

Hermann Schlattermund  
 Productos Químicos  
 Hamburgo - Alemania  
 control de calidad  
 aprobado / approved / freigegeben

75380428  
 13467525  
 NL02081785

CERTIFICATE OF ANALYSIS NO: 20001211

LOT NO: 20046

COMMODITY: Lactose-PP 200 Mesh , pharmaceutical grade

ITEM NO: 388

MANUFACTURING DATE: 12.10.2020

EXPIRATION DATE: 11.10.2023

**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**

|                                               | <u>Method</u>               | <u>Limit</u>    | <u>Result</u> |
|-----------------------------------------------|-----------------------------|-----------------|---------------|
| - appearance of powder                        |                             | white           | white         |
| - clarity of solution                         | USP 43 / JP 17              | clear           | clear         |
| - color of solution (extinction 400 nm)       | USP 43 / JP 17              | ≤ 0,04          | 0,005         |
| - protein and light-absorbing impurities      |                             |                 |               |
| extinction (210 - 220) nm                     | USP 43 / Ph.Eur. 10 / JP 17 | ≤ 0,25          | 0,038         |
| extinction (270 - 300) nm                     | USP 43 / Ph.Eur. 10 / JP 17 | ≤ 0,07          | 0,006         |
| - acidity or alkalinity (ml 0,1 N NaOH)       | USP 43 / Ph.Eur. 10 / JP 17 | ≤ 0,4 ml        | 0,3 ml        |
| - specific rotation (cal. on anhydrous basis) | USP 43 / Ph.Eur. 10 / JP 17 | +54,4° - +55,9° | + 54,5 °      |
| - residue on ignition / sulfated ash          | USP 43 / Ph.Eur. 10 / JP 17 | ≤ 0,1 %         | 0,06 %        |
| - loss on drying                              | USP 43 / Ph.Eur. 10 / JP 17 | ≤ 0,5 %         | 0,05 %        |
| - water                                       | n. Karl Fischer             | 4,5-5,5 %       | 5,1 %         |
| - pH                                          | 10 % solution               | 3,8-5,5         | 4,48          |
| - particle size <63µm 81,9 % (80,0 ±10%)      | <90µm 92,6% (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    | < 1/g      | < 1/g      |
| - moulds             | YGC-Agar, 25°C/5d      | ≤ 20/g     | < 10/g     |
| - yeasts             | YGC-Agar, 25°C/5d      | ≤ 20/g     | < 10/g     |

**External tests**

|                                             |                                                     |                                             |  |
|---------------------------------------------|-----------------------------------------------------|---------------------------------------------|--|
| - heavy metals: - Pb, As, Cd, Ni, Co, V     | <b>last results: Lot 20039 prod. on: 17.08.2020</b> |                                             |  |
| - Hg                                        | EN-ISO 17294-2:2004                                 | ≤ 0,5 ppm                                   |  |
| - aflatoxin M1                              | Direct Mercury Analyzer                             | ≤ 0,5 ppm                                   |  |
| - polychlorinated biphenyls                 | § 64 LFGB                                           | < 0,05 ppb                                  |  |
| - pesticide                                 | IDF 75 C: 1991                                      | corresponds to pollutant maximum quantities |  |
| - E. coli                                   | IDF 75 C: 1991                                      | corresponds to residue maximum quantities   |  |
| - Listeria monocytogenes / salmonellae      | § 64 LFGB                                           | < 0,3 /g (MPN)                              |  |
| - Bacillus cereus                           | § 64 LFGB                                           | not detected in 25g                         |  |
| - coagulase-positive staphylococcus         | § 64 LFGB                                           | < 100/g                                     |  |
| - Clostridium perfringens                   | § 64 LFGB                                           | not detected in 1g                          |  |
| - sulphite reducing anaerobic spore formers | § 64 LFGB                                           | < 10/g                                      |  |
|                                             | VDLUFA M7.18.4                                      | < 0,3 /g (MPN)                              |  |

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

Rosenheim, den 29.10.2020

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