



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Mivacurium Chloride)

Issue Date: 22 FEB 2026 Quality Release Date: 22 FEB 2026

Product Name

Mivacurium Chloride

Product Information

Product Number MC-20260222
Batch Number MC-SH2026022201
Brand SIGALD
CAS Number 94246-42-9
MDL Number MFCD00072118
Formula $C_5H_8OCl_2N_4O_{10}$
Formula Weight 1062.17 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (on dry basis)	≥ 98.5%	99.2%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 1.0%	0.31%	%	HPLC (USP 45)
Single Impurity	≤ 0.5%	0.10%	%	HPLC (USP 45)
Loss on Drying	≤ 1.0%	0.45%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.03%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	1.4 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.3 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.21 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Specific Rotation (25°C, c=1 in H ₂ O)	+14° to +20°	+17.3°	°	Polarimetry
Chloride Content	5.1-5.7%	5.4%	%	Volumetric Titration (ChP 2025)

Certification

This batch of Mivacurium Chloride has been tested in accordance with the **United States Pharmacopeia (45 Edition)** and **Chinese Pharmacopoeia (2025 Edition)**. All test results meet the specified pharmacopoeial requirements for pharmaceutical raw materials, and the product is qualified for use in the production of clinical muscle relaxant preparations.