

CERTIFICATE OF ANALYSIS

Product : **BACITRACIN**
Product number : B0106
Batch number : 012919
Date of production : xx-06-2016
Date of analysis : 27-06-2016
Date of expiry : 30-06-2020

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	6.5		1.0 % in H ₂ O
Composition:				
- Bacitracin A	≥ 40.0	51.5	%	HPLC
- Bacitracin A, B1, B2 and B3	≥ 70.0	81.7	%	HPLC
Related peptides	≤ 20.0	11.2	%	HPLC
Impurity E (Bacitracin F)	≤ 6.0	1.5	%	HPLC
Loss on drying	≤ 5.0	1.0	%	3 h 60°C, P ₂ O ₅ , < 0.1 kPa
Sulphated ash	≤ 1.0	0.0	%	
Assay	≥ 60	75	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: 10-05-2017



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