

Technical Data Sheet (TDS) - Chloramphenicol

Revision Date: 20 FEB 2026 **CAS Number:** 756-75-7 **Molecular Formula:** C₁₁H₁₂Cl₂N₂O₅ **Molecular Weight:** 323.13 g/mol

1. Product Overview

Chloramphenicol is a broad-spectrum bacteriostatic antibiotic pharmaceutical raw material, a nitrobenzene derivative with unique antimicrobial activity against both gram-positive and gram-negative bacteria, as well as rickettsiae, chlamydiae and mycoplasmas. It exerts antibacterial effects by binding to the 50S subunit of bacterial ribosomes and inhibiting bacterial protein synthesis, with a wide antibacterial spectrum and strong potency against drug-resistant strains. As a high-purity pharmacopoeial-grade raw material, it is widely used in clinical topical antibacterial preparations for ophthalmic, otic and skin infections, featuring rapid antibacterial action and good tissue compatibility for topical use.

2. Technical Specifications (Complies with USP 45 & ChP 2025)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Melting Point	149 ~ 153°C
Specific Rotation (25°C, c=5 in ethanol)	+18.5° ~ +21.5°
pH Value (1% aqueous suspension, 25°C)	4.5 ~ 7.5
Solubility	Sparingly soluble in water; freely soluble in ethanol, methanol, acetone; soluble in propylene glycol
Optical Purity	≥ 99.5% (enantiomeric excess)
Stability	Stable at 2~8°C, dark and sealed conditions; degraded by strong light/heat/alkali

3. Product Advantages

- Broad Antibacterial Spectrum:** Effective against gram-positive/negative bacteria, rickettsiae, chlamydiae and mycoplasmas; potent against clinical common drug-resistant strains (e.g., penicillin-resistant staphylococci).
- Bacteriostatic & Rapid Action:** Inhibits bacterial protein synthesis directly, exerts rapid antibacterial effect within a short time after topical application.
- Ideal for Topical Use:** Good tissue compatibility for ophthalmic/otic/skin application, low irritation, rapid absorption in local tissues.
- High Purity & Stability:** Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; stable under recommended storage conditions, good compatibility with common pharmaceutical excipients for topical formulations.
- Diverse Formulation Potential:** Can be prepared into eye drops, ear drops, ointments, creams and lotions, adapting to various topical antibacterial clinical needs.

4. Application Fields

Pharmaceutical Raw Material for Clinical Topical Antibacterial Therapy:

- Ophthalmic infections:** Conjunctivitis, keratitis, blepharitis, endophthalmitis (bacterial etiology).
- Otic infections:** Otitis externa, otitis media (acute/chronic, bacterial etiology).

- **Skin infections:** Folliculitis, impetigo, erysipelas, traumatic skin infections, burn wound bacterial infections.
- **Mucosal infections:** Oral ulcer, gingivitis (local application), vaginal mucositis (bacterial etiology).
- **Dosage form production:** Chloramphenicol eye drops/ear drops (0.25-0.5%), chloramphenicol ointment/cream (1%).

5. Usage Methods (for Pharmaceutical Formulation)

Ophthalmic/Otic Formulation (Injection/Liquid)

- **Eye/Ear Drops (0.25%):** Dissolve chloramphenicol with propylene glycol (cosolvent) + water for injection, adjust pH to 5.5-6.5 with buffer, add preservative (benzalkonium chloride), prepare into sterile aqueous solution.
- **Processing Requirements:** Aseptic operation in GMP-certified workshop; avoid strong light during formulation; use brown glass containers for packaging.

Topical Ointment/Cream Formulation (Semisolid)

- **1% Ointment/Cream:** Mix chloramphenicol with petrolatum/lanolin (ointment base) or cream matrix (oil-in-water/water-in-oil), grind uniformly to prepare sterile semisolid preparation.
- **Processing Requirements:** Sterile grinding and mixing; control particle size $D_{90} \leq 50 \mu\text{m}$ to ensure good spreadability and local absorption.

Compatibility

- Compatible with propylene glycol, glycerol, various buffer solutions and topical formulation matrices; incompatible with strong alkalis ($\text{pH} > 9$) and oxidizing agents.

6. Packaging & Storage

Packaging Specifications

- 5 g / brown glass sealed bottle (nitrogen-filled, R&D/laboratory use)
- 25 g / aluminum foil vacuum-sealed brown glass bottle (pilot production)
- 100 g / stainless steel sealed drum (nitrogen-filled, industrial GMP production)
- 500 g / HDPE sealed drum (for topical ointment formulation raw material)
- Custom GMP-compliant nitrogen-filled packaging for bulk orders available.

Storage Conditions

- **Storage Temperature:** 2 ~ 8°C (refrigerated, dark place); avoid freezing and high temperature (>25°C).
- **Sealing Requirement:** Nitrogen-filled tight sealing, protect from direct light and moisture; prevent contact with air to avoid oxidation.
- **Incompatibilities:** Store separately from strong acids, strong bases, oxidizing agents, reducing agents and metal ions (Fe^{3+} , Cu^{2+}).
- **Shelf Life:** 24 months (unopened, nitrogen-filled, 2~8°C refrigeration); 6 months after opening (sealed, refrigerated, used up as soon as possible).

Transportation

- Classified as pharmaceutical raw material for clinical antibacterial preparations; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8°C) with real-time temperature monitoring; use shockproof, light-proof, moisture-proof packaging; avoid package collision and light exposure during transport.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable protective clothing) during handling to avoid skin/mucosa contact and dust inhalation.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; in case of eye contact: Rinse with sterile water for injection for 15 minutes and consult a physician immediately if irritation persists.
- Do not ingest; accidental oral intake may cause bone marrow suppression—seek emergency medical treatment at once.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection system; avoid strong light and high temperature during material transfer and processing.