



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (COA)

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

### Product Information

Product Number DON-20260228

Batch Number DON-SH2026022801

Brand SIGALD

CAS Number 103474-53-9

MDL Number MFCD00869156

Formula  $C_{24}H_{29}NO_3 \cdot HCl$

Formula Weight 415.96 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)	$\geq 98.5\%$	99.7%	%	HPLC
Loss on Drying	$\leq 0.5\%$	0.15%	%	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	0.02%	%	550°C Ignition Method
Heavy Metals (Pb)	$\leq 5$ ppm	0.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 1$ ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity $\leq 0.5\%$ ; Total $\leq 1.0\%$	Each $\leq 0.10\%$ ; Total $\leq 0.30\%$	%	HPLC
Melting Point	210-214°C	212.4°C	°C	Capillary Melting Point Method
pH Value (0.5% aq. solution, 25°C)	3.5-5.5	4.2	-	Digital pH Meter
Solubility	Soluble in water, freely soluble in methanol	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	8.2-9.0%	8.6%	%	Volumetric Titration
Sulfate Content	$\leq 0.03\%$	0.005%	%	Volumetric Titration

### Certification

This batch of Donepezil 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.