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Technical Data Sheet (TDS) - Metronidazole

Revision Date: 18 FEB 2026**CAS Number**: 443-48-1**Molecular Formula**: $C_6H_9N_3O_3$**Molecular Weight**: 171.16 g/mol

1. Product Overview

Metronidazole is a high-purity pharmacopoeial-grade nitroimidazole antimicrobial pharmaceutical raw material, with broad-spectrum antibacterial activity against anaerobic bacteria, as well as specific inhibitory effects on Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia. It exerts its pharmacodynamic effect by inhibiting the DNA synthesis and replication of pathogenic microorganisms, leading to the death of bacteria and protozoa. As a classic clinical antimicrobial raw material, it features high potency, clear mechanism of action, good tissue penetration and diverse formulation potential, and is widely used in the production of clinical oral, injectable and topical pharmaceutical preparations for treating anaerobic infections and protozoan diseases.

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	159 ~ 163℃
pH Value (0.1% aqueous suspension, 25℃)	5.0 ~ 7.0
Solubility	Sparingly soluble in water; freely soluble in ethanol, methanol, acetone; soluble in dimethyl sulfoxide (DMSO)
Optical Purity	≥ 99.5% (enantiomeric excess)
Stability	Stable at 2~8℃, dark and sealed conditions; degraded by strong light/heat/alkali

3. Product Advantages

1. **Broad-Spectrum Antimicrobial Activity**: Potent against most anaerobic bacteria (Clostridium, Bacteroides, Fusobacterium); specific anti-protozoal effect on Trichomonas, Amoeba and Giardia, no cross-resistance with other antibiotics.
2. **Good Pharmacokinetic Properties**: Rapid absorption after oral administration, high bioavailability, good tissue penetration (can reach abscesses, cerebrospinal fluid and reproductive tract tissues).
3. **High Purity & Stable Quality**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; stable under recommended storage conditions, good compatibility with common pharmaceutical excipients.
4. **Diverse Formulation Potential**: Can be prepared into oral tablets/capsules, sterile injections, vaginal suppositories, topical gels/ointments, adapting to multiple clinical administration routes.
5. **Low Toxicity & High Safety**: Low adverse reaction rate at clinical doses, mild side effects (gastrointestinal discomfort), and the side effects are reversible after drug withdrawal.

4. Application Fields

Pharmaceutical Raw Material for Clinical Antimicrobial & Anti-Protozoal Therapy:

- **Anaerobic bacterial infections**: Intra-abdominal infection, pelvic infection, skin and soft tissue infection, central nervous system infection, dental infection caused by anaerobic bacteria.
- **Protozoan diseases**: Trichomoniasis vaginitis, amebic dysentery, amebic liver abscess, giardiasis.
- **Surgical prophylaxis**: Prophylaxis of anaerobic infections in abdominal, pelvic and orthopedic surgeries.

- **Dosage form production**: 0.2g metronidazole oral tablets, 0.5g metronidazole injection, 0.5g metronidazole vaginal suppositories, 1% metronidazole topical gel.

5. Usage Methods (for Pharmaceutical Formulation)

Oral Formulation (Tablets/Capsules)

- **0.2g Oral Tablet**: Mix metronidazole with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant) and magnesium stearate (lubricant), granulate, compress and coat to prepare oral tablets.
- **Processing Requirements**: Dry granulation at low temperature (<60℃) to avoid drug degradation; control tablet hardness at 4-6 kg for good disintegration.

Injectable Formulation (Sterile Injection)

- **0.5g/100mL Injection**: Dissolve metronidazole with water for injection plus propylene glycol (cosolvent), adjust pH to 6.0-7.0 with sodium hydroxide buffer, add edetate disodium (chelating agent), sterile filter and fill in ampoules/vials.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; avoid strong light during formulation; use brown glass containers for packaging.

Topical Formulation (Suppositories/Gels)

- **0.5g Vaginal Suppository**: Melt cocoa butter/polyethylene glycol (suppository base) at low temperature, mix with metronidazole powder uniformly, mold and solidify to prepare sterile suppositories.
- **1% Topical Gel**: Mix metronidazole with carbomer (gelling agent), glycerol (humectant) and triethanolamine (pH adjuster), stir uniformly to prepare topical gel with good spreadability.

6. Packaging & Storage

Packaging Specifications

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

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **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℃ refrigeration); 6 months after opening (sealed, refrigerated, used up as soon as possible).

Transportation

- Classified as pharmaceutical raw material for clinical antimicrobial preparations; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8℃) 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 gastrointestinal discomfort—seek emergency medical treatment at once and conduct symptomatic treatment.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection system; avoid strong light and high temperature during material transfer and processing.