

CERTIFICATE OF ANALYSIS

Product LACTOSE MONOHYDRATE

Product number L1372 Batch number 013212 Date of production xx-06-2017 30-06-2022 Date of expiry

Storage conditions in tightly closed container at room temperature

Appearance	SPECIFICATION white or almost white, crystalline	RESULT complies	UNITS	REMARKS
	powder			
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	o	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

drs. M. van Wissen, pharmacist Released by:

Department of Quality Control Duchefa B.V.

Date: 27-09-2017

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

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