

CERTIFICATE OF ANALYSIS

Product : **VANCOMYCIN HYDROCHLORIDE**
 Product number : V0155
 Batch number : 014401
 Date of production : 19-01-2019
 Date of expiry : 31-01-2021

Packaging and storage : store in a well-closed container, dry and at a temperature 2 – 8°C

| Description | SPECIFICATION | RESULT | UNITS | REMARKS |
|----------------------------|---|----------------------|-------|-----------------|
| Solubility | a white or almost white powder freely soluble in water, slightly soluble in ethanol (96%) | complies complies | | hygroscopic |
| Identification: | | | | |
| - A (HPLC) | conform | complies | | |
| - B (chlorides) | conform | complies | | |
| Appearance of solution | conform | complies | | |
| pH | 2.5 – 4.5 | 3.2 | | |
| Related substances: | conform | complies | | HPLC |
| - any impurity | ≤ 4.0 | 0.85 | % | |
| - total impurities | ≤ 7.0 | 4.6 | % | |
| Water | ≤ 5.0 | 2.8 | % | Karl Fischer |
| Sulphated ash | ≤ 1.0 | 0.11 | % | |
| Ethanol (residual solvent) | ≤ 5000 | 100 | ppm | |
| Vancomycin B | ≥ 93.0 | 95.4 | % | |
| Potency | ≥ 1050 | 1109 | IU/mg | anhydrous basis |

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: 08-03-2019

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