

## **CERTIFICATE OF ANALYSIS**

| Product               | : | VANCOMYCIN HYDROCHLORIDE   |
|-----------------------|---|--|
| Product number        | : | V0155  |
| Batch number          | : | 015620   |
| Date of production    | : | 22-04-2020   |
| Date of expiry        | : | 30-04-2022   |
|                       |   |  |
| Packaging and storage | : | store in a well-closed container, dry and at a temperature 2-8°C |

| Description<br>Solubility<br>Identification: | <b>SPECIFICATION</b><br>a white or almost white powder<br>freely soluble in water,<br>slightly soluble in ethanol (96%) | <b>RESULT</b> complies complies | UNITS | <b>REMARKS</b><br>hygroscopic |
|--|---|---------------------------------|-------|-------------------------------|
| - A (HPLC)                                   | conform   | complies                        |       |                               |
| - B (chlorides)                              | conform   | complies                        |       |                               |
| Appearance of solution                       | conform   | complies                        |       |                               |
| pH   | 2.5 - 4.5   | 2.83                            |       |                               |
| Related substances                           | conform   | complies                        |       | HPLC                          |
| Water  | ≤ 5.0   | 1.6                             | %     | Karl Fischer                  |
| Sulphated ash                                | $\leq 1.0$  | 0.13                            | %     |                               |
| Ethanol (residual solvent)                   | 5000  | 69                              | ppm   |                               |
| Vancomycin B                                 | ≥ 91.0  | 94.34                           | %     |                               |
| Potency                                      | ≥ 1050  | 1079                            | IU/mg | anhydrous basis               |

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: 29-07-2020

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

Duchefa Biochemie B.V.



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