

CERTIFICATE OF ANALYSIS

Product : **BACITRACIN**
 Product number : B0106
 Batch number : 013260
 Date of production : 30-09-2015
 Date of analysis : 21-04-2016
 Date of expiry : 31-08-2019

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 ₂ O
pH	6.0 – 7.0	6.2		1.0 % in H ₂ O
Composition:				
- Bacitracin A	≥ 40.0	65.1	%	HPLC
- Bacitracin A, B1, B2 and B3	≥ 70.0	93.3	%	HPLC
Related peptides	≤ 20.0	6.7	%	HPLC
Impurity E (Bacitracin F)	≤ 6.0	1.3	%	HPLC
Loss on drying	≤ 5.0	0.3	%	3 h 60°C, P ₂ O ₅ , < 0.1 kPa
Sulphated ash	≤ 1.0	0.1	%	
Assay	≥ 60	71	IU/mg	dried substance

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: 13-10-2017



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