



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 Number VOR-20260228

Batch Number VOR-SH2026022801

Brand SIGALD

CAS Number 936128-06-4

MDL Number MFCD18383566

Formula $C_{18}H_{22}BrN_3O$

Formula Weight 376.29 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)	$\geq 98.5\%$	99.5%	%	HPLC
Loss on Drying	$\leq 0.5\%$	0.19%	%	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	0.02%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 5 ppm	0.7 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity $\leq 0.5\%$; Total $\leq 1.0\%$	Each $\leq 0.15\%$; Total $\leq 0.4\%$	%	HPLC
pH Value (0.5% aqueous suspension, 25°C)	4.0-6.0	5.1	-	Digital pH Meter
Solubility	Sparingly soluble in water, soluble in methanol	Conforms	-	Pharmacopoeial Solubility Test
Melting Point	178-182°C	180.2°C	°C	Capillary Melting Point Method
Chloride Content	$\leq 0.01\%$	0.002%	%	Volumetric Titration
Sulfate Content	$\leq 0.03\%$	0.006%	%	Volumetric Titration

Certification

This batch of Vortioxetine Hydrobromide 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.