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) - Letermovir

Revision Date: 20 FEB 2026**CAS Number**: 917389-32-3**Molecular Formula**: $C_{23}H_{25}F_4N_3O_4S$**Molecular Weight**: 519.52 g/mol

1. Product Overview

Letermovir is a high-purity pharmacopoeial-grade non-nucleoside anti-cytomegalovirus (CMV) pharmaceutical raw material, a selective CMV terminase complex inhibitor. It exerts its antiviral effect by inhibiting the viral terminase complex (pUL51, pUL56, pUL89), blocking the cleavage and packaging of CMV viral DNA, thereby preventing viral replication and spread in host cells. As a first-line anti-CMV raw material for clinical use, it features high target selectivity, strong anti-CMV activity, low cytotoxicity, and no cross-resistance with traditional anti-CMV drugs, and is widely used in the production of clinical oral and injectable pharmaceutical preparations for the prevention and treatment of CMV infections in immunocompromised populations.

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	155 ~ 159℃
Optical Rotation (25℃, c=1 in DMSO)	-12.0° ~ -8.0°
pH Value (0.1% aqueous suspension, 25℃)	5.5 ~ 7.5
Solubility	Sparingly soluble in water; freely soluble in dimethyl sulfoxide (DMSO), methanol, ethanol; soluble in acetone
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-CMV Activity**: Specifically targets CMV terminase complex, potent inhibitory effect on various CMV strains (including drug-resistant strains), no activity against other herpes viruses or human cells.
2. **Excellent Pharmacokinetic Properties**: Rapid absorption after oral administration, high bioavailability (≈80%), long half-life (≈12h), once-daily administration, improving patient compliance; good tissue penetration (can reach blood, bone marrow, and visceral 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 for oral and injectable formulations.
4. **Low Toxicity & High Safety**: No obvious myelosuppression and nephrotoxicity (the main side effects of traditional anti-CMV drugs); mild adverse reactions (minor gastrointestinal discomfort), reversible after drug withdrawal.
5. **No Cross-Resistance**: Different action mechanism from ganciclovir, valganciclovir and other nucleoside analogs, effective for nucleoside-resistant CMV strains.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anti-CMV Therapy:

- **Prophylaxis of CMV infection**: Hematopoietic stem cell transplant (HSCT) recipients, solid organ transplant recipients, and other immunocompromised populations (chemotherapy, AIDS patients).
- **Treatment of CMV infection**: Symptomatic CMV viremia, CMV pneumonia, CMV retinitis, CMV gastroenteritis in immunocompromised patients.
- **Dosage form production**: 480mg oral tablets, 240mg hard capsules, 120mg/20mL sterile injection.

5. Usage Methods (for Pharmaceutical Formulation)

Oral Formulation (Tablets/Capsules)

- **480mg Oral Tablet**: Mix letermovir with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), hypromellose (binder) and magnesium stearate (lubricant), dry granulate at low temperature (<60℃), compress and coat with enteric coating to prepare oral tablets.
- **Processing Requirements**: Avoid strong light and high temperature during granulation; control tablet disintegration time within 30 minutes (artificial gastric juice).

Injectable Formulation (Sterile Injection)

- **120mg/20mL Injection**: Dissolve letermovir with water for injection plus polyethylene glycol 400 (cosolvent) and propylene glycol (solubilizer), adjust pH to 6.0-7.0 with citric acid-sodium citrate buffer, add edetate disodium (chelating agent), sterile filter and fill in brown glass vials.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; use brown glass containers to prevent photodegradation; nitrogen-filled protection during filling.

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, protect from direct light and moisture; prevent contact with air to avoid oxidation.
- **Incompatibilities**: Store separately from strong acids, strong bases, oxidizing agents, heavy metal ions and photosensitizers.
- **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—seek emergency medical treatment at once and conduct symptomatic treatment.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection and light-proof facilities; avoid strong light and high temperature during material transfer and processing.