



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Issue Date: 20 FEB 2026 Quality Release Date: 20 FEB 2026

Product Information

Product Number EPH-20260220
Batch Number EPH-SH2026022001
Brand SIGALD
CAS Number 5056-23-9
MDL Number MFCD00012015
Formula $C_{17}H_{25}NO \cdot HCl$
Formula Weight 295.85 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	White to off-white crystalline powder	White crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	$\geq 98.5\%$	99.8%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	$\leq 0.5\%$	0.12%	%	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	0.01%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 5 ppm	0.6 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity $\leq 0.5\%$; Total $\leq 1.0\%$	Each $\leq 0.08\%$; Total $\leq 0.25\%$	%	HPLC
Melting Point	175-179°C	177.2°C	°C	Capillary Melting Point Method
pH Value (1% aq. solution, 25°C)	4.0-6.0	5.1	-	Digital pH Meter
Solubility	Soluble in water, freely soluble in methanol	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	11.8-12.8%	12.3%	%	Volumetric Titration
Sulfate Content	$\leq 0.03\%$	0.004%	%	Volumetric Titration

Certification

This batch of product has been tested in accordance with EP 10.0, USP 45 and Chinese Pharmacopoeia (2020) standards for pharmaceutical raw materials and meets all specified requirements. It is qualified for use.