



# 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 QTF-20260228

Batch Number QTF-SH2026022801

Brand SIGALD

CAS Number 111974-72-2

MDL Number MFCD00867324

Formula  $C_{21}H_{25}N_3O_2S \cdot C_4H_4O_4$

Formula Weight 515.57 g/mol

### Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	White to pale yellow crystalline powder	White crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	≥ 98.5%	99.5%	%	HPLC
Loss on Drying	≤ 0.5%	0.15%	%	105°C, 2h Gravimetry
Residue on Ignition	≤ 0.1%	0.02%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	0.9 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	Each ≤ 0.1%; Total ≤ 0.3%	%	HPLC
Melting Point	174-178°C	Capillary Melting Point Method		
Solubility	Sparingly soluble in water, soluble in methanol	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	0.002%	%	Volumetric Titration
Sulfate Content	≤ 0.03%	0.006%	%	Volumetric Titration
Acidity/Alkalinity	Acidic (pH 4.0-6.0, 1% in water)	5.2	-	Digital pH Meter
Fumaric Acid Content	14.5-15.5%	15.1%	%	Titration

### Certification

This batch of Quetiapine Fumarate 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.