Certificate of Analysis

Customer number	:	**Lot/ Batchnumber**	: 1040LHJ
Customer name	:	**Date of production**	: 03.2019
Delivery number	:	**Expiry date**	: 02.2022
Delivery Date	:	**Order number**	:
Material number	: 0659113	**Your order number**	:
Material description	: Pharmatose® 200M (EU) Milled lactose monohydrate USP-NF, Ph.Eur., JP Bag, PE liner, 25 kg net		

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.	FrieslandCampina internal		Nearly colourless	Pass
Lactose Clarity of sol.	FrieslandCampina internal		Clear	Pass
UV-Abs. 1% sol. 210-220 nm	USP-NF; Ph.Eur.; JP		≤ 0.25	0.05
UV-Abs. 1% sol. 270-300 nm	USP-NF; Ph.Eur.; JP		≤ 0.07	0.01
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	0.3
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
Yeast and Mould (cfu/g)	Pharmacopeia Harmonized Methods	cfu/g	≤ 10	<10
Escherichia coli (10 g)	Pharmacopeia Harmonized Methods		Negative	Negative
Salmonella (500 g)	equal to ISO 6579		Negative	Negative

OTHERS

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <45 µm	equal to ISO 4610	%(m)	50-65	57

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <100 µm	equal to ISO 4610	%(m)	90-100	94
Particle size <150 µm	equal to ISO 4610	%(m)	96-100	99
Particle size <250 µm	equal to ISO 4610	%(m)	99-100	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
N.C.B.-laan 80
5462 GE Veghel, The Netherlands

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