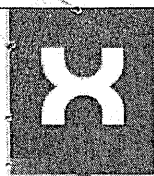


	Codice (Product Code): 39047 9V	Batch EV: 1211203 004 Batch Supplier: 108DFKT	Data produzione (Production date): 01/10/2021 Scadenza (Expiry Date)/Retest: 30/09/2024
---	---	--	--



DFE
pharma

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

Page nr. 1/2

0810289859-000010-20211128-135004-Z006-3420_VG_18-000001

Certificate of Analysis

Customer number	: 161430	Lot/ Batchnumber	: 108DFKT ✓
Customer name	: Eigenmann & Veronelli S.p.A	Date of production	: 10.2021 ✓
Delivery number	: 810289859	Expiry date	: 09.2024
Delivery Date	: 30.11.2021	Order number	: 14217860
Material number	: 0659137	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

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

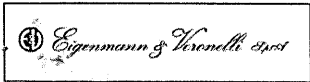
Data di stampa: 09/12/2021

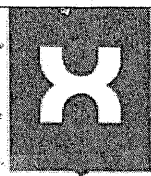
Mod. 66 - Rev. 3 del 20/05/2019

EIGENMANN & VERONELLI S.p.A.

Via della Mosa, 6 - 20017 RHO (MI)

Pagina 1 di 2

	Codice (Product Code): 39047 9V	Batch EV: 1211203 004 Batch Supplier : 108DFKT	Data produzione (Production date): 01/10/2021 Scadenza (Expiry Date)/Retest: 30/09/2024
---	--	---	--



DFE
pharma

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

Page nr. 2/2

0810289859-000010-20211128-135004-Z006-3420_VG_18-000001

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

Released by: Lynn Rijt
Released on: Nov 17, 2021

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

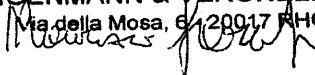
Manufacturer: DFE Pharma GmbH & Co. KG, Goch, Germany (formerly named "DMV-Fonterra Excipients GmbH & Co. KG")

Data di stampa: 09/12/2021

Mod. 66 – Rev. 3 del 20/05/2019

EIGENMANN & VERONELLI S.p.a.

Via della Mosa, 6 - 20017 RHO (MI)



Pagina 2 di 2