



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (Chloramphenicol)

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

### Product Name

Chloramphenicol

### Product Information

Product Number CH-20260220  
Batch Number CH-SH2026022001  
Brand SIGALD  
CAS Number 756-75-7  
MDL Number MFCD00004474  
Formula  $C_{11}H_{12}Cl_2N_2O_5$   
Formula Weight 323.13 g/mol

### Test Results

Test	Specification (Pharmacopoeial Standard)	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%	99.6%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.18%	%	HPLC (USP 45)
Single Impurity	≤ 0.1%	0.03%	%	HPLC (USP 45)
Loss on Drying	≤ 0.5%	0.12%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.02%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.8 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.11 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	149 ~ 153°C	151.5°C	°C	Melting Point Apparatus
Specific Rotation (25°C, c=5 in ethanol)	+18.5° to +21.5°	+20.2°	°	Polarimetry
pH Value (1% aqueous suspension, 25°C)	4.5 ~ 7.5	6.0	-	Digital pH Meter

### Certification

This batch of Chloramphenicol 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 antibacterial preparations.