

Certificate of Analysis

Productname: Sorbitolum liquidum non crist.

Inspection No: I07785/1021/536
Batchnumber: 21D12-T09-090285
Expiration date: 11.02.2026
Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0
Original Manuf. Date: 11.2.2021

Sample Unit: 1 x 50 ml
Batch Size: 23 x 5 l

Identification of producer: V00792
Batch no. of vendor: E529V

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------------------|---|---------|---------------------|---------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Clear, colourless, syrupy liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | Assay, HPLC | Contract Lab |
| Identification B | +1,5 - +3,5 | +2,5 | ° | Optical rotation | Fagron CZ |
| Identification C | Conform | Conform | | Clear syrupy liquid | Fagron CZ |
| TESTS | | | | | |
| Appearance of solution | Clear, colourless | Conform | | 14% m/V | Fagron CZ |
| Conductivity | ≤ 10 | 0,2 | μS.cm ⁻¹ | | Fagron CZ |
| Reducing sugars | ≤ 0,2 | < 0,2 | % | Glucose equivalent | Fagron CZ |
| Reducing sugars after hydrolysis | ≤ 9,3 | < 9,3 | % | Glucose equivalent | Fagron CZ |
| Water (Karl Fischer) | 28,0 - 32,0 | 29,1 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | ≤ 2 x 10 ³ | Conform | CFU/g | | Contract Lab |
| TYMC | ≤ 2 x 10 ² | Conform | CFU/g | | Contract Lab |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | | Data Producer |
| Residual solvents | CPMP/ICH/82 260/2006 | Conform | | | Data Producer |
| Metallic residues | ICH Q3D on elemental impurities | Conform | | | Data Producer |
| ASSAY | | | | | |
| Anhydrous substance | 68,0 - 72,0 | 70,9 | % | HPLC | Contract Lab |
| D-glucitol | 72,0 - 92,0 | 77,6 | % | Anhydrous, HPLC | Contract Lab |

Name Fagron a.s. (CZ)
 Kontrolní laboratoř č. 536

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 27.10.2021
Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.

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|-------------|--|------------------|---------------------------|------------------|------------------|
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