

# CONCORD BIOTECH LIMITED

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## Analytical Development Lab Test Report

Late 2010/12


Product	Vancomycin Hydrochloride	A. R. No.	CBL-DMP(034)24
Batch No.	DMP(034)24	Mfg Date	May 2012
Batch Size	2.3 Kg	Retest Date	Apr 2015


S. N.	Tests	Specification	Observation
1.	Appearance	White or almost white, hygroscopic powder.	White hygroscopic powder.
2.	Solubility	Freely soluble in water, slightly soluble in ethanol (96%).	Freely soluble in water, slightly soluble in ethanol (96%).
3.	Identification (a) By HPLC  (b) Chemical test	The retention time of the principal peak in the chromatogram obtained with test solution (a) is similar to that of the principal peak in the chromatogram obtained with the reference solution under the test for Vancomycin B. It gives reaction of chloride.	Complies  Complies
4.	Appearance of solution (10% w/v solution in water)	The solution should be clear and its absorbance at 450 nm should be not greater than 0.10.	Complies 0.06
5.	pH (50g in 10 mL of water)	2.5 to 4.5	2.9
6.	Vancomycin B	NLT 93.0%	93.8%
7.	Related substance Specific Impurity A. N-demethylvancomycin B B. [ $\beta$ -Asp <sup>3</sup> ] vancomycin B C. Aglucovancomycin D. Desvancosaminylvancomycin B Any other impurity Total Impurities	Maximum 4.0 per cent Maximum 4.0 per cent Maximum 4.0 per cent Maximum 4.0 per cent Maximum 2.0 per cent Maximum 7.0 per cent	0.92% 0.10% 0.13% 0.43% 0.87% 6.2%
8.	Heavy Metals	NMT 30 ppm	Complies
9.	Water Content (%w/w By KFR)	NMT 5.0%	3.9%
10.	Sulphated Ash	NMT 1.0%	0.10%
11.	Assay (Anhydrous substance).	Minimum 1050 IU/mg	1076 IU/mg

Storage: Preserve in an airtight containers, Protected from light, in a cold place.

Remarks: The material complies as per Ph Eur. and in house specification no.SPC/QC/FP/013-03 with respect to above tests.

Date of Report: 18/05/2012

Compiled By   
Date: 18/05/12

Checked By   
Date: 18/05/12