

CERTIFICATE OF ANALYSIS

Batch: 21D09-A100201448

Product: Sorbitolum liquidum non crystallisabile Ph. Eur. 1 kg

Expiry date: 30 SEP 2022

Analysed according to Ph. Eur. 07/2019:0437

PERFORMED ANALYSIS AND RESULTS

| Analysis | Specification | Result | Remark |
|--------------------------------------|---------------------------------|------------|--------------------------|
| Appearance | Clear, colourless syrupy liquid | CONFORM | |
| Identification A | CONFORM | CONFORM | HPLC |
| Identification B | + 1,5 - 3,5 ° | CONFORM | Refractive index |
| Identification C | Clear | CONFORM | 25 °C, Data producer |
| Appearance | Clear and colourless | CONFORM | |
| Conductivity | <= 10 µS/cm | CONFORM | Data producer |
| Reducing sugars | <= 0,20 % | CONFORM | Data producer |
| Reducing sugars after hydrolysis | <= 9,3 % | CONFORM | Data producer |
| Water | CONFORM | CONFORM | Data producer |
| Lead | <= 0,5 ppm | CONFORM | AAS, Data Producer |
| Nickel | <= 1,0 ppm | CONFORM | AAS, Data Producer |
| Assay sorbitol | 68,0 - 72,0 % m/m | 70,3 % m/m | Anhydrous, Data producer |
| Assay D-glucitol | 72,0 – 92,0 % m/m | CONFORM | Anhydrous, Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | CONFORM | Data producer |
| Metallic residues | CHMP/SWP/4446/2000 | CONFORM | Data producer |
| Total Aerobic Microbial Count (TAMC) | <= 1000 CFU/g | CONFORM | Data producer |
| Total Yeasts and Moulds Count (TYMC) | <= 100 CFU/g | CONFORM | Data producer |

RELEASE:

Conclusion: Conform

Date: 19 APR 2021

BATCH RELEASED BY:

X. Van Eecke

Head of QA - Responsible Pharmacist

This is an electronic signature