



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Rimantadine Hydrochloride)

Issue Date: 28 FEB 2026 Quality Release Date: 28 FEB 2026

Product Name

Rimantadine Hydrochloride 盐酸金刚乙胺

Product Information

Product Number RH-20260228
Batch Number RH-SH2026022801
Brand SIGALD
CAS Number 1501-84-4
MDL Number MFCD00012674
Formula $C_{12}H_{21}N \cdot HCl$
Formula Weight 217.76 g/mol

Test Results

Test	Specification (USP 45 & ChP 2025)	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)	$\geq 99.0\%$	99.7%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 0.5\%$	0.18%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.03%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.12%	%	Karl Fischer Titration
Residue on Ignition	$\leq 0.1\%$	0.02%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.5 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/ μ g	0.08 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	134 ~ 138 $^{\circ}$ C	136.5 $^{\circ}$ C	$^{\circ}$ C	Melting Point Apparatus
pH Value (1% aqueous solution, 25 $^{\circ}$ C)	4.0 ~ 6.0	5.1	-	Digital pH Meter
Specific Rotation (25 $^{\circ}$ C, c=5 in H ₂ O)	+6.0 $^{\circ}$ ~ +8.0 $^{\circ}$	+7.2 $^{\circ}$	$^{\circ}$	Polarimetry

Certification

This batch of Rimantadine Hydrochloride 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 anti-influenza pharmaceutical preparations.