CERTIFICATE OF ANALYSIS

Spec. No.: 10000000042 Version 05

Delivery No.: 80950305
Material: **13007670 GranuLac® 200**

Lot No. L101851024

Manufact. Date	Retest Date
W10Y2024	W08Y2027

DEFINITION/CHARACTERS/PRODUCTION
GRANULAC 200 is MEGGLE's brand name for a milled lactose.
GRANULAC 200 conforms to the monograph "Lactose Monohydrate" in the Ph. Eur., USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation.
GRANULAC 200 conforms to the monograph "Lactose Monohydrate" in the Chinese Pharmacopoeia (ChP). Testing is performed using the methods indicated below.
GRANULAC 200 is a white or almost white, crystalline, odourless powder. It is freely but slowly soluble in water, practically insoluble in ethanol (96 per cent), chloroform and ether.
GRANULAC 200 is Halal and Kosher certified and suitable for a vegetarian diet.

Production and release site: MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg am Inn, Germany

The management system of MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg am Inn, Germany has been certified meeting the requirements of GMP and GDP according to EXCiPACT™.

Additional regulatory information is available under www.meggle-excipients.com.

	Method	Specification	Unit	Result
IDENTIFICATION				
Identification A/Ph. Eur. 2.2.24/Infrared absorption spectrophotometry		conforms		conforms*
Identification B/USP-NF <201>/Thin-layer chromatographic identification test		conforms		conforms*
Identification D/Ph. Eur. 2.5.12/Water		conforms		conforms
Identification (1)/ChP <0512>/HPLC		conforms		conforms*
TESTS				
Appearance of solution	Ph. Eur. 2.2.1 Instrumental method (max 3 NTU equals "The solution S is clear")	max 3	NTU	0.3
Appearance of solution	Ph. Eur. 2.2.2 *Method II*	The solution is not more intensely coloured than reference solution BY_7		conforms
Absorbance: proteins and light-absorbing impurities at 400 nm	Ph. Eur. 2.2.25	max 0.04		0.00

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Registered Office: 83512 Wasserburg am Inn, Germany · Registergericht AG Traunstein HRA 7828 · VAT-Id.Nr.: DE813497582

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	Method	Specification	Unit	Result
Absorbance: proteins and light-absorbing impurities from 270 to 300 nm	Ph. Eur. 2.2.25	max 0.07		0.02
Absorbance: proteins and light-absorbing impurities from 210 to 220 nm	Ph. Eur. 2.2.25	max 0.25		0.04
Acidity or alkalinity	Ph. Eur. Lactose Monohydrate	The solution is colourless		conforms
Acidity or alkalinity	Ph. Eur. Lactose Monohydrate/Requirement of *0.1 M sodium hydroxide* to change the colour of the indicator to pink or red	max 0.4	ml	0.3
Specific optical rotation (anhydrous substance)	Ph. Eur. 2.2.7	54.4 - 55.9	°	55.4
Water	Ph. Eur. 2.5.12	4.5 - 5.5	%	5.1
Loss on drying	USP-NF <731>	max 0.5	%	0.1
Sulfated ash	Ph. Eur. 2.4.14	max 0.1	%	conforms*
Particle size distribution < 32 µm	Ph. Eur. 2.9.38/Air-entrainment method (air-jet sieving); 10 g; + 0.1 g Al_2O_3; p = 1500 - 2500 Pa; 2 min	45 - 75	%	45 - 61
Particle size distribution < 100 µm	Ph. Eur. 2.9.38/Air-entrainment method (air-jet sieving); 10 g; + 0.1 g Al_2O_3; p = 1500 - 2500 Pa; 2 min	min 90	%	92 - 100
Heavy metals	JP <1.07> Method 1, ChP <0821 Method 1> tested with ICP-MS acc. to Ph. Eur. 5.20/USP-NF <232> and <233>/ICH Q3D	max 5	µg/g	conforms*
Arsenic (As)	ChP <0822 Method 1> tested with ICP-MS acc. to Ph. Eur. 5.20/USP-NF <232> and <233>/ICH Q3D	max 2	µg/g	conforms*

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	Method	Specification	Unit	Result
Assay: Lactose calculated on the anhydrous basis	ChP <0512>	98.0 - 102.0	%	conforms*
Related substances	ChP <0512>	max 0.5	%	conforms*

MICROBIAL CONTAMINATION

Total aerobic microbial count (TAMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	max 100	cfu/g	1
Total combined yeasts/moulds count (TYMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	max 10	cfu/g	< 1
Escherichia coli	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence	/10 g	absence*
Salmonella spp.	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence	/100 g	absence

* The conformity to specification is assured by periodical testing and/or conforms when tested.

CONTAINER/STORAGE
Tight container. Storage in an unopened, originally packed MEGGLE container at room temperature under dry and odour-free conditions.

This document is valid without signature.

Wasserburg: 03.04.2024
Quality assurance
Matthias Gschwendtner

The above data do not release purchaser from performing an incoming control. A legally binding assurance for the suitability of the product for a defined application purpose cannot be derived from the above.

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