

CERTIFICATE OF ANALYSIS

Product : BACITRACIN

Product number : B0106
Batch number : 012618
Date of analysis : 21-04-2014
Date of expiry : 31-08-2019

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

Appearance Solubility	SPECIFICATION white or almost white powder freely soluble in water and in ethanol (96%)	RESULT complies complies	UNITS	REMARKS hygroscopic
Identification:				
- B (composition)	conform	complies		HPLC
- C (residue on ignition)	conform	complies		
Appearance of solution	clear	complies		1.0 % in H ₂ O
рН	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: 19-12 -2016

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