

DEFINITION/CHARACTERS/PRODUCTION

SPHEROLAC 100 is MEGGLE's brand name for a sieved, free flowing lactose.

SPHEROLAC 100 conforms to the monograph "Lactose Monohydrate" in the Ph. Eur., USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation.

SPHEROLAC 100 conforms to the monograph "Lactose Monohydrate" in the Chinese Pharmacopoeia (ChP). Testing is performed using the methods indicated below.

SPHEROLAC 100 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>.

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
Identification (1)/ChP <0512>/HPLC	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 <i>Method II</i>	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 °
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 < 63 µm	Ph. Eur. 2.9.38/Mechanical agitation (dry sieving method); 25 g; + 0.1 g Al ₂ O ₃ ; amplitude 2.0 mm; interval 10 s; 10 min	max 20 %

	Method	Specification
Particle size distribution < 200 µm	Ph. Eur. 2.9.38/Mechanical agitation (dry sieving method); 25 g; + 0.1 g Al ₂ O ₃ ; amplitude 2.0 mm; interval 10 s; 10 min	min 75 %
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
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
Assay: Lactose calculated on the anhydrous basis	ChP <0512>	98.0 - 102.0 %
Related substances	ChP <0512>	max 0.5 %

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 10 cfu/g
<i>Escherichia coli</i>	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence /10 g
<i>Salmonella</i> spp.	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence /100 g

STORAGE

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

This specification was electronically released.