



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Bilastine)

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

Product Name

Bilastine 比拉斯汀

Product Information

Product Number BIL-20260220
Batch Number BIL-SH2026022001
Brand SIGALD
CAS Number 200800-47-7
MDL Number MFCD09743666
Formula $C_{28}H_{37}N_3O_2$
Formula Weight 447.62 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)	≥ 99.0%	99.7%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.13%	%	HPLC (USP 45)
Single Impurity	≤ 0.1%	0.02%	%	HPLC (USP 45)
Loss on Drying	≤ 0.5%	0.06%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.04 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.05 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	215 ~ 219°C	217.3°C	°C	Melting Point Apparatus
pH Value (0.1% DMSO suspension, 25°C)	6.0 ~ 8.0	6.8	-	Digital pH Meter
Optical Rotation (25°C, c=1 in DMSO)	0° ± 2°	0.2°	°	Polarimetry

Certification

This batch of Bilastine 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-allergic pharmaceutical preparations.