

CERTIFICATE OF ANALYSIS NO: 18001273

LOT NO: 18044

COMMODITY: Lactose-PP 200 Mesh, pharmaceutical grade

ITEM NO: 388

MANUFACTURING DATE: 09.08.2018

EXPIRATION DATE: 08.08.2021

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	0,004
- protein and light-absorbing impurities			
extinction (210 - 220) nm	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,25	0,034
extinction (270 - 300) nm	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,07	0,005
- acidity or alkalinity (ml 0,1 N NaOH)	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,4 ml	0,2 ml
- specific rotation (cal. on anhydrous basis)	USP 41 / Ph.Eur. 9 / JP 17	+54,4° - +55,9°	+ 55,6 °
- residue on ignition / sulfated ash	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,1 %	0,06 %
- loss on drying	USP 41 / Ph.Eur. 9 / JP 17	≤ 0,5 %	0,04 %
- water	n. Karl Fischer	4,5-5,5 %	5,1 %
- pH	10 % solution	3,8-5,5	4,51
- particle size <63µm 79,7 % (80,0 ±10%) <90µm 91,7% (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

- heavy metals: - Pb, As, Cd, Ni, Co, V	EN-ISO 17294-2:2004	≤ 0,5 ppm	
- Hg	Direct Mercury Analyser	≤ 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	VDLUF A M7.18.4	< 0,3 /g (MPN)	

23.08.2018