

Certificate of Analysis

Product name: **Tritici amyllum**

Batch number / Weight: **23C02-B12-229368 / 1 KG**

Analysed according to: **Ph.Eur.11**

Number of analysis / Inspection Code **23C02-B12 / INS-23-3401**

Reference Code / No.: **V01176 / E3419**

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------------|---|---------------------|-------|-----------------|
| Appearance | Very fine, white powder that cracks when pressed between the fingers | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| pH | 4,5 - 7,0 | 6,41 | | |
| Foreign matter | Conform | Conform | | |
| Iron | <= 10 | <10 | ppm | |
| Total protein | <= 0,3 | 0,08 | % | |
| Total protein | (corresponding to 0.048 % of nitrogen) | | | |
| Oxidising substances | <=20 | Conform | ppm | |
| Sulphur dioxide | <= 50 | 11,9 | ppm | |
| Loss on drying | <=15,0 | 12,15 | % | |
| Sulphated ash | <=0,6 | 0,14 | % | |
| 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 |
| Total aerobic microbial count | <=10 ³ | 5,0*10 ¹ | CFU/g | |
| Total yeasts and moulds | <=10 ² | <10 | CFU/g | |
| Salmonella | Negatief / 10 g | Conform | | |
| E. coli | Negatief / g | Conform | | |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAPL, EISpol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

30-05-2023

Expiration: 01-08-2026

Conclusion: APPROVED

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