

## CERTIFICATE OF ANALYSIS

Product : **LACTOSE MONOHYDRATE**  
 Product number : L1372  
 Batch number : 012432  
 Date of production : xx-07-2015  
 Date of expiry : 30-06-2020

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 <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	°	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: 10-10-2016



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