

Certificate of Analysis

Product	D(+)-Glucose anhydrous pure EP, USP (pharma grade)
Brand	Labochem

Product number	LC-5938
Lot number	62F0AD08
Synonyms	Dextrose
Formula	C ₆ H ₁₂ O ₆
Molecular weight	180.16 g/mol
CAS number	50-99-7
Storage	below 25°C
Manufacturing date	July 2022
Retest period (months)	48
Retest date	July 2026

We herewith confirm that this product meets the requirements of the European Pharmacopoeia (EP) and the US Pharmacopoeia (USP).

TSE/BSE declaration: The product is manufactured wholly from synthetic and plant materials and does not contain any raw materials produced from or substances derived of animal origin. Moreover this product is not derived from specific risk materials as defined in Guideline EMEA/410/01 final Rev. 03/2004.

All packaging materials are not of animal origin. The product does not come in contact with animal products during storage or transportation.

Depending on the quantity we either use PE-Flascs with original lids or PE-cans with original lid with PE-bags inside or card boxes with PE-bags inside.

Parameter	Specification	Result
Assay (calc. on anhydrous substance)	97.5 - 102.0 %	99.8 %
Appearance	white to off white crystalline powder	complies
Identity (IR)	passes test	complies
Identity (spec. rotation, calc. on anhydrous substance)	passes test	complies
Identity (HPLC)	passes test	complies
Identity (water)	passes test	complies
Appearance of solution	passes test	complies
Color and clarity of solution	passes test	complies
Titration acid	max. 0.002 meq/g	complies
Conductivity	max. 20 µS/cm	3.0 µS/cm
Spec. rotation (α _{25/D})	52.5 to 53.0°	52.8°
In water insoluble matter	max. 0.005 %	complies

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Parameter	Specification	Results
Chloride (Cl)	max. 0.01 %	complies
Sulfate (SO ₄)	max. 0.005 %	complies
Heavy metals (as Pb)	max. 0.0005 %	complies
Fe (Iron)	max. 0.0005 %	complies
Related substances [sum of impurities A (maltose) and B (isomaltose)]	max. 0.4 %	complies
Related substances [Impurity C (maltotriose)]	max. 0.2 %	complies
Related substances [Impurity D (fructose)]	max. 0.15 %	complies
Related substances (unspecified impurities)	max. 0.1 %	complies
Related substances (Sum of all impurities)	max. 0.5 %	complies
Dextrin	passes test	complies
Soluble starch, sulfite	max. 0.0015 %	complies
Starch	passes test	complies
Residual solvents (ICH Q3C)	excluded by the manufacturing process	complies
Loss on drying (105°C)	max. 0.2 %	complies
Water (acc. to Karl Fischer)	max. 1.0 %	complies
Sulfated ash (600°C)	max. 0.02 %	complies
Microbiological purity (Total aerobic microbial count (TAMC))	max. 100 CFU/g	complies
Microbiological purity (Total yeast and mould count (TYMC))	max. 100 CFU/g	complies
Gram negative Bacteria (absent in 1 g)	passes test	complies

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Parameter	Specification	Results
Escherichia coli (absent in 1 g)	passes test	complies
Pseudomonas aeruginosa (absent in 1 g)	passes test	complies
Staphylococcus aureus (absent in 1 g)	passes test	complies
Candida albicans (absent in 1 g)	passes test	complies
Salmonella ssp (absent in 10 g)	passes test	complies
Endotoxins	max. 10 I.U./g	complies

Einhausen, 23.08.2022	Quality control: M.F.
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For a greener laboratory



neoFroxx GmbH

Marie-Curie-Str. 3 | 64683 Einhausen | Germany
Phone +49 6251 989 24 0 | Fax +49 6251 989 24 10
E-Mail info@neofroxx.com | www.neofroxx.com