

Certificate of Analysis

Product name: **Natrii acetat trihydricus**

Batch number / Weight: **22F02-B06-223710 / 1 KG**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22F02-B06 / INS-22-5056**

Reference Code / No.: **V01183 / 3086921**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white crystalline powder or colourless crystals | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | 39,0 - 40,5 | Conform | % | |
| Appearance of solution | Clear / Colourless | Conform | | |
| pH | 7,5 - 9,0 | 8,86 | | |
| Reducing substances | Conform | Conform | | |
| Chlorides | <= 200 | <200 | ppm | |
| Sulphates | <= 200 | <200 | ppm | |
| Aluminium | <= 0,2 | 0,0 | ppm | |
| Calcium and magnesium | <= 50 | Conform | ppm | |
| Iron | <= 10 | Conform | ppm | |
| Loss on drying | 39,0 - 40,5 | 39,70 | % | |
| Assay | 99,0 - 101,0 | 100,42 | %m/m | |
| 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 |

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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

Release:
Ewelina Gadzinowska
Qualified Person

06-10-2022

Expiration: 23-01-2025

Conclusion: APPROVED

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