

CERTIFICATE OF ANALYSIS

Product : **LACTOSE MONOHYDRATE**
 Product number : L1372
 Batch number : 018321
 Date of production : xx-10-2023
 Date of expiry : 31-10-2028

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	5.1	%	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	+55.4	°	droge stof
Absorbance	conform	complies		UV
Heavy metals	≤ 5	complies	ppm	as Pb
Sulphated ash	≤ 0.1	< 0.1	%	
Assay	98.0 – 102.0	100.3	%	HPLC

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: 09-02-2024



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