

CERTIFICATE OF ANALYSIS

Product : **VANCOMYCIN HYDROCHLORIDE**
 Product number : V0155
 Batch number : 013264
 Date of production : 30-08-2017
 Date of analysis : 13-09-2017
 Date of expiry : 31-08-2019

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:	conform	complies		
- A (HPLC)	conform	complies		
- B (chlorides)	conform	complies		
Appearance of solution	conform	complies		
pH	2.5 – 4.5	3.5		50 mg/ml H ₂ O HPLC
Related substances:				
- any impurity	≤ 4.0	0.68	%	
- total impurities	≤ 7.0	4.0	%	
Water	≤ 5.0	2.0	%	Karl Fischer
Sulphated ash	≤ 1.0	0.04	%	
Heavy metals	≤ 30	< 30	ppm	
Bacterial endotoxin test	≤ 0.25	< 0.25	IU/mg	
Ethanol (residual solvent)	≤ 0.5	0.01	%	
Vancomycin B	≥ 93.0	96.0	%	
Potency	≥ 1050	1107	IU/mg	anhydrous basis

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

Conclusion: approved

Released by:

p/o

drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 24-10-2017

S. de Bree
S. de Bree

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