



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis

**Product Name: Promocaine Hydrochloride**  
**Product Information**

Product Number PRO-20260215  
Batch Number PRO-SH2026021501  
Brand SIGALD  
CAS Number 637-58-1  
MDL Number MFCD00012600  
Formula  $C_{16}H_{27}ClN_2O_2$   
Molecular Weight 314.85 Da  
Quality Release Date 15 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)	$\geq 99.0\%$	99.6%	%	High Performance Liquid Chromatography (HPLC)
Melting Point	148-152°C	150.2°C	°C	Capillary Melting Point Apparatus
Loss on Drying	$\leq 0.5\%$	0.09%	%	Gravimetry (105°C, 2h)
Residue on Ignition	$\leq 0.1\%$	0.01%	%	600°C Ignition Method
pH Value (1% aq. solution, 25°C)	4.0-6.0	5.1	-	Digital pH Meter
Heavy Metals (Pb)	$\leq 10$ ppm	0.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 2$ ppm	0.05 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride ( $Cl^-$ , Calculated)	9.5-10.5%	10.1%	%	Volumetric Method (Silver Nitrate)
Sulfate ( $SO_4^{2-}$ )	$\leq 0.01\%$	0.001%	%	Turbidimetric Method
Related Substances	$\leq 0.5\%$	0.04%	%	HPLC
Total Aerobic Microorganisms	$\leq 100$ CFU/g	4 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Particle Size (Pass through)	$\geq 95\%$ 80 mesh	99%	-	Sieve Analysis
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

### Certification

This batch of product has been tested in accordance with USP/EP/BP pharmaceutical raw material industrial standards and meets all specified requirements. It is qualified for use in pharmaceutical preparations, topical local anesthetic formulations and clinical medical applications.

Issue Date: 15 FEB 2026