

## **Certificate of Analysis**

Product name:

Batch number / Weight:

Analysed according to:

## Agar pulv. 21K05-B02-218570 / 100 G

Ph. Eur. 01/2017:0232

| Tests                             | Requirement                                  | Result  | Unit    | Standard remark |
|-----------------------------------|--|---------|---------|-----------------|
| Appearance                        | Colorless or Yellow-white powder             | Conform |         |                 |
| Identification A                  | Conform                                      | Conform |         |                 |
| Identification B                  | Brownish violet / pale yellow                | Conform |         |                 |
| Identification C                  | White  | Conform |         |                 |
| Identification D                  | Conform                                      | Conform |         |                 |
| Swelling capacity                 | >= 10  | 10      | ml      |                 |
| Insoluble substances              | <= 1,0                                       | 0,54    | %       |                 |
| Gelatine                          | Conform                                      | Conform |         |                 |
| Loss on drying                    | <= 20,0                                      | 8,06    | %       | 105 °C          |
| Total ash                         | <=5,0  | 1,08    | %       |                 |
| Total aerobic microbial count (TA | A <=1000                                     | <10     | CFU / g |                 |
| Total yeasts and moulds (TYMC)    | ) <=100                                      | <10     | CFU / g |                 |
| E. coli                           | Negative / gram                              | Conform |         |                 |
| Salmonella                        | Negative / 10 gram                           | Conform |         |                 |
| Metallic residues                 | CHMP/ICH/353369/2013                         | Conform |         | Data producer   |
| Residual solvents                 | CPMP/ICH/82 260/06                           | Conform |         | Data producer   |
| TSE/BSE-statement:                | No contamination with TSE/BSE-risk materials | Conform |         | Data producer   |

Analysis performed by the authorized lab.

Release: Ewelina Gadzinowska Qualified Person

08-02-2022

Expiration: 30-06-2023

Conclusion: APPROVED

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