



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Quality Release Date: 26 FEB 2026 Issue Date: 26 FEB 2026

Product Information

Product Name Clomipramine Hydrochloride
Product Number CH-20260226
Batch Number CH-SH2026022601
Brand SIGALD
CAS Number 10340-25-3
MDL Number MFCD00012647
Formula $C_{19}H_{23}ClN_2 \cdot HCl$
Formula Weight 351.32 g/mol
Molecular Form Tricyclic antidepressant pharmaceutical active ingredient (TCA)

Test Results

Test	Specification (Pharmacopoeial Standard USP/EP/CP)	Result	Unit	Test Method
Appearance (Color)	White to off-white	Off-white	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (On Anhydrous Basis)	98.5-101.0%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Water Content	≤ 0.5%	0.21%	%	Karl Fischer Titration
Residue on Ignition	≤ 0.1%	0.03%	%	Ignition at 600°C±50°C
Heavy Metals (Pb)	≤ 10 ppm	0.9 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances (Individual)	≤ 0.3%	0.07%	%	HPLC
Related Substances (Total)	≤ 0.8%	0.25%	%	HPLC
Melting Point	215-220°C	217.3°C	°C	Capillary Melting Point Method
pH Value (1% aqueous, 25°C)	3.5-4.5	4.0	-	Digital pH Meter
Optical Rotation (25°C, 1% in MeOH)	0° ± 0.5°	0.1°	°	Polarimetry
Loss on Drying	≤ 0.5%	0.2%	%	Gravimetric Method (105°C, 2h)
Microbial Limit	Complies	Complies	-	Pharmacopoeial Microbiological Test
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 Clomipramine Hydrochloride and meets all specified requirements. It is qualified for pharmaceutical API use for research and formulation development.