NEWAY SINOPHC TECH. LIMITED
ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com；Phone:+86-021-50350029 https://www.newayphc.com

Technical Data Sheet (TDS) - Isoniazid

Revision Date: 22 FEB 2026**CAS Number**: 54-85-3**Molecular Formula**: $C_6H_7N_3O$**Molecular Weight**: 137.14 g/mol

1. Product Overview

Isoniazid is a high-purity pharmacopoeial-grade anti-tuberculosis pharmaceutical raw material, a classic synthetic hydrazide anti-mycobacterial agent with highly selective and potent inhibitory effects on *Mycobacterium tuberculosis*. It exerts its anti-tuberculosis effect by inhibiting the synthesis of mycolic acid, an essential component of the mycobacterial cell wall, leading to the disruption of cell wall structure and bacterial death. As a first-line core anti-tuberculosis drug, it features strong bactericidal activity, good water solubility, high bioavailability, and wide tissue penetration, and is widely used in the production of clinical oral and injectable pharmaceutical preparations for the treatment of all forms of tuberculosis (pulmonary and extrapulmonary).

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	170 ~ 173℃
pH Value (1% aqueous solution, 25℃)	5.0 ~ 6.5
Water Solubility	Freely soluble in water; soluble in ethanol; slightly soluble in ether
Stability	Stable at 2~8℃, dark and sealed conditions; degraded by strong light/heat/alkali
Microbial Limit	Total bacterial count ≤ 100 CFU/g; E. coli negative; Mold & yeast ≤ 10 CFU/g

3. Product Advantages

1. **High Selective Anti-TB Activity**: Potent bactericidal effect on *Mycobacterium tuberculosis* (including intracellular and extracellular bacteria); minimal activity against other bacteria, low side effect risk.
2. **Excellent Pharmacokinetic Properties**: Rapid and complete absorption after oral administration (bioavailability ≈95%), wide tissue penetration (can reach lung, liver, kidney, bone, and cerebrospinal fluid), effective for both pulmonary and extrapulmonary tuberculosis.
3. **High Purity & Stable Quality**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; good chemical stability under recommended storage conditions, compatible with common pharmaceutical excipients.
4. **Good Solubility & Formulation Flexibility**: Freely soluble in water, easy to prepare oral solid/liquid and injectable formulations, suitable for all clinical administration routes.
5. **Core First-Line Anti-TB Drug**: Synergistic effect with rifampicin, ethambutol and pyrazinamide; the cornerstone of clinical tuberculosis combination therapy, high cure rate for sensitive strains.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anti-Tuberculosis Therapy:

- **Pulmonary Tuberculosis**: Active pulmonary tuberculosis, latent tuberculosis infection, recurrent pulmonary tuberculosis.
- **Extrapulmonary Tuberculosis**: Tuberculous meningitis, lymph node tuberculosis, bone/joint tuberculosis, abdominal tuberculosis, renal tuberculosis.

- **Pediatric & Adult Tuberculosis**: Suitable for tuberculosis treatment in all age groups (with dosage adjustment for children).
- **Dosage form production**: 50mg/100mg/300mg oral tablets, 100mg capsules, 50mg/mL oral syrup, 100mg/2mL sterile injection.

5. Usage Methods (for Pharmaceutical Formulation)

Oral Formulation (Tablets/Capsules)

- **300mg Oral Tablet**: Mix isoniazid with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), and magnesium stearate (lubricant), dry granulate at low temperature (<60℃), compress and coat to prepare oral tablets.
- **Processing Requirements**: Control granule moisture ≤ 0.5% to avoid hydrolysis; tablet disintegration time ≤ 15 minutes (water).

Injectable Formulation (Sterile Injection)

- **100mg/2mL Injection**: Dissolve isoniazid with sterile water for injection, adjust pH to 5.5-6.0 with dilute hydrochloric acid/sodium hydroxide, add edetate disodium (stabilizer), sterile filter and fill in glass ampoules/vials.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; avoid strong light during preparation and filling; use neutral glass containers to prevent adsorption.

Oral Liquid Formulation (Syrup)

- **50mg/mL Oral Syrup**: Dissolve isoniazid with purified water, add sucrose (sweetener), citric acid (flavor adjuster) and methylparaben (preservative), stir to dissolve and fix volume; suitable for pediatric and elderly patients.

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 oral 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 to prevent oxidation and moisture absorption; protect from direct light.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents, and metal ions (Fe^{3+} , Cu^{2+}).
- **Shelf Life**: 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated).

Transportation

- Classified as pharmaceutical raw material for clinical anti-infective 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; apply mild emollient if irritation occurs.
- In case of eye contact: Rinse with sterile water for injection for 15 minutes; consult a physician immediately if irritation persists.
- Do not ingest; accidental oral intake may cause gastrointestinal discomfort and neurological reactions—seek emergency medical treatment at once and conduct symptomatic treatment.