Danone GmbH · Schönfeldstraße 12a · 83022 Rosenheim

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13467525
NL02075739

CERTIFICATE OF ANALYSIS NO: 19001385
LOT NO: **19051**
COMMODITY: Lactose-PP 200 Mesh , pharmaceutical grade ITEM NO: 388
MANUFACTURING DATE: 21.10.2019 EXPIRATION DATE: 20.10.2022

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	**0,001**
- protein and light-absorbing impurities			
extinction (210 - 220) nm	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,25	**0,038**
extinction (270 - 300) nm	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,07	**0,014**
- acidity or alkalinity (ml 0,1 N NaOH)	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,4 ml	**0,3 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 %	**0,03 %**
- loss on drying	USP 42 / Ph.Eur. 9 / JP 17	≤ 0,5 %	**0,04 %**
- water	n. Karl Fischer	4,5-5,5 %	**5,2 %**
- pH	10 % solution	3,8-5,5	**4,51**
- particle size <63µm **81,6 %** (80,0 ±10%)	<90µm **92,3%** (90,0 ±10%)		
Microbiological tests			
- total plate count	CASO-Agar, 30°C/48h	< 100/g	**< 7/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 — **last results: Lot 19039 prod. on: 08.08.2019**

- heavy metals: - Pb, As, Cd, Ni, Co, V	EN-ISO 17294-2:2004	**≤ 0,5 ppm**
- Hg	Direct Mercury Analyzer	**≤ 0,5 ppm**
- aflatoxin M1	§ 64 LFGB	**< 0,05 ppb**
- polychlorinated biphenyls	IDF 75 C: 1991	**corresponds to pollutant maximum quantities**
- pesticide	IDF 75 C: 1991	**corresponds to residue maximum quantities**
- E. coli	§ 64 LFGB	**< 0,3 /g (MPN)**
- Listeria monocytogenes / salmonellae	§ 64 LFGB	**not detected in 25g**
- Bacillus cereus	§ 64 LFGB	**< 100/g**
- coagulase-positive staphylococcus	§ 64 LFGB	**not detected in 1g**
- Clostridium perfringens	§ 64 LFGB	**< 10/g**
- sulphite reducing anaerobic spore formers	VDLUFA M7.18.4	**< 0,3 /g (MPN)**

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

Rosenheim, den 04.11.2019

i.A. Gertraud Bachmaier
(Head of Quality and Food Safety)