



CERTIFICATE OF ANALYSIS

Spec. No.: 10000000042 Version 05

Delivery No.: 81012869
Material: 13007670 GranuLac® 200

Lot No. L101853024

Manufact. Date
W30Y2024

Retest Date
W28Y2027

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
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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
Absorbance: proteins and light-absorbing impurities at 400 nm	Ph. Eur. 2.2.25	max 0.04		0.00