

**Certificate of Analysis**

Customer number	: 160800	Lot/ Batchnumber	: 1096BSP
Customer name	: LABO SMEETS N.V.	Date of production	: 12.04.2022
Delivery number	: 811119106	Retest date	: 10.04.2025
Delivery Date	: 30.06.2022	Order number	: 15278651
Material number	: 0502118	Your order number	: 221953 OD
Material description	Lactochem® Fine Powder		
	Milled lactose monohydrate		
	USP-NF, Ph.Eur., JP		
	Bag, PE liner, 25 kg net		

METAPHARMACEUTICAL

N DE LOTE:

0330623

29 JUN. 2023

Analysis**Chemical & Physical**

Characteristic	Method of analysis	Unit	Specification	Results
Infrared absorption spectrum / Id A	USP-NF; Ph.Eur.; JP		Conforms to reference	Pass
Water / Id D Ph.Eur.	USP-NF; Ph.Eur.; JP	%(m)	4.5-5.5	5.1
Appearance of solution	Ph.Eur.		Not more intensely coloured than ref BY7	Pass
Lactose colour of sol.	USP-NF; JP		Nearly colourless	Pass
Lactose clarity of sol.	USP-NF; Ph.Eur.; JP		Clear	Pass
UV-Abs. 1% sol. 210-220 nm	USP-NF; Ph.Eur.; JP		≤ 0.25	0.02
UV-Abs. 1% sol. 270-300 nm	USP-NF; Ph.Eur.; JP		≤ 0.07	0.00
UV-Abs. 10% sol. 400 nm	USP-NF; Ph.Eur.; JP		≤ 0.04	0.00
Acidity (0.1N NaOH/6g)	USP-NF; Ph.Eur.; JP	ml	≤ 0.4	0.3
Specific optical rotation (anhydrous bas	USP-NF; Ph.Eur.; JP	Degree	54.4-55.9	55.1
Heavy Metals	USP-NF; Ph.Eur.; JP		max 5 ppm	Pass
Loss on Drying (2 hrs, 80°C)	USP-NF; JP	%(m)	≤ 0.5	0.1
Residue on ignition / Sulfated ash	USP-NF; Ph.Eur.; JP	%(m)	≤ 0.1	<0.1

Microbiological

Characteristic	Method of analysis	Unit	Specification	Results
Total Aerobic Micro Count	Pharmacopeia Harmonized Methods	cfu/g	≤ 100	<100
Total Yeast & Mould Count	Pharmacopeia Harmonized Methods	cfu/g	≤ 10	<10
Gram negative bile tolerant m.o. (1 g)	Pharmacopeia Harmonized Methods		Negative	Negative
Escherichia coli (10 g)	Pharmacopeia Harmonized Methods		Negative	Negative
Salmonella (5*25g)	equal to ISO 6579		Negative	Negative

OTHERS

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <75 µm	equal to ISO 4610	%(m)	60-80	62

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <150 µm	equal to ISO 4610	%(m)	≥ 95	96
Particle size <250 µm	equal to ISO 4610	%(m)	≥ 99	100

Remarks
Product Description: alpha-lactose monohydrate pharmaceutical grade

Identification: conforms USP-NF, Ph.Eur, JP current at time of manufacture.

Characteristics: A white or almost white, odourless, crystalline powder freely soluble in water, practically insoluble in ethanol.

Residual solvents: CPMP/ICH/283/95 and USP-NF Chapter 467
No class 1, 2, 3 solvents are used during production.

Production site:
FrieslandCampina
Needseweg 23
7271 AB Borculo, The Netherlands

Released by: Dinant Veldink
Released on: May 2, 2022

This document has been produced electronically and is valid without signature.

Manufacturer: DFE Pharma GmbH & Co. KG, Goch, Germany (formerly named "DMV-Fonterra Excipients GmbH & Co. KG")