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NL02074481

CERTIFICATE OF ANALYSIS NO: 19001233

LOT NO: 19045

COMMODITY: Lactose-PP 200 Mesh , pharmaceutical grade

ITEM NO: 388

MANUFACTURING DATE: 17.09.2019

EXPIRATION DATE: 16.09.2022

Specification: min. 99,8% Lactose-monohydrate - white, crystalline, odourless powder

- No solvents, listed in the ICH Q3C Guideline are used in our manufacturing process.

Physical-chemical tests

	Method	Limit	Result
- appearance of powder		white	white
- clarity of solution	USP 42 / JP 17	clear	clear
- color of solution (extinction 400 nm)	USP 42 / JP 17	≤ 0,04	0,003
- protein and light-absorbing impurities			
extinction (210 - 220) nm	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,25	0,089
extinction (270 - 300) nm	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,07	0,046
- acidity or alkalinity (ml 0,1 N NaOH)	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,4 ml	0,2 ml
- specific rotation (cal. on anhydrous basis)	USP 42 / Ph.Eur. 9 / JP 17	+54,4° - +55,9°	+ 55,3 °
- residue on ignition / sulfated ash	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,1 %	0,04 %
- loss on drying	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,5 %	0,14 %
- water	n. Karl Fischer	4,5-5,5 %	5,1 %
- pH	10 % solution	3,8-5,5	4,65
- particle size <63µm 79,9 % (80,0 ±10%)	<90µm 90,7% (90,0 ±10%)		

Microbiological tests

- total plate count	CASO-Agar, 30°C/48h	< 100/g	< 5/g
- coli-test	LST-Bouillon, 36°C/48h	negative/g	negative/g
- enterobacteriaceae	VRBD-Agar, 37°C/24h	negative/g	negative/g
- moulds	YGC-Agar, 25°C/5d	max 10/g	< 10/g
- yeasts	YGC-Agar, 25°C/5d	max 10/g	< 10/g

External tests

- heavy metals: - Pb, As, Cd, Ni, Co, V
- Hg

- aflatoxin M1

- polychlorinated biphenyls

- pesticide

- E. coli

- Listeria monocytogenes / salmonellae

- Bacillus cereus

- coagulase-positive staphylococcus

- Clostridium perfringens

- sulphite reducing anaerobic spore formers

last results: Lot 19039 prod. on: 08.08.2019

EN-ISO 17294-2:2004 ≤ 0,5 ppm

Direct Mercury Analyzer ≤ 0,5 ppm

§ 64 LFGB < 0,05 ppb

IDF 75 C: 1991 corresponds to pollutant maximum quantities

IDF 75 C: 1991 corresponds to residue maximum quantities

§ 64 LFGB < 0,3 /g (MPN)

§ 64 LFGB not detected in 25g

§ 64 LFGB < 100/g

§ 64 LFGB not detected in 1g

§ 64 LFGB < 10/g

VDLUF A M7.18.4 < 0,3 /g (MPN)

The above product (Pharma Lactose) is manufactured at our plant Danone GmbH, Rosenheim, Germany