



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Information

Item	Details
Product Name	Bupivacaine Hydrochloride
Product Number	BH-20260225
Batch Number	BH-SH2026022501
Brand	SIGALD
CAS Number	14252-80-3
MDL Number	N/A
Formula	C ₁₈ H ₂₈ N ₂ O ·HCl
Formula Weight	324.89 g/mol
Quality Release Date	25 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 (Bupivacaine Hydrochloride)	≥ 99.0%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	0.07%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.01%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 5 ppm	0.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.08 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	≤ 0.5%	0.11%	%	HPLC
Chloride (Cl ⁻)	10.9-11.5%	11.2%	%	Volumetric Method
Sulfate (SO ₄ ²⁻)	≤ 0.05%	0.002%	%	Turbidimetric Method
Melting Point	255-260°C	257.6°C	°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	4.5-6.0	5.3	-	Digital pH Meter
Total Bacterial Count	≤ 10 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with the industrial standards for Bupivacaine Hydrochloride and meets all specified requirements. It is qualified for use.
Issue Date:25 FEB 2026