



Certificate of Analysis

1.00894.9010 Sucralose powder EMPROVE® ESSENTIAL Ph Eur,ChP,NF,JPE
Batch K95884589

	Spec. Values		Batch Values	
Assay (HPLC, calc. on anhydrous substance)	98.0 - 102.0	%	100.5	%
Assay (HPLC, calc. on anhydrous substance) (ChP)	98.0 - 102.0	%	101.3	%
Assay (calc. on anhydrous substance) (JPE)	98.0 - 102.0	%	99.7	%
Appearance of substance (description)	ballied powder		ballied powder	
Appearance of substance (color)	almost white		almost white	
Identity (HPLC)	conforms		conforms	
Identity (TLC)	conforms		conforms	
Identity (IR)	conforms		conforms	
Identity (Spec. rotation (Ph Eur))	conforms		conforms	
Spec. Rotation $[\alpha]_{20/D}$ (calc. on anhydrous substance) (Ph Eur/JPE)	+84.0 - +87.5	°	+86.5	°
Spec. Rotation $[\alpha]_{20/D}$ (calc. on anhydrous substance) (NF/ChP)	+84.0 - +87.5	°	+85.8	°
Appearance of solution (10 %, water)	conforms		conforms	
pH-Test	Decrease of 1 pH unit max.		Decrease of 1 pH unit max.	
Heavy metals (as Pb)	≤ 0.0010	%	≤ 0.0010	%
Methanol	≤ 0.1	%	≤ 0.1	%
Methanol (ChP)	≤ 0.1	%	≤ 0.1	%
Cyclohexane	≤ 3880	ppm	≤ 3880	ppm
N,N-Dimethylformamide	≤ 880	ppm	≤ 880	ppm
Acetic acid	≤ 5000	ppm	≤ 5000	ppm
Ethyl acetate	≤ 5000	ppm	≤ 5000	ppm
Other residual solvents (ICH Q3C)	excluded by production process		excluded by production process	
Hydrolysis products	≤ 0.1	%	≤ 0.1	%
Impurities H and I	≤ 0.1	%	≤ 0.1	%
Monosaccharide-Chloride (as Fructose)	≤ 0.16	%	≤ 0.16	%
Related substances (Ph Eur/ChP)	≤ 0.5	%	≤ 0.5	%
Related substances (NF)	≤ 0.5	%	≤ 0.5	%
Other Disaccharide-Chlorides	≤ 0.5	%	≤ 0.5	%
Triphenylphosphine oxide	≤ 150	ppm	≤ 150	ppm
Residue on ignition	≤ 0.7	%	≤ 0.7	%
Water (according to Karl Fischer)	≤ 2.0	%	< 0.2	%
Particle Size (d90)	≤ 12	µm	13	µm
Microbiological purity (Total aerobic microbial count (TAMC))	≤ 1·10 ³	CFU/g	≤ 1·10 ³	CFU/g
Microbiological purity (Total yeast and mould count (TYMC))	≤ 1·10 ²	CFU/g	≤ 1·10 ²	CFU/g
Bile tolerant Gram negative Bacteria (absent in 1 g)	conforms		conforms	
Escherichia coli (absent in 1 g)	conforms		conforms	

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Pseudomonas aeruginosa (absent in 1 g)	conforms	conforms
Staphylococcus aureus (absent in 1 g)	conforms	conforms
Candida albicans (absent in 1 g)	conforms	conforms
Salmonella ssp (absent in 10 g)	conforms	conforms

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to Ph Eur, ChP, NF, JPE

Date of manufacture (DD.MM.YYYY) 14.02.2024

Date of examination (DD.MM.YYYY) 25.06.2024

Minimum shelf life (DD.MM.YYYY) 28.02.2027

Julian Hofmann

Responsible laboratory manager quality control

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