

Certificate of Analysis

Product name: Urea

Batch number / Weight: 22F02-B16-221668 / 5 KG

Analysed according to: Ph. Eur. 10.8

Number of analysis / Inspection Code 22F02-B16 / INS-22-5431

Reference Code / No.: V01229 / V 034-2022

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|--|---------------------|---------|-----------------|
| Appearance | White, crystalline powder or colourless crystals | Conform | | |
| Identification A | 132 - 135 | 134,3 | °C | |
| Identification B | Conform | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Alcalinity | Conform | Conform | | |
| Biuret | <= 0,1 | Conform | % | |
| Ammonium | <= 500 | Conform | ppm | |
| Loss on drying | <=1,0 | 0,21 | % | |
| Sulphated ash | <= 0,1 | 0,00 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 98,5 - 101,5 (dried substance) | 100,14 | %m/m | |
| E. coli | Negative / gram | Conform | | |
| Total aerobic microbial count (TA) | <=10 ³ | 0,2x10 ⁴ | CFU / g | |
| Total yeasts and moulds (TYMC) | <=10 ² | <1 | CFU/g | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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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 Fagron PL lab,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

22-08-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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