

CERTIFICATE OF ANALYSIS NO: 18001643

LOT NO: 18055

COMMODITY: Lactose-PP 200 Mesh , pharmaceutical grade

ITEM NO: 388

MANUFACTURING DATE: 02.10.2018

EXPIRATION DATE: 01.10.2021

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 41 / JP 17	clear	clear
- color of solution (extinction 400 nm)	USP 41 / JP 17	≤ 0,04	0,002
- protein and light-absorbing impurities			
extinction (210 - 220) nm	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,25	0,038
extinction (270 - 300) nm	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,07	0,006
- acidity or alkalinity (ml 0,1 N NaOH)	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,4 ml	0,3 ml
- specific rotation (cal. on anhydrous basis)	USP 41 / Ph.Eur. 9 / JP 17	+54,4° - +55,9°	+ 55,4 °
- residue on ignition / sulfated ash	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,1 %	0,08 %
- loss on drying	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,5 %	0,03 %
- water	n. Karl Fischer	4,5-5,5 %	5,1 %
- pH	10 % solution	3,8-5,5	4,44
- particle size <63µm 81,9 % (80,0 ±10%)	<90µm 99,2% (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

last results: Lot 18043 prod. on: 08.08.2018

- 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)	