



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Quality Release Date: 28 FEB 2026 Issue Date: 28 FEB 2026

Product Information

Product Name Paroxetine Hydrochloride
Product Number PH-20260228
Batch Number PH-SH2026022801
Brand SIGALD
CAS Number 78246-49-8
MDL Number MFCD00867626
Formula $C_{19}H_{21}FNO_3 \cdot HCl$
Formula Weight 365.84 g/mol
Molecular Form Selective Serotonin Reuptake Inhibitor (SSRI) API

Test Results

Test	Specification (Pharmacopoeial Standard USP/EP/CP)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (On Anhydrous Basis)	98.5-101.0%	99.7%	%	High Performance Liquid Chromatography (HPLC)
Water Content	≤ 5.0%	3.2%	%	Karl Fischer Titration
Residue on Ignition	≤ 0.1%	0.03%	%	Ignition at 600°C±50°C
Heavy Metals (Pb)	≤ 10 ppm	1.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.4 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances (Individual)	≤ 0.5%	0.12%	%	HPLC
Related Substances (Total)	≤ 1.0%	0.35%	%	HPLC
Optical Rotation (25°C, 1% in H ₂ O)	-88.0° to -95.0°	-91.5°	°	Polarimetry
pH Value (1% aqueous, 25°C)	5.0-6.0	5.5	-	Digital pH Meter
Melting Point	120-125°C	122.8°C	°C	Capillary Melting Point Method
Ethanol Soluble Substances	Complies	Complies	-	Pharmacopoeial Method
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with USP, EP and CP pharmacopoeial standards for Paroxetine Hydrochloride and meets all specified requirements. It is qualified for pharmaceutical API use for research and formulation development.