



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

Quality Release Date: 26 FEB 2026 Issue Date: 26 FEB 2026

Product Information

Product Name Bacitracin
Product Number BCT-20260226
Batch Number BCT-SH2026022601
Brand SIGALD
CAS Number 1405-87-0
MDL Number MFCD00082073
Formula $C_{66}H_{103}N_{17}O_{16}S$
Formula Weight 1422.70 g/mol
Molecular Form Polypeptide Antibiotic (Gram-positive bacteriostatic)

Test Results

Test	Specification (Pharmacopoeial/Industrial Standard)	Result	Unit	Test Method
Appearance (Color)	White to pale yellow	Off-white	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (Potency, on dry basis)	≥ 65.0 IU/mg	68.5 IU/mg	IU/mg	Microbiological Assay (Staphylococcus aureus)
Loss on Drying	$\leq 5.0\%$	2.1%	%	Gravimetric Method (60°C, 4h, vacuum)
Residue on Ignition	$\leq 1.0\%$	0.3%	%	Ignition at 600°C \pm 50°C
Heavy Metals (Pb)	≤ 10 ppm	1.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
pH Value (1% aqueous suspension, 25°C)	5.5-7.5	6.2	-	Digital pH Meter
Water Content	$\leq 5.0\%$	1.9%	%	Karl Fischer Titration
Total Aerobic Count	≤ 100 CFU/g	15 CFU/g	CFU/g	Plate Count Method
E. coli/Staphylococcus aureus	Negative	Negative	-	Microbiological Detection
Related Substances	$\leq 5.0\%$	1.5%	%	Reverse-Phase High Performance Liquid Chromatography (RP-HPLC)
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with Chinese Pharmacopoeia (CP), USP and EP standards for Bacitracin and meets all specified requirements. It is qualified for pharmaceutical and industrial grade use.