

Certificate of Analysis

Product name: Sorbitolum apyrogen

Batch number / Weight: 23C16-B03-231633 / 5 KG

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 23C16-B03 / INS-23-3724

Reference Code / No.: V01176 / E413L

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|----------------------------------------------|---------|---------------------------|-----------------|
| Appearance | (almost) white, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Conductivity | ≤ 20 | 2,381 | $\mu\text{S} / \text{cm}$ | |
| Reducing sugars | $\leq 0,2$ | $< 0,2$ | % | |
| Related substance | Conform | Conform | | |
| Any impurity | $\leq 2,0$ | 0,92 | % | |
| Total impurities | $\leq 3,0$ | 1,65 | % | |
| Water (Karl Fischer) | $\leq 1,5$ | 0,26 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay | 97,0 - 102,0 | 98,75 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Total yeasts and moulds (TYMC) | $\leq 10^2$ | < 1 | CFU/g | |
| Total aerobic microbial count (TA) | $\leq 10^3$ | < 1 | CFU/g | |
| Escherichia coli | Absence in 1g | Conform | | |
| Salmonella | Negative / 10 gram | Conform | | |
| Endotoxins | $< 2,5$ | $< 2,5$ | IU/g | |

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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, EI Spol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

18-10-2023

Expiration: 11-11-2025

Conclusion: APPROVED

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