Acros Organics BV (Thermo Fisher Scientific)
Janssen Pharmaceuticalaan 3a
Geel,
2440, Belgium

CERTIFICATE OF ANALYSIS

Thermo Fisher Scientific's Quality System has been found to conform to Quality Management System Standard ISO9001:2015 by Intertek. Certificate Number. 2317548

Catalogue Number	36889
Lot Number	A0473003
Description	alpha-D-Lactose monohydrate,USP/NF, Ph.Eur., JP
CAS Number	5989-81-1
Quality Test/Release Date	02/Jun/2025
Suggested retest date	02/Jun/2028
Country of Origin	NETHERLANDS
Declaration of Origin	bovine (cattle)
BSE/TSE	The product is manufactured by crystallisation of whey

Result Name	Units	Specifications	Test Value
Appearance (Color)		White to almost white	White
Appearance (Form)		Amorphous powder, crystals or crystalline powder	Amorphous powder
Identification		Conform USP/NF, EP, JP	Conform USP/NF, EP, JP
Appearance of solution		Clear and not more intensely colored than ref. BY7	Clear and not more intensely colored than ref. BY7
Clarity and color of solution		Clear and nearly colorless	Clear and nearly colorless
Residue after ignition	%	=<0.1	=<0.1
Water	%	4.5 to 5.5	5.1
Loss on drying	%	=<0.5 (80°C, 2 h)	0.2 (80°C, 2 h)
Acidity/alkalinity	ml/6g	=<0.4 (ml 0.1N NaOH/6g)	0.2 (ml 0.1N NaOH/6g)
Specific optical rotation		+54.4° to +55.9° (20°C, 589 nm) (c=10, H2O/NH3)	+55.3° (20°C, 589 nm) (c=10, H2O/NH3)
Specific optical rotation		After 30 min., on anhydrous substance	After 30 min., on anhydrous substance
UV		(1 % in water) 1 cm cell	(1 % in water) 1 cm cell
UV		at 210 nm A: =<0.25	at 210 nm A:0.05
UV		at 220 nm A: =<0.25	at 220 nm A:0.05
UV		at 270 nm A: =<0.07	at 270 nm A:0.01
UV		at 300 nm A: =<0.07	at 300 nm A:0.01
UV		(c=10, 1 cm cell)	(c=10, 1 cm cell)
UV		at 400 nm A: =<0.04	at 400 nm A: =<0.04
Heavy metals	ppm	=<5	=<5
Microbial contamination	CFU/g	=<100 total aerobic microbial count	=<100 total aerobic microbial count
Microbial contamination	CFU/g	=<50 total yeasts and moulds	=<10 total yeasts and moulds
Microbial contamination		(Escherichia coli in 10 g) Absent	(Escherichia coli in 10 g) Absent
Microbial contamination		(Salmonellae in 100 g) Absent	(Salmonellae in 100 g) Absent
Particle size	%	50 to 65 (=< 45 µm)	59 (=< 45 µm)
Particle size	%	>=90 (=< 100 µm)	>=92 (=< 100 µm)
Particle size	%	>=96 (=< 150 µm)	100 (=< 150 µm)
Particle size	%	>=99 (=< 250 µm)	100 (=< 250 µm)

Note: The data listed is valid for all package sizes of this lot of this product, expressed as an extension of the catalogue number listed above.

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Geert Torfs
Supervisor, QC

Products are processed under ISO 9001:2015 quality management systems and samples are tested for conformance to the noted specifications. Certain data may have been supplied by third parties. We disclaim the implied warranties of merchantability and fitness for a particular purpose, and the accuracy of third-party data or information associated with the product. Products are for research and development use only. Products are not for direct administration to humans or animals. It is the responsibility of the final formulator or end user to determine suitability, and to qualify and/or validate each product for its intended use.

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