



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 (Isoniazid)

Issue Date: 22 FEB 2026 Quality Release Date: 22 FEB 2026

Product Name

Isoniazid 异烟肼

Product Information

Product Number IN-20260222
Batch Number IN-SH2026022201
Brand SIGALD
CAS Number 54-85-3
MDL Number MFCD00007505
Formula $C_6H_7N_3O$
Formula Weight 137.14 g/mol

Test Results

Test	Specification (USP 45 & ChP 2025)	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)	$\geq 99.0\%$	99.6%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 0.5\%$	0.16%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.02%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.08%	%	Vacuum Drying at 105°C for 2h
Residue on Ignition	$\leq 0.1\%$	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.3 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.07 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/ μ g	0.06 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	170 ~ 173°C	171.8°C	°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	5.0 ~ 6.5	5.8	-	Digital pH Meter
Water Solubility	Clear solution	Clear solution	-	Visual & Turbidity Test

Certification

This batch of Isoniazid 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 anti-tuberculosis pharmaceutical preparations.