

CERTIFICATE OF ANALYSIS

Product : **VANCOMYCIN HYDROCHLORIDE**
 Product number : V0155
 Batch number : 017824
 Date of production : 17-09-2021
 Date of expiry : 30-09-2024

Packaging and storage : store in a well-closed container, dry and at a temperature 2 – 8°C

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	a white or almost white powder	complies		hygroscopic
Solubility	freely soluble in water, slightly soluble in ethanol (96%)	complies		
Identification:				
- A (HPLC)	conform	complies		
- B (chlorides)	conform	complies		
Appearance of solution	conform	complies		
pH	2.5 – 4.5	2.80		
Related substances	conform	complies		HPLC
Water	≤ 5.0	2.1	%	Karl Fischer
Sulphated ash	≤ 1.0	0.14	%	
Ethanol (residual solvent)	5000	42	ppm	
Vancomycin B	≥ 91.0	93.96	%	
Potency	≥ 1050	1083	IU/mg	anhydrous basis

This certificate of analysis is conform the results of the manufacturer.

This batch has been checked according to Ph.Eur. 11.0 by Synergy Healty Utrecht B.V. and has been approved by dr. R. Santing, QP. Date: 08-06-2023

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance of solution	conform	complies		
pH	2.5 – 4.5	2.8		
Water	≤ 5.0	2.9	%	Karl Fischer
Potency	≥ 1050	1063	IU/mg	anhydrous basis

Conclusion: approved

Released by:

Q. de Hoog, MSc, pharmacist
Department of Quality Control Duchefa B.V.

Date: 21-06-2023

The buyer is responsible to test each batch to ensure the product is suitable for its specific purpose.

Duchefa Biochemie B.V.