

## **CERTIFICATE OF ANALYSIS**

SPECTINOMYCIN DIHYDROCHLORIDE PENTAHYDRATE Product

Product number S0188 Batch number 014258 Manufacturing date 08-04-2018 30-04-2021 Expiry date

store dry at 2 - 8 °C Storage conditions

| Description<br>Solubility | SPECIFICATION white or almost white powder freely soluble in water, very slightly soluble in alcohol | RESULT<br>complies<br>complies | UNITS | REMARKS<br>slightly hygroscopic |
|---------------------------|--|--------------------------------|-------|---------------------------------|
| Identification:           |  |                                |       |                                 |
| - IR spectrum             | conform  | complies                       |       |                                 |
| - chloride                | conform  | complies                       |       |                                 |
| Appearance of solution    | clear and colourless   | complies                       |       |                                 |
| pH                        | 3.8 - 5.6  | 4.9                            |       |                                 |
| Specific optical rotation | +15 - +21  | +18.5                          | 0     |                                 |
| Related substances        | conform  | complies                       |       |                                 |
| Water                     | 16.0 - 20.0  | 18.1                           | %     |                                 |
| Sulphated ash             | ≤ 1.0  | 0.2                            | %     |                                 |
| Assay                     | 93.0 - 102.0   | 95.5                           | %     | 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: 11-01-2019

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

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