

**Certificate of Analysis**

Customer number : 160560
Customer name : PT Signa Husada
Delivery number : 813141918
Delivery Date : 16.05.2024
Material number : 0743826
Material description : HMS Impalpable (NZ)
Milled lactose monohydrate
USP-NF, Ph.Eur., JP
Bag, PE liner, 25 kg net

Lot/ Batchnumber : 23262562
Date of production : 18.12.2023
Expiry date : 16.12.2026
Order number : 17344729
Your order number : PH240124

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		0.00-0.25	0.02
UV-Abs. 1% sol. 270-300 nm	USP-NF; Ph.Eur.; JP		0.00-0.07	0.01
UV-Abs. 10% sol. 400 nm	USP-NF; Ph.Eur.; JP		0.00-0.04	0.00
Acidity (0.1N NaOH/6g)	USP-NF; Ph.Eur.; JP	ml	0.0-0.4	0.2
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)	0.0-0.5	0.0
Residue on Ignition / Sulfated ash	USP-NF; Ph.Eur.; JP	%(m)	0.0-0.1	<0.1

Microbiological

Characteristic	Method of analysis	Unit	Specification	Results
Total Aerobic Micro Count	Pharmacopeia Harmonized Methods	cfu/g	0-100	<100
Total Yeast & Mould Count	Pharmacopeia Harmonized Methods	cfu/g	0-10	<10
Escherichia coli (10 g)	Pharmacopeia Harmonized Methods		Negative	Negative
Salmonella (750g)	equal to ISO 6579		Negative	Negative

OTHERS

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <75 µm	Internal, ATM sonic sifter	%(m)	78-86	81
Particle size <180 µm	Internal, ATM sonic sifter	%(m)	>=98	99

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





DFE
pharma

DFE Pharma GmbH & Co. KG / PO Box 20 21 20 / D-47568 Goch

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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:
Fonterra Limited, Kaponga, New Zealand

Released by: Adora Joy Torres
Released on: Feb 22, 2024



y RRS at 15:57:12, 20/05/2024

DFE Pharma GmbH & Co. KG
Kleber Straße 17, D-47568 Goch / Germany
P.O. Box 20 21 20, D-47568 Goch / Germany
Tel.: +49 (0) 2823 92 88 77 - 0
Fax: +49 (0) 2823 92 88 77 - 99

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17/04/26