

## CERTIFICATE OF ANALYSIS

Product LACTOSE MONOHYDRATE

Product number L1372 Batch number 013710 Date of production xx-06-2017 Date of expiry 30-06-2022

Storage conditions in tightly closed container at room temperature

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

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: 20-04-2018

Sale 18:00

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

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