



Certificate of Analysis

D-Sorbitol USP/FCC

Catalog Number: SO1004
Lot Number: 0104905
CAS Number: 50-70-4
Synonym(s): D-Glucitol
Molecular Formula: C₆H₁₄O₆
Molecular Weight: 182.17
Storage: 15°C – 30°C
Date of Manufacture: June 7, 2018
Retest Date: June 6, 2020

Test	Specification	Result
Appearance	White, crystalline powder	Conforms
Assay (HPLC) ^{1,2}	91.0 – 100.5%	98.5%
Identification ^{1,2} A Color Reaction (Catechol, H ₂ SO ₄) B Retention Time (HPLC)	To pass test To pass test	Conforms Conforms
Solubility	Very soluble in water, practically insoluble in alcohol	Conforms
Clarity & Color of Solution ¹	Clear & colorless	Conforms
pH (10%, H ₂ O)	3.5 – 7.0	6.3
Moisture (LOD) ^{1,2}	≤ 1.5%	0.27%
Residue on Ignition ^{1,2}	≤ 0.1%	< 0.10%
Reducing Sugar ^{1,2}	≤ 0.3%	< 0.3%
Chloride ¹	≤ 50ppm	< 50ppm
Sulfate ¹	≤ 100ppm	< 100ppm
Heavy Metals (As Pb) ²	≤ 10ppm	< 10ppm
Nickel ^{1,2}	≤ 1.0ppm	< 1ppm
Total Aerobic Count ¹	≤ 1,000cfu/g	< 1000cfu/g
Yeast & Mold	≤ 100cfu/g	< 100cfu/g
Coliform	Negative	Conforms
<i>E. coli</i>	Negative	Conforms
<i>Salmonella</i>	Negative	Conforms
Endotoxin	≤ 2.5cfu/g	< 2.5cfu/g

This lot meets the specifications for USP36-NF31¹ and FCCX².

Approved by:

John Grubb, PhD

Date: January 7, 2019



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