

CERTIFICATE OF ANALYSIS

Product : **LACTOSE MONOHYDRATE**
 Product number : L1372
 Batch number : 013532
 Date of production : xx-06-2017
 Date of expiry : 30-06-2022

 Storage conditions : in tightly closed container at room temperature

| | SPECIFICATION | RESULT | UNITS | REMARKS |
|---------------------------|---|----------|-------|-------------------------|
| Appearance | white or almost white, crystalline powder | complies | | |
| Identification : | | | | |
| - A (IR-spectrum) | conform | complies | | |
| - D (water) | 4.5 – 5.5 | complies | | Karl Fischer |
| Appearance of solution | clear and colour ≤ ref.sol. BY ₇ | complies | | 10% in H ₂ O |
| Acidity/alkalinity | ≤ 0.4 | 0.2 | ml | 0.1N NaOH |
| Specific optical rotation | +54.4 – +55.9 | +55.0 | ° | droge stof |
| Absorbance | conform | complies | | UV |
| Heavy metals | ≤ 5 | complies | ppm | as Pb |
| Water | 4.5 – 5.5 | 5.1 | % | Karl Fischer |
| Sulphated ash | ≤ 0.1 | < 0.1 | % | |

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: 07-02-2018



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