



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Certificate of Analysis (Midazolam Maleate)

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

### Product Name

Midazolam Maleate

### Product Information

Product Number MM-20260220

Batch Number MM-SH2026022001

Brand SIGALD

CAS Number 81826-61-1

MDL Number MFCD00058477

Formula  $C_{18}H_{13}ClFN_3 \cdot C_4H_4O_4$

Formula Weight 441.82 g/mol

### Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (on dry basis)	$\geq 99.0\%$	99.4%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 0.5\%$	0.22%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.04%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.17%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	$\leq 0.1\%$	0.02%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	$\leq 10$ ppm	1.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 2$ ppm	0.3 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	$\leq 0.5$ EU/ $\mu$ g	0.16 EU/ $\mu$ g	EU/ $\mu$ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	120 ~ 124°C	122.3°C	°C	Melting Point Apparatus
Specific Rotation (25°C, c=1 in CH <sub>3</sub> OH)	+108° to +118°	+113.5°	°	Polarimetry

### Certification

This batch of Midazolam Maleate has been tested in accordance with the **United States Pharmacopeia (45 Edition)** and **Chinese Pharmacopoeia (2025 Edition)**. All test results meet the specified pharmacopoeial requirements for pharmaceutical raw materials, and the product is qualified for use in the production of clinical sedative and anesthetic preparations.