SPECIFICATION
DURALAC® H

SAP-Nr./No. 10000000177	Version: 7	Gültig ab/effective from: 03.05.2021	1 / 2

DEFINITION/CHARACTERS/PRODUCTION

DURALAC H is MEGGLE's brand name for an anhydrous lactose (Lactosum anhydricum).
DURALAC H conforms to the monograph "Anhydrous Lactose" in the United States Pharmacopeia-National Formulary (USP-NF). This monograph is harmonized between USP-NF, Ph. Eur. and JP.
DURALAC H conforms to the monograph "Anhydrous Lactose" in the Chinese Pharmacopoeia (ChP). Testing is performed using the methods indicated below.
DURALAC H is O-ß-D-galactopyranosyl-(1→4)-ß-D-glucopyranose (ß-lactose), or a mixture of O-ß-D-galactopyranosyl-(1→4)-ß-D-glucopyranose and O-ß-D-galactopyranosyl-(1→4)-α-D-glucopyranose (α-lactose).
DURALAC H is a white or almost white, crystalline, odorless powder. It is freely but slowly soluble in water, practically insoluble in ethanol (96 per cent), chloroform and ether.

Subcontracted production and release site: Agropur inc., 719 North Main Street, Le Sueur, MN 56058, USA

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 Anhydrous Lactose	The clarity of the Sample solution is the same as that of water or its opalescence is not more pronounced than that of the Reference suspension, and it is not more colored than the Reference solution
Clarity and color of solution, absorbance at 400 nm	USP-NF Anhydrous Lactose	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 Anhydrous Lactose	The solution is colourless
Acidity or alkalinity	USP-NF Anhydrous Lactose/Requirement of 0.1 N sodium hydroxide 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*	NMT 1.0 %
Loss on drying	USP-NF <731>	NMT 0.5 %
Residue on ignition	USP-NF <281>	NMT 0.1 %
Content of alpha and beta anomers	USP-NF Anhydrous Lactose, modified	reporting %
Particle size distribution < 45 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	NMT 20 %

	Method	Specification
Particle size distribution < 150 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	40 - 65 %
Particle size distribution < 250 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	NLT 80 %
Heavy metals	JP <1.07> Method 2, 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
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 100 cfu/g
Total combined yeasts and molds count (TYMC)	Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05>	NMT 10 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 /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.