



CERTIFICATE OF ANALYSIS

Spec. No.: 1000000042 Version 04

Delivery No.: 80672652
Material: 13007670 GranuLac® 200

Lot No. L101854321

Manufact. Date W43Y2021
Retest Date W42Y2024

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.

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 <https://www.meggle-pharma.com>.

	Method	Specification	Unit	Result
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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
Acidity or alkalinity	Ph. Eur. Lactose Monohydrate	The solution is colourless		conforms



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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
Absorbance: proteins and light-absorbing impurities at 400 nm	Ph. Eur. 2.2.25	max 0.04		0.00
Absorbance: proteins and light-absorbing impurities from 210 to 220 nm	Ph. Eur. 2.2.25	max 0.25		0.03
Absorbance: proteins and light-absorbing impurities from 270 to 300 nm	Ph. Eur. 2.2.25	max 0.07		0.01
Water	Ph. Eur. 2.5.12	4.5 - 5.5	%	5.1
Loss on drying	USP-NF <731>	max 0.5	%	0.2
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 ₂ O ₃ ; p = 1500 - 2500 Pa; 2 min	45 - 75	%	48 - 57
Particle size distribution < 100 µm	Ph. Eur. 2.9.38/Air-entrainment method (air-jet sieving); 10 g; + 0.1 g Al ₂ O ₃ ; p = 1500 - 2500 Pa; 2 min	min 90	%	90 - 96
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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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	0
<i>Escherichia coli</i>	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence	/10 g	absence*
<i>Salmonella</i> 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.

The fulfills the demands of the relevant German and EU Regulations for fixing maximum levels of residues and containments, including dioxin.

CONTAINER/STORAGE

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

