



# 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 Polymyxin B (Sulfate)  
Product Number PMB-20260226  
Batch Number PMB-SH2026022601  
Brand SIGALD  
CAS Number 1404-26-8  
MDL Number MFCD00078615  
Formula  $C_{56}H_{108}N_{16}O_{13} \cdot H_2SO_4$   
Formula Weight 1301.65 g/mol  
Molecular Form Cyclic Polypeptide Antibiotic (Gram-negative bactericidal)

### Test Results

Test	Specification (Pharmacopoeial/Industrial Standard)	Result	Unit	Test Method
Appearance (Color)	White to pale pink	White	-	Visual Inspection
Appearance (Form)	Hygroscopic powder	Hygroscopic powder	-	Visual Inspection
Assay (Potency, on dry basis)	$\geq 6000$ IU/mg	6350 IU/mg	IU/mg	Microbiological Assay (Escherichia coli)
Loss on Drying	$\leq 7.0\%$	3.2%	%	Gravimetric Method (60°C, 4h, vacuum)
Residue on Ignition	$\leq 2.0\%$	0.8%	%	Ignition at 600°C±50°C
Heavy Metals (Pb)	$\leq 10$ ppm	2.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 1$ ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
pH Value (1% aqueous solution, 25°C)	5.0-7.5	5.8	-	Digital pH Meter
Water Content	$\leq 7.0\%$	2.8%	%	Karl Fischer Titration
Sulfate Content	10.0-14.0%	12.3%	%	Titrimetric Method
Total Aerobic Count	$\leq 100$ CFU/g	8 CFU/g	CFU/g	Plate Count Method
Pathogens (E. coli/Pseudomonas aeruginosa)	Negative	Negative	-	Microbiological Detection
Related Substances	$\leq 6.0\%$	2.0%	%	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 Polymyxin B and meets all specified requirements. It is qualified for pharmaceutical and industrial grade use.