SPECIFICATION
GRANULAC® 200

SAP-Nr./No. 10000000042	Version: 2	Gültig ab/effective from: 01.01.2018	1 / 2

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: Molkerei MEGGLE Wasserburg GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg, Germany

The management system of Molkerei MEGGLE Wasserburg 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.

IDENTIFICATION

Method	Specification
Identification A/Ph. Eur. 2.2.24/Infrared absorption spectrophotometry	conforms
Identification B/USP-NF <201>/Thin-layer chromatographic identification test	conforms
Identification D/Ph. Eur. 2.5.12/Water	conforms

TESTS

	Method	Specification
Appearance of solution	Ph. Eur. 2.2.1 Instrumental method (max 3 NTU equals "The solution S is clear")	max 3 NTU
Appearance of solution	Ph. Eur. 2.2.2 *Method II*	The solution is not more intensely coloured than reference solution BY_7
Absorbance: proteins and light-absorbing impurities at 400 nm	Ph. Eur. 2.2.25	max 0.04
Absorbance: proteins and light-absorbing impurities from 270 to 300 nm	Ph. Eur. 2.2.25	max 0.07
Absorbance: proteins and light-absorbing impurities from 210 to 220 nm	Ph. Eur. 2.2.25	max 0.25
Acidity or alkalinity	Ph. Eur. Lactose Monohydrate	The solution is colourless
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
Specific optical rotation (anhydrous substance)	Ph. Eur. 2.2.7	+54.4 - +55.9 °
Heavy metals	JP <1.07> Method 1	max 5 µg/g
Water	Ph. Eur. 2.5.12	4.5 - 5.5 %
Loss on drying	USP-NF <731>	max 0.5 %
Sulfated ash	Ph. Eur. 2.4.14	max 0.1 %
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 %

	Method	Specification
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 %

MICROBIAL CONTAMINATION

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

STORAGE

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

This specification was electronically released.