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Vancomycin Hydrochloride Capsules

DEFINITION

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

IDENTIFICATION

Change to read:

- ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
Sample: Disperse the contents of 1 Capsule in about 20 mL of chloroform. Pass the liquid through a suitable filter. Rinse the filter and residue with chloroform. Dry the residue in a vacuum at 60° for 1 h.

ASSAY

- [ANTIBIOTICS—MICROBIAL ASSAYS \(81\)](#)
Analysis: Proceed as directed, using NLT 5 Capsules blended at high speed in a glass blender jar for 3–5 min with a sufficient volume of *Buffer B.4* to yield a stock solution having a convenient concentration of vancomycin. Dilute a volume of this stock 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.
Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)
Medium: Water; 900 mL
Apparatus 1: 100 rpm
Time: 45 min
Sample solution: Sample per [Dissolution \(711\)](#)
Analysis: Determine the amount of vancomycin dissolved by assaying a filtered portion of the *Sample solution* as directed for vancomycin under [Antibiotics—Microbial Assays \(81\)](#).
Tolerances: NLT 85% (Q) of the labeled amount of vancomycin is dissolved.
- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

SPECIFIC TESTS

- [WATER DETERMINATION, Method I \(921\)](#): NMT 8.0%

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 CAPSULES	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](#)

Most Recently Appeared In:

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