



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Information

Item	Details
Product Name	Dexmedetomidine Hydrochloride
Product Number	DHM-20260229
Batch Number	DHM-SH2026022901
Brand	SIGALD
CAS Number	153006-60-5
MDL Number	N/A
Formula	C ₁₃ H ₁₆ N ₂ ·HCl
Formula Weight	236.74 g/mol
Quality Release Date	29 FEB 2026

Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (Dexmedetomidine Hydrochloride)	≥ 99.5%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Optical Purity (S-enantiomer)	≥ 99.8%	99.9%	%	Chiral HPLC
Loss on Drying	≤ 0.3%	0.05%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.008%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 2 ppm	0.08 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.05 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	≤ 0.3%	0.08%	%	HPLC
Chloride (Cl ⁻)	15.0-15.6%	15.3%	%	Volumetric Method
Sulfate (SO ₄ ²⁻)	≤ 0.02%	0.001%	%	Turbidimetric Method
Melting Point	143-147°C	145.2°C	°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	4.5-7.0	5.8	-	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Solubility in Water	Freely soluble	Complies	-	Pharmacopoeia Method
Supplier Information	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with the industrial standards for Dexmedetomidine Hydrochloride and meets all specified requirements. It is qualified for use.
Issue Date: 29 FEB 2026