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	12509
Lot Number	A0431786
Description	alpha-D-Lactose monohydrate,99.5+%
CAS Number	5989-81-1
Quality Test/Release Date	28/Dec/2025
Suggested retest date	28/Dec/2028
Country of Origin	NETHERLANDS
Declaration of Origin	bovine (cattle)
BSE/TSE	The product is derived from cow milk

Result Name	Units	Specifications	Test Value
Appearance (Color)		White to almost white	White
Appearance (Form)		Crystalline powder	Crystalline powder
Infrared spectrum		Conforms	Conforms
HPLC	%	>=99.50	99.90
Loss on drying	%	=<0.5 (80°C, 2 h)	0.1 (80°C, 2 h)
Sulfated ash	%	=<0.1	=<0.1
Water	%	4.5 to 5.5 (K.F.)	4.9 (K.F.)
Specific optical rotation		+54.4° to +55.9° (20°C, 589 nm) (c=10, H2O/NH3)	+54.9° (20°C, 589 nm) (c=10, H2O/NH3)
Specific optical rotation		On dry substance	On dry substance
Acidity/alkalinity	ml/6g	=<0.4 (ml 0.1N NaOH/6g)	0.3 (ml 0.1N NaOH/6g)
Absorbance		Passes test	Passes test
Appearance of solution		Passes test	Passes test
Microbial contamination		Passes test	Passes test

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.

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.