

CERTIFICATE OF ANALYSIS

Product : **BACITRACIN**
Product number : B0106
Batch number : 014155
Date of analysis : 15-01-2018
Date of expiry : 30-09-2021

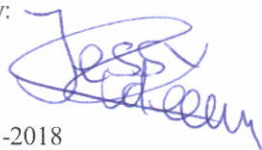
Packaging and storage : in an airtight container at a temperature between 2 – 8 °C

| | 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 ₂ O |
| pH | 6.0 – 7.0 | 6.2 | | 1.0 % in H ₂ 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 ₂ O ₅ , < 0.1 kPa |
| Sulphated ash | ≤ 1.0 | 0.0 | % | |
| Assay | ≥ 60 | 76 | IU/mg | dried substance |

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

Conclusion: approved

Released by:



drs. J. van der Eem, pharmacist
Department of Quality Control Duchefa B.V.

Date: 23-11-2018

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