



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
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Certificate of Analysis (COA)

Product Name: Bupivacaine

Item	Details
Product Number	BUP-20260222
Batch Number	BUP-SH2026022201
Brand	SIGALD
CAS Number	2180-92-9
MDL Number	MFCD00008852
Formula	C ₁₈ H ₂₈ N ₂ O
Molecular Weight	288.43 Da
Quality Release Date	22 FEB 2026

Test	Specification(USP/EP/BP)	Result	Unit	Method
Appearance	White to off-white crystalline powder	White crystalline powder	-	Visual
Assay (HPLC, dry basis)	≥ 99.0%	99.8%	%	HPLC
Melting Point	105–109 °C	107.3 °C	°C	Capillary
Loss on Drying	≤ 0.5%	0.07%	%	Gravimetry
Residue on Ignition	≤ 0.1%	0.01%	%	Ignition
pH (1% suspension, 25 °C)	6.0–8.0	6.9	-	pH Meter
Heavy Metals (Pb)	≤ 10 ppm	0.1	ppm	AAS
Heavy Metals (As)	≤ 2 ppm	0.05	ppm	AFS
Chloride (Cl ⁻)	≤ 0.01%	0.001%	%	Volumetric
Sulfate (SO ₄ ²⁻)	≤ 0.01%	0.001%	%	Turbidimetric
Related Substances	≤ 0.5%	0.03%	%	HPLC
Total Aerobic Microbes	≤ 100 CFU/g	2 CFU/g	CFU/g	Plate count
E. coli	Negative	Negative	-	Micro test
Particle Size	≥95% through 80 mesh	99%	-	Sieve

Certification This batch complies with USP/EP/BP pharmaceutical standards. Qualified for injectable & topical local anesthetic use.

Issue Date: 22 FEB 2026