



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Certificate of Analysis (COA)

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

Product Information

Product Name Duloxetine Hydrochloride

Product Number DUL-20260228

Batch Number DUL-SH2026022801

Brand SIGALD

CAS Number 136434-34-9

MDL Number MFCD00867626

Formula C₁₈H₁₉NOS · HCl

Formula Weight 333.88 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)	≥ 98.5%	99.3%	%	HPLC
Loss on Drying	≤ 0.5%	0.19%	%	105°C, 2h Gravimetry
Residue on Ignition	≤ 0.1%	0.02%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	1.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.3 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	Each ≤ 0.2%; Total ≤ 0.4%	%	HPLC
Melting Point	176-182°C	179.5°C	°C	Capillary Melting Point Method
Solubility	Soluble in water, methanol	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	10.5-11.5% (dry basis)	10.9%	%	Volumetric Titration
Optical Rotation	+101.0° to +107.0° (1% in methanol)	+104.2°	-	Polarimetry

Certification

This batch of Duloxetine Hydrochloride 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.