

## **CERTIFICATE OF ANALYSIS**

Product

LACTOSE MONOHYDRATE

Product number Batch number Date of production Date of expiry

L1372 012736 xx-07-2015

30-06-2020

Storage conditions

in tightly closed container at room temperature

Appearance	SPECIFICATION white or almost white, crystalline powder	RESULT complies	UNITS	REMARKS
Identification:				
- A (IR-spectrum)	conform	complies		
- D (water)	4.5 - 5.5	complies		Karl Fischer
Appearance of solution	clear and colour ≤ ref.sol. BY <sub>7</sub>	complies		10% in H <sub>2</sub> O
Acidity/alkalinity	≤ 0.4	0.3	ml	0.1N NaOH
Specific optical rotation	+54.4 - +55.9	+55.1	0	droge stof
Absorbance	conform	complies		UV
Heavy metals	≤ 5	complies	ppm	as Pb
Water	4.5 - 5.5	4.8	%	Karl Fischer
Sulphated ash	≤ 0.1	0.02	%	

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: 21-02-2017

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

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