



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

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Certificate of Analysis Finished Product

Product Name	VANCAN 500 Injection	A.R. No.	ARN/FP/25/040
Generic Name	Vancomycin Hydrochloride for Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2549A	Sampled by	Anuj Verma
Batch Size	10,000 Vials	Sampled on	17/10/2025
Mfg. Date	10/2025	Date of Testing	18/10/2025
Exp. Date	09/2027	Date of Release	01/11/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	A. In the test for Vancomycin B, the retention time of the principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution. B. It gives reaction (A) of chloride.	Complies Complies
3.	Appearance of solution	A 10% solution of Vancomycin hydrochloride is clear and the absorbance of the solution at 450 nm is not more than 0.1.	Complies
4.	Uniformity of weight	Average weight $\pm 10\%$	-2.59 & +2.35%
5.	Average weight	Informative $\pm 2\%$.	552.8 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	3.04
7.	Vancomycin B	NLT 88.0%	99.99%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	Not detected
	Total impurities	NMT 12.0%	Not detected
9.	Water	NMT 5% w/w	2.53%w/w
10.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/vial	112/vial 2/vial
	(B.) Visual Particle	Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies

Analysis by

Checked by



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11.	Sterility	No microbial growth should be observed.	Complies		
12.	Bacterial Endotoxins	NMT 2.5 EU/ml of Vancomycin.	Less than 2.5 EU/ml of Vancomycin.		
13.	Assay: (By Microbiology) Each glass vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vancomycin Hydrochloride (Sterile) Eq. to Vancomycin IP		500 mg	505.147 mg	101.03%	90.0% to 115.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/HIS.

Analysis by: <i>[Signature]</i> NAME: NIKHIL SHARMA	Checked by: <i>[Signature]</i> NAME: SUFIYAN ANSARI	Approved by: <i>[Signature]</i> NAME: MRS. SWATI DHAWAN
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