



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title :

Certificate of Analysis Finished Product

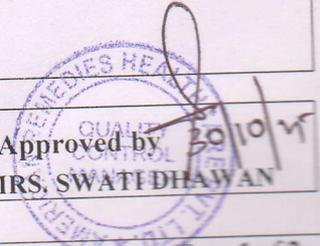
Product Name	VANCAN 1000 Injection	A.R. No.	ARN/FP/25/037
Generic Name	Vancomycin Hydrochloride for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN2552A	Sampled by	Rakesh
Batch Size	15,000 Vials	Sampled on	15/10/2025
Mfg. Date	10/2025	Date of Testing	16/10/2025
Exp. Date	09/2027	Date of Release	30/10/2025

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
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 $\pm 10\%$	-1.98 & +2.77%
5.	Average weight	Informative $\pm 2\%$.	1098.5 mg
6.	pH	2.5 to 4.5 (5% w/v solution of Vancomycin Hcl).	2.98
7.	Vancomycin B	NLT 88.0%	99.53%
8.	Related substances		
	Single maximum impurity	NMT 4.0%	0.45%
	Total impurities	NMT 12.0%	0.45%
9.	Water	NMT 5%w/w	2.42%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	275/vial 3/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 30/10/2025
NAME: NIKHIL SHARMA

Checked by 30/10/25
NAME: SUFIYAN ANSARI

Approved by 30/10/25
NAME: MRS. SWATI DHAWAN





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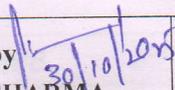
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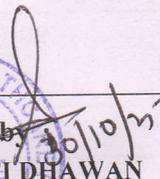
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11.	Sterility	No microbial growth should be observed.	Complies		
12.	Bacterial Endotoxins	NMT 2.5 EU/ml of Vancomycin.	Less than 2.5 EU/ml of Vancomycin.		
13.	Assay: (By Microbiology) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vancomycin Hydrochloride (Sterile) IP Eq. to Vancomycin		1000 mg	1012.120 mg	101.21%	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/HS.

Analysis by 
NAME: NIKHIL SHARMA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI DHAWAN

