phase: Dissolve 2.2 g of 1-heptanesulfonic acid sodium salt in about 500 mL of water, add 125 mL of acetonitrile and 10 mL of acetic acid, and dilute with water to 1 L.

Rinse solution: 10% acetonitrile in water. [NOTE—Use to rinse needle and column.]

System suitability solution: Equivalent to 1 mg/mL of vancomycin B from [USP Vancomycin B with Monodechlorovancomycin RS](#) in water

Standard solution: Equivalent to 50 µg/mL of vancomycin B, from *System suitability solution*

Sample solution: 1 mg/mL of Vancomycin Hydrochloride in water

Blank: Water

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6 mm × 25 cm; packing L1

Column temperature: 60°

Autosampler temperature: 5°

Flow rate: 1.5 mL/min

Injection volume: 50 µL

[NOTE—This procedure is sensitive to temperature changes. Sufficient tubing should be placed in the column oven to ensure that the samples have reached 60° before separation.]

System suitability

Samples: *System suitability solution*, *Standard solution*, *Sample solution*, and *Blank*

[NOTE—*Blank* and *Standard solution* run times are about 90 min. *System suitability solution* and *Sample solution* run times are about 120 min.]

[NOTE—The relative retention times for vancomycin B and monodechlorovancomycin are 1.0 and 1.1, respectively.]

Suitability requirements

Selectivity: The chromatogram for the *Blank* does not contain peaks that interfere with vancomycin B or monodechlorovancomycin.

Retention times: ±3.0% between monodechlorovancomycin in the *Sample solution* and the mean of the monodechlorovancomycin peaks in the *Standard solution*

Resolution: NLT 1.5 between vancomycin B and monodechlorovancomycin, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of monodechlorovancomycin in the portion of Vancomycin Hydrochloride taken:

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

r_U = peak area of monodechlorovancomycin in the *Sample solution*

r_S = average peak area of the vancomycin B peak in the *Standard solution*

C_S = concentration of [USP Vancomycin B with Monodechlorovancomycin RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Vancomycin Hydrochloride in the *Sample solution* (mg/mL)

P = potency of vancomycin B in [USP Vancomycin B with Monodechlorovancomycin RS](#) (mg/mg)

Acceptance criteria: NMT 4.7% of monodechlorovancomycin is found.

SPECIFIC TESTS

- **STERILITY TESTS (71):** Where the label states that Vancomycin Hydrochloride is sterile, 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*.
- **BACTERIAL ENDOTOXINS TEST (85):** Where the label states that Vancomycin Hydrochloride is sterile or must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.33 USP Endotoxin Unit/mg of vancomycin.
- **pH (791):** 2.5–4.5, 50 mg/mL in water
- **WATER DETERMINATION, Method I (921):** NMT 5.0%
- **COMPOSITION 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)