



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: PregabalinProduct Information

Item	Details
Product Number	PREG-20260220
Batch Number	PREG-SH2026022001
Brand	SIGALD
CAS Number	148553-50-8
MDL Number	MFCD00969625
Formula	C ₈ H ₁₇ NO ₂
Formula Weight	159.23 g/mol
Quality Release Date	20 FEB 2026

Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance	White to off-white crystalline powder	White crystalline powder	-	Visual Inspection
Assay (HPLC)	≥ 99.5%	99.8%	%	HPLC (USP 45)
Melting Point	190-194°C	192.5°C	°C	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	0.15%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.02%	%	800±25°C
Heavy Metals (Pb)	≤ 5 ppm	1.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Optical Rotation ([α] ₂₀ ^D)	+14.5° to +16.5°	+15.8°	°	1% in water, 100mm tube
Related Substances (Individual)	≤ 0.05%	0.02%	%	HPLC
Related Substances (Total)	≤ 0.3%	0.08%	%	HPLC
Solubility in Water	Freely soluble	Complies	-	USP Solubility Test
pH Value (5% in water, 25°C)	5.0-7.0	6.2	-	Digital pH Meter

Certification This batch of Pregabalin has been tested in accordance with the relevant industrial and pharmaceutical raw material standards (USP 45/Ph. Eur. 10.0), and all test results meet the specified requirements. The product is qualified for use.

Issue Date: 20 FEB 2026