



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: Sugammadex Sodium
Product Information

Product Number SUG-20260228
Batch Number SUG-SH2026022801
Brand SIGALD
CAS Number 356373-20-9
MDL Number MFCD08056466
Formula C₆₀ H₉₀ Na₈ O₃₆ S₈
Molecular Weight 2179.71 Da
Quality Release Date 28 FEB 2026

Test Results

Test	Specification (USP/EP/BP Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Free-flowing crystalline powder	-	Visual Inspection
Assay (HPLC, dry basis)	≥ 98.0%	99.2%	%	High Performance Liquid Chromatography (HPLC)
Melting Point	210-215°C (decomp)	212.8°C	°C	Capillary Melting Point Apparatus
Loss on Drying	≤ 1.0%	0.35%	%	Gravimetry (105°C, 2h)
Residue on Ignition	≤ 0.1%	0.02%	%	600°C Ignition Method
pH Value (5% aq. solution, 25°C)	5.0-7.5	6.3	-	Digital pH Meter
Heavy Metals (Pb)	≤ 10 ppm	0.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.08 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride (Cl ⁻)	≤ 0.01%	0.002%	%	Volumetric Method
Sulfate (SO ₄ ²⁻)	≤ 0.01%	0.003%	%	Turbidimetric Method
Related Substances	≤ 1.0%	0.15%	%	HPLC
Total Aerobic Microorganisms	≤ 100 CFU/g	5 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Endotoxin	≤ 0.5 EU/mg	0.12 EU/mg	EU/mg	Limulus Amebocyte Lysate Test
Particle Size (Pass through)	≥95% 100 mesh	99%	-	Sieve Analysis
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with USP/EP/BP pharmaceutical raw material industrial standards and meets all specified requirements. It is qualified for use in pharmaceutical preparations, neuromuscular block reversal formulations and clinical anesthetic applications.

Issue Date:28 FEB 2026