

## CERTIFICATE OF ANALYSIS

Product : **RIFAMPICIN**  
Product number : R0146  
Batch number : 013928  
Date of analysis : 27-07-2018  
Expiry date : 31-07-2022

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

|                           | SPECIFICATION                   | RESULT   | UNITS             | REMARKS                 |
|---------------------------|---------------------------------|----------|-------------------|-------------------------|
| Appearance                | red crystalline powder          | complies |                   |                         |
| Solubility                | soluble in dilute acid solution | complies |                   |                         |
| pH                        | 4.5 – 6.5                       | 5.7      |                   | 1 % in H <sub>2</sub> O |
| Related substances:       |                                 |          |                   | HPLC                    |
| - Rifampicin quinone      | ≤ 1.5                           | 0.2      | %                 |                         |
| - Each other substance    | ≤ 1.0                           | complies | %                 |                         |
| - Sum of other substances | ≤ 3.5                           | 2        | %                 |                         |
| Heavy metals              | ≤ 20                            | complies | ppm               |                         |
| Loss on drying            | ≤ 1.0                           | 0.3      | %                 |                         |
| Sulphated ash             | ≤ 0.1                           | 0.06     | %                 |                         |
| Assay                     | 97 – 102                        | 99       | %                 | dried substance         |
| Bulk density              | ≥ 0.7                           | 0.72     | g/cm <sup>3</sup> |                         |

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: 31-07-2018



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