



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 (Doxylamine Succinate)

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

Product Name

Doxylamine Succinate 多西拉胺琥珀酸盐

Product Information

Product Number DS-20260222

Batch Number DS-SH2026022201

Brand SIGALD

CAS Number 562-10-7

MDL Number MFCD00058538

Formula $C_{17}H_{22}N_2O \cdot C_4H_6O_4$

Formula Weight 388.46 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)	$\leq 0.5\%$	0.10%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.02%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.07%	%	Vacuum Drying at 60°C for 4h
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	0.05 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/ μ g	0.04 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	104 ~ 108°C	106.2°C	°C	Melting Point Apparatus
pH Value (1% aqueous solution, 25°C)	4.0 ~ 6.0	5.1	-	Digital pH Meter
Optical Rotation (25°C, c=1 in H ₂ O)	0° \pm 2°	0.3°	°	Polarimetry

Certification

This batch of Doxylamine Succinate 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 antihistamine and sedative-hypnotic pharmaceutical preparations.