

CERTIFICATE OF ANALYSIS

Product : **D-SORBITOL**
 Product number : S0807
 Batch number : 015361
 Date of analysis : 20-03-2020
 Date of expiry : 31-03-2025

Packaging and storage : store dry at room temperature in a well closed container

| | SPECIFICATION | RESULT | UNITS | REMARKS |
|---------------------------|---|----------|-------|---------------------------|
| Appearance | white or almost white, crystalline powder | complies | | |
| Solubility | soluble in water | complies | | |
| Appearance of solution | clear and colourless | complies | | |
| Identification | conform | complies | | |
| pH | 3.5 – 7.0 | 5.4 | | |
| Specific rotation | +4.0 – +7.0 | +4.5 | ° | anhydrous substance |
| Conductivity | ≤ 20 | 1.1 | μS/cm | |
| Chloride | ≤ 0.002 | < 0.002 | % | |
| Sulfate | ≤ 0.010 | < 0.010 | % | |
| Heavy metals | ≤ 5 | < 5 | ppm | |
| Arsenic | ≤ 1 | < 1 | ppm | |
| Nickel | ≤ 1 | < 1 | ppm | |
| Lead | ≤ 0.5 | < 0.5 | ppm | |
| Related substances: | | | | HPLC, Ph.Eur. |
| - Any impurity (mannitol) | ≤ 2.0 | 0.6 | % | |
| - Total impurities | ≤ 3.0 | 0.7 | % | |
| Reducing sugars | ≤ 0.11 | 0.04 | % | as glucose |
| Sulfated ash | ≤ 0.02 | < 0.01 | % | |
| Loss on drying | ≤ 3.0 | < 3.0 | % | |
| Water | ≤ 1.5 | 0.4 | % | |
| Assay | 97.0 – 100.5 | 99.1 | % | HPLC, anhydrous substance |

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist
Department of Quality Control Duchefa B.V.

Date: 17-04-2020



The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.

Duchefa Biochemie B.V.