



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 ZAL-20260228

Batch Number ZAL-SH2026022801

Brand SIGALD

CAS Number 151386-49-3

MDL Number MFCD00867946

Formula C₁₇ H₁₅ N₅ O

Formula Weight 305.34 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% | 99.4% | % | HPLC |
| Loss on Drying | ≤ 0.5% | 0.17% | % | 105°C, 2h Gravimetry |
| Residue on Ignition | ≤ 0.1% | 0.02% | % | 550°C Ignition Method |
| Heavy Metals (Pb) | ≤ 5 ppm | 0.6 ppm | ppm | Atomic Absorption Spectrometry (AAS) |
| Heavy Metals (As) | ≤ 1 ppm | 0.2 ppm | ppm | Atomic Fluorescence Spectrometry (AFS) |
| Related Substances | Each impurity ≤ 0.5%; Total ≤ 1.0% | Each ≤ 0.18%; Total ≤ 0.45% | % | HPLC |
| Melting Point | 185-189°C | 187.3°C | °C | Capillary Melting Point Method |
| Solubility | Sparingly soluble in water, soluble in dimethyl sulfoxide | Conforms | - | Pharmacopoeial Solubility Test |
| Chloride Content | ≤ 0.01% | 0.002% | % | Volumetric Titration |
| Sulfate Content | ≤ 0.03% | 0.005% | % | Volumetric Titration |
| Acidity/Alkalinity | Neutral (pH 6.0-8.0, 0.1% in DMSO) | Neutral | - | Digital pH Meter |
| Optical Rotation | 0° ± 1° (racemic mixture) | 0.05° | - | Polarimetry |

Certification

This batch of Zaleplon 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.