



# 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 ZPH-20260228

Batch Number ZPH-SH2026022801

Brand SIGALD

CAS Number 103639-82-5

MDL Number MFCD00867302

Formula  $C_{21}H_{21}ClN_4O_2 \cdot HCl$

Formula Weight 441.34 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)	$\geq 98.5\%$	99.6%	%	HPLC
Loss on Drying	$\leq 0.5\%$	0.21%	%	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	0.03%	%	550°C Ignition Method
Heavy Metals (Pb)	$\leq 5$ ppm	0.9 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 $\leq 0.12\%$ ; Total $\leq 0.35\%$	%	HPLC
Melting Point	238-242°C	240.5°C	°C	Capillary Melting Point Method
pH Value (1% aq. suspension, 25°C)	4.0-6.0	5.2	-	Digital pH Meter
Solubility	Sparingly soluble in water, soluble in methanol	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	15.8-16.8%	16.3%	%	Volumetric Titration
Sulfate Content	$\leq 0.03\%$	0.007%	%	Volumetric Titration

### Certification

This batch of Ziprasidone 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.