

Certificate of Analysis

Product name: **Gelatina pulv.**

Batch number / Weight: **21H03-B01-217889 / 100 G**

Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|--|---------|---------|-----------------|
| Appearance | (Brown) yellow powder | Conform | | |
| Identification A | Violet | Conform | | |
| Identification B | Conform | Conform | | |
| pH | 3,8 - 7,6 | 5,5 | | |
| Conductivity | <=1 | 0,2 | mS / cm | |
| Sulphur dioxide | <=50 | Conform | ppm | |
| Peroxides | <=10 | Conform | ppm | |
| Gel strength | 100 - 120 | 117 | % | |
| | | 135 | g | |
| Iron | <=30 | Conform | ppm | |
| Chromium | <=10 | Conform | ppm | |
| Zinc | <=30 | Conform | ppm | |
| Loss on drying | <=15,0 | 12,0 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Total aerobic microbial count (TA) | <=1000 | <10 | CFU / g | |
| Total yeasts and moulds (TYMC) | <=100 | <10 | CFU / g | |
| E. coli | Negative / gram | Conform | | |
| Salmonella | Negative / 10 gram | Conform | | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

24-03-2022

Expiration: 28-02-2025

Conclusion: APPROVED

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