



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (COA)

**Product Name: Dibucaine Hydrochloride**

### Product Information

Item	Details
Product Number	DIB-20260226
Batch Number	DIB-SH2026022601
Brand	SIGALD
CAS Number	22616-39-1
MDL Number	MFCD00012611
Molecular Formula	C <sub>20</sub> H <sub>29</sub> N <sub>3</sub> O <sub>2</sub> ·HCl
Molecular Weight	379.93 Da
Quality Release Date	26 FEB 2026

### Test Results

Test	Specification (USP/EP/BP Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Free-flowing crystalline powder	-	Visual Inspection
Assay (HPLC, dry basis)	≥ 99.0%	99.7%	%	HPLC
Melting Point	96–100°C	98.4°C	°C	Capillary Method
Loss on Drying	≤ 0.5%	0.08%	%	Gravimetry (105°C, 2h)
Residue on Ignition	≤ 0.1%	0.01%	%	600°C Ignition
pH (1% aq. solution, 25°C)	4.5–6.5	5.3	-	pH Meter
Heavy Metals (Pb)	≤ 10 ppm	0.1 ppm	ppm	AAS
Heavy Metals (As)	≤ 2 ppm	0.05 ppm	ppm	AFS
Chloride (Calculated)	9.0–10.0%	9.5%	%	Volumetry
Sulfate (SO <sub>4</sub> <sup>2-</sup> )	≤ 0.01%	0.001%	%	Turbidimetry
Related Substances	≤ 0.5%	0.03%	%	HPLC
Total Aerobic Microorganisms	≤ 100 CFU/g	2 CFU/g	CFU/g	Plate Count
E. coli	Negative	Negative	-	Microbiological Test
Particle Size	≥95% pass 80 mesh	99%	-	Sieve Analysis

### Certification

This batch complies with USP/EP/BP pharmaceutical standards. Qualified for use in topical / mucosal local anesthetic formulations and scientific research. Issue Date: 26 FEB 2026