SPECIFICATION
LACTOSE MONOHYDRATE LOW ENDOTOXIN

DEFINITION/CHARACTERS/PRODUCTION

LACTOSE MONOHYDRATE LOW ENDOTOXIN is MEGGLE's generic name for a sieved lactose with low endotoxin content.
LACTOSE MONOHYDRATE LOW ENDOTOXIN conforms to the monograph "Lactose Monohydrate" in the USP-NF, Ph. Eur. and JP. The monograph has undergone pharmacopoeial harmonisation.
LACTOSE MONOHYDRATE LOW ENDOTOXIN conforms to the monograph "Lactose Monohydrate" in the Chinese Pharmacopoeia (ChP). Testing is performed using the methods indicated below.
LACTOSE MONOHYDRATE LOW ENDOTOXIN is the monohydrate of O-ß-D-galactopyranosyl-(1→4)-α-D-glucopyranose.
LACTOSE MONOHYDRATE LOW ENDOTOXIN is a white or almost white, odourless, crystalline powder. It is freely but slowly soluble in water, practically insoluble in ethanol (96 per cent), chloroform and ether. The particle size is typically below 900 µm.

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/USP-NF <197K>/Infrared spectroscopy	conforms
Identification B/USP-NF <201>/Thin-layer chromatographic identification test	conforms
Identification (1)/ChP <0512>/HPLC	conforms

TESTS

	Method	Specification
Clarity and color of solution	USP-NF Lactose Monohydrate	The sample solution is clear and nearly colorless
Clarity and color of solution, absorbance at 400 nm	USP-NF Lactose Monohydrate	NMT 0.04
Protein and light-absorbing impurities in the range of 270 - 300 nm	USP-NF <857>	NMT 0.07
Protein and light-absorbing impurities in the range of 210 - 220 nm	USP-NF <857>	NMT 0.25
Acidity or alkalinity	USP-NF Lactose Monohydrate	The solution is colourless
Acidity or alkalinity	USP-NF Lactose Monohydrate/Requirement of 0.1 N sodium hydroxide VS to produce a pink or red color	NMT 0.4 ml
Optical rotation (specific rotation) calculated on the anhydrous basis	USP-NF <781S> *Specific rotation*	+54.4 - +55.9 °
Water determination	USP-NF <921> *Method I*	4.5 - 5.5 %
Loss on drying	USP-NF <731>	NMT 0.5 %
Residue on ignition	USP-NF <281>	NMT 0.1 %
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	NMT 5 µg/g

	Method	Specification
Arsenic (As)	ChP <0822 Method 1> tested with ICP-MS acc. to Ph. Eur. 5.20/USP-NF <232> and <233>/ICH Q3D	NMT 2 µg/g
Assay: Lactose calculated on the anhydrous basis	ChP <0512>	98.0 - 102.0 %
Related substances	ChP <0512>	NMT 0.5 %

MICROBIAL CONTAMINATION

	Method	Specification
Total aerobic microbial count (TAMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	NMT 10 cfu/g
Total combined yeasts and molds count (TYMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	NMT 10 cfu/g
Bile-tolerant gram-negative bacteria	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence /10 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
Pseudomonas aeruginosa	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence /10 g
Staphylococcus aureus	Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05>	absence /10 g
Burkholderia cepacia	USP-NF <60>	absence /10 g
Bacterial endotoxins	Ph. Eur. 2.6.14/USP-NF <85>/JP <4.01>	NMT 5 EU/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.