

## CERTIFICATE OF ANALYSIS

Product : **LACTOSE MONOHYDRATE**  
 Product number : L1372  
 Batch number : 010306  
 Date of production : xx-11-2013  
 Date of expiry : 30-11-2018

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		
Appearance of solution	clear and colour ≤ ref.sol. BY <sub>7</sub>	complies		
Acidity/alkalinity	≤ 0.4	complies	ml	
Specific optical rotation	+54.4 – +55.9	+55.2	°	
Absorbance	conform	complies		
Heavy metals	≤ 5	complies	ppm	as Pb
Water	4.5 – 5.5	5.1	%	Karl Fischer
Sulphated ash	≤ 0.1	0.03	%	
Microbiology:				
- Total viable aerobic count	≤ 100	< 10	cfu/g	
- Escherichia coli	negative	complies	/10 g	

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: 01-04-2014



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