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Vancomycin Hydrochloride for Oral Solution

DEFINITION

Vancomycin Hydrochloride for Oral Solution contains the equivalent of NLT 90.0% and NMT 115.0% of the labeled amount of vancomycin
 $(C_{66}H_{75}Cl_2N_9O_{24})$.

ASSAY

• [ANTIBIOTICS—MICROBIAL ASSAYS \(81\)](#)

Sample solution: Dissolve the contents of 1 container of Vancomycin Hydrochloride for Oral Solution in water as directed in the labeling. Dilute a portion of this solution with *Buffer B.4* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the standard.

Analysis: Proceed as directed for vancomycin in the chapter.

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#)

For powder packaged in single-unit containers: Meets the requirements

• [DELIVERABLE VOLUME \(698\)](#)

For powder packaged in multiple-unit containers: Meets the requirements

SPECIFIC TESTS

• [pH \(791\)](#): 2.5–4.5, for a solution constituted as directed in the labeling

• [WATER DETERMINATION, Method I \(921\)](#): NMT 5.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Vancomycin Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
VANCOMYCIN HYDROCHLORIDE FOR ORAL SOLUTION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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