CERTIFICATE OF ANALYSIS

Spec. No.: 10000000176 Version 07

Delivery No.:

Material: **13005072** **GranuLac® 200**

Lot No. L101851924

Manufact. Date W19Y2024

Expiry Date W17Y2027

DEFINITION/CHARACTERS/PRODUCTION

GRANULAC 200 is MEGGLE's brand name for a milled lactose.
GRANULAC 200 conforms to the monograph "Lactose Monohydrate" in the European Pharmacopoeia (Ph. Eur.). This monograph is harmonized between Ph. Eur., USP-NF and JP.
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).

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

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

Additional regulatory information is available under https://www.meggle-pharma.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*
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 BY7		conforms
Acidity or alkalinity	Ph. Eur. Lactose Monohydrate	The solution is colourless		conforms

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	Method	Specification	Unit	Result
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	0.2
Specific optical rotation (anhydrous substance)	Ph. Eur. 2.2.7	54.4 - 55.9	°	55.2
Absorbance at 400 nm	Ph. Eur. 2.2.25	max 0.04		0.00
Absorbancefrom 270 to 300 nm	Ph. Eur. 2.2.25	max 0.07		0.03
Absorbance from 210 to 220 nm	Ph. Eur. 2.2.25	max 0.25		0.05
Heavy metals	Ph. Eur. 2.4.8 Method A	max5	µg/g	conforms*
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-entertainment method (air-jet sieving); 10 g; + 0.1 g Al2O3; p = 1500 - 2500 Pa: 2 min	45 - 75	%	47 - 56
Particle size distribution < 100 µm	Ph. Eur. 2.9.38/Air-entertainment method (air-jet sieving); 10 g; + 0.1 g Al2O3; p = 1500 - 2500 Pa: 2 min	min 90	%	93 - 96

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MICROBIAL CONTAMINATION

Total aerobic microbial count (TAMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	max 100	cfu/g	4
Total combined yeasts/moulds count (TYMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	max 50	cfu/g	0
Escherichia coli	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence	/10 g	absence*
Salmonefla spp.	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence	/10 g	absence

* The conformity to specification is assured by periodical testing.

CONTAINER/STORAGE

Well-closed 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: 15.07.2024
Quality assurance
Dr. G. Müller

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