



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Issue Date: 20 FEB 2026 Quality Release Date: 20 FEB 2026

Product Information

Product Name Clozapine
Product Number CLP-20260220
Batch Number CLP-SH2026022001
Brand SIGALD
CAS Number 5786-21-0
MDL Number MFCD00058977
Formula C₁₈H₁₉CIN₄
Formula Weight 326.83 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	Yellow to pale yellow crystalline powder	Yellow crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	≥ 98.0%	98.7%	%	HPLC
Loss on Drying	≤ 0.5%	0.18%	%	105°C, 2h Gravimetry
Residue on Ignition	≤ 0.1%	0.04%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	1.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.5%	Each impurity ≤ 0.3%; Total ≤ 0.8%	%	HPLC
Chloride Content	10.8-11.5% (on dry basis)	11.2%	%	Volumetric Titration
Melting Point	183-187°C	185.2°C	°C	Capillary Melting Point Method
Solubility	Sparingly soluble in water, soluble in chloroform/methanol	Conforms	-	Solubility Test
Sulfated Ash	≤ 0.1%	0.02%	%	Pharmacopoeial Ash Test

Certification

This batch of Clozapine has been tested in accordance with the relevant pharmacopoeial and industrial standards (EP/USP/CP), and meets all specified quality requirements. It is qualified for use as a pharmaceutical raw material.