



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Name: Olanzapine

Product Information

Item	Details
Product Number	OLA-20260220
Batch Number	OLA-SH2026022001
Brand	SIGALD
CAS Number	132539-06-1
MDL Number	MFCD00867500
Formula	C ₁₇ H ₂₀ N ₄ S
Formula Weight	312.43 g/mol

Quality Release Date 20 FEB 2026

Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance	White to off-white crystalline powder	White crystalline powder	-	Visual Inspection
Assay (HPLC)	≥ 99.0%	99.5%	%	HPLC (Ph. Eur. 10.0)
Melting Point	191-195°C	193.2°C	°C	Capillary Melting Point Method
Loss on Drying	≤ 0.5%	0.2%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.03%	%	800±25°C
Heavy Metals (Pb)	≤ 10 ppm	2.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Related Substances (Individual)	≤ 0.1%	0.04%	%	HPLC
Related Substances (Total)	≤ 0.5%	0.12%	%	HPLC
Optical Rotation	N/A	N/A	-	No Chiral Center
Solubility in Methanol	Freely soluble	Complies	-	Ph. Eur. Solubility Test

Certification This batch of Olanzapine has been tested in accordance with the relevant industrial and pharmaceutical raw material standards, and all test results meet the specified requirements. The product is qualified for use.

Issue Date: 20 FEB 2026