



Certificate of Analysis

928
N/01

Customer number	:	Lot/ Batchnumber	:	108DFKT
Customer name	:	Date of production	:	10.2021
Delivery number	:	Expiry date	:	09.2024
Delivery Date	:	Order number	:	14217860
Material number	:	Your order number	:	121008456
Material description	:	HMS Impalpable (EU)		
	:	Milled lactose monohydrate		
	:	USP-NF, Ph.Eur., JP, Ch.P		
	:	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	5.0
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	0.03
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	55.4
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
Arsenic	CP	ppm	≤ 2	<0.00
Assay by HPLC	CP	%	98.0 - 102.0	100.7
Identification by HPLC	CP		Pass	Pass
Related substances by HPLC	CP		Pass	Pass

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)	48-65	57
Particle size <100 µm	equal to ISO 4610	%(m)	83-100	93
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.

All methods of analysis are compliant or cross-validated with Ch.P

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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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")