

## CERTIFICATE OF ANALYSIS

Product : **BACITRACIN**  
 Product number : B0106  
 Batch number : 013991  
 Date of analysis : 15-01-2018  
 Date of expiry : 30-09-2021

Packaging and storage : in an airtight container at a temperature between 2 – 8 °C

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white or almost white powder	complies		hygroscopic
Solubility	freely soluble in water and in ethanol (96%)	complies		
Identification:				
- B (composition)	conform	complies		HPLC
- C (residue on ignition)	conform	complies		
Appearance of solution	clear	complies		1.0 % in H <sub>2</sub> O
pH	6.0 – 7.0	6.2		1.0 % in H <sub>2</sub> O
Composition:				
- Bacitracin A	≥ 45.0	56.1	%	HPLC
- Bacitracin A, B1, B2 and B3	≥ 77.0	84.8	%	HPLC
Related substances	conform	complies		HPLC
Impurity E (Bacitracin F)	≤ 4.0	0.6	%	HPLC
Loss on drying	≤ 5.0	0.9	%	3 h 60°C, P <sub>2</sub> O <sub>5</sub> , < 0.1 kPa
Sulphated ash	≤ 1.0	0.0	%	
Assay	≥ 60	101.04	IU/mg	dried substance

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

Conclusion: approved

Released by:

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

Date: 29-08-2018

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