



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Certificate of Analysis

### Product Information

Item	Details
Product Name	Ropivacaine Mesylate
Product Number	RM-20260218
Batch Number	RM-SH2026021801
Brand	SIGALD
CAS Number	132530-03-7
MDL Number	N/A
Formula	$C_{17}H_{26}N_2O \cdot CH_4O_3S$
Formula Weight	374.59 g/mol
Quality Release Date	18 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 (Ropivacaine Mesylate)	$\geq 99.5\%$	99.8%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	$\leq 0.3\%$	0.04%	%	105°C, 2 hours
Residue on Ignition	$\leq 0.1\%$	0.005%	%	600±25°C Ignition Method
Heavy Metals (Pb)	$\leq 2$ ppm	0.05 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 1$ ppm	0.02 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	$\leq 0.3\%$	0.06%	%	HPLC
Methanesulfonate ( $CH_3SO_3^-$ )	19.0-21.0%	20.2%	%	Volumetric Method
Sulfate ( $SO_4^{2-}$ )	$\leq 0.02\%$	0.001%	%	Turbidimetric Method
Melting Point	144-148°C	146.3°C	°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	4.0-6.0	4.8	-	Digital pH Meter
Total Bacterial Count	$\leq 5$ CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	$\leq 5$ 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 Ropivacaine Mesylate and meets all specified requirements. It is qualified for use.

Issue Date:18 FEB 2026