

## **CERTIFICATE OF ANALYSIS**

Product : GENTAMICIN SULFATE

Product number : G0124
Batch number : 015824
Date of production : xx-01-2020
Date of analysis : 29-10-2020
Date of expiry : 31-01-2025

Packaging and storage : store at room temperature

| Description<br>Identification           | SPECIFICATION white or off- white powder conform | RESULT complies complies | UNITS | REMARKS<br>hygroscopic |
|---|--|--------------------------|-------|------------------------|
| pH                                      | 3.5 - 5.5  | 4.9                      |       |                        |
| Specific optical rotation               | +107 - +121                                      | +116                     | 0     |                        |
| Sulphate                                | 32.0 - 35.0                                      | 32.4                     | %     | anhydrous substance    |
| Water                                   | ≤ 15.0   | 8.0                      | %     | Karl Fischer           |
| Potency:                                |  |                          |       |                        |
| <ul> <li>anhydrous substance</li> </ul> | ≥ 590  | 652                      | IU/mg |                        |

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: 23-11-2020

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