Duchefa Biochemie b.v.

biochemicaliën
biochemicals

CERTIFICATE OF ANALYSIS

Product	:	**VANCOMYCIN HYDROCHLORIDE**
Product number	:	V0155
Batch number	:	012751
Date of production	:	17-01-2017
Date of analysis	:	02-09-2017
Date of expiry	:	31-01-2019
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	3.7		50 mg/ml H_2O
Related substances:				HPLC
- any impurity	≤ 4.0	0.62	%	
- total impurities	≤ 7.0	3.6	%	
Water	≤ 5.0	2.3	%	Karl Fischer
Sulphated ash	≤ 1.0	0.10	%	
Heavy metals	≤ 30	< 30	ppm	
Bacterial endotoxin test	≤ 0.25	< 0.25	IU/mg	
Ethanol (residual solvent)	≤ 0.5	0.02	%	
Vancomycin B	≥ 93.0	96.4	%	
Potency	≥ 1050	1087	IU/mg	anhydrous basis

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

Conclusion: approved
Released by: drs. M. van Wissen, pharmacist
Department of Quality Control Duchefa B.V.

Date: 27-02-2017

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

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