



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Issue Date: 25 FEB 2026

Quality Release Date: 25 FEB 2026

Product Information

Product Number GAB-20260225

Batch Number GAB-SH2026022501

Brand SIGALD

CAS Number 60142-96-3

MDL Number MFCD00043226

Formula C₉ H₁₇ NO₂

Formula Weight 171.24 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	White crystalline powder	White crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	≥ 98.5%	99.4%	%	HPLC
Loss on Drying	≤ 0.5%	0.21%	%	105°C, 2h Gravimetry
Residue on Ignition	≤ 0.1%	0.03%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	1.6 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.4 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	Each ≤0.2%; Total ≤0.5%	%	HPLC
pH Value (1% aqueous solution, 25°C)	5.0-7.0	6.2	-	Digital pH Meter
Solubility	Soluble in water, slightly soluble in ethanol	Conforms	-	Pharmacopoeial Solubility Test
Optical Rotation	0° ± 1° (1% in water, racemic)	0.1°	-	Polarimetry
Chloride Content	≤ 0.01%	0.003%	%	Volumetric Titration
Sulfate Content	≤ 0.03%	0.008%	%	Volumetric Titration

Certification

This batch of Gabapentin has been tested in accordance with EP 10.0, USP 45 and Chinese Pharmacopoeia (2020) standards. All test results meet the specified quality requirements, and the product is qualified for use as a pharmaceutical raw material.