



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 NTZ-20260228
Batch Number NTZ-SH2026022801
Brand SIGALD
CAS Number 146-22-5
MDL Number MFCD00005525
Formula $C_{15}H_{11}N_3O_3$
Formula Weight 281.27 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	Pale yellow crystalline powder	Pale yellow crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	≥ 98.5%	High Performance Liquid Chromatography (HPLC)		
Loss on Drying	≤ 0.5%	105°C, 2h Gravimetry		
Residue on Ignition	≤ 0.1%	550°C Ignition Method		
Heavy Metals (Pb)	≤ 10 ppm	Atomic Absorption Spectrometry (AAS)		
Heavy Metals (As)	≤ 2 ppm	Atomic Fluorescence Spectrometry (AFS)		
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC		
Melting Point	226-231 °C	Capillary Melting Point Method		
Solubility	Sparingly soluble in ethanol, practically insoluble in water	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	Volumetric Titration		
Sulfate Content	≤ 0.03%	Volumetric Titration		
Acidity/Alkalinity	Neutral (pH 6.0-8.0, 0.5% in ethanol)	Neutral	-	Digital pH Meter

Certification

This batch of Nitrazepam 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.