



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 (Cimetidine)

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

Product Name

Cimetidine 西咪替丁

Product Information

Product Number CIM-20260220
Batch Number CIM-SH2026022001
Brand SIGALD
CAS Number 51481-61-9
MDL Number MFCD00058243
Formula $C_{10}H_{16}N_6S$
Formula Weight 252.34 g/mol

Test Results

Test	Specification (USP 45 & ChP 2025 Pharmaceutical Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection (25°C)
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection (25°C)
Assay (on dry basis)	98.5 ~ 101.5%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 1.0%	0.08%	%	HPLC (USP 45 Method)
Single Impurity	≤ 0.2%	0.01%	%	HPLC (USP 45 Method)
Loss on Drying	≤ 0.5%	0.05%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 5 ppm	0.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
pH Value (1% aq. suspension, 25°C)	4.5 ~ 6.0	5.2	-	Digital pH Meter
Melting Point	139 ~ 144°C	141.5°C	°C	Melting Point Apparatus
Total Bacterial Count	≤ 100 CFU/g	12 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Salmonella	Negative	Negative	-	Microbiological Detection
Water Solubility (25°C)	≥ 1 g/100 mL	1.3 g/100 mL	g/100 mL	Shake Flask Method

Certification

This batch of product has been tested in accordance with the pharmacopoeial and industrial standards for Cimetidine and meets all specified requirements. It is qualified for use as a pharmaceutical raw material for anti-ulcer and acid-suppressing preparations.