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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Baloxavir Marboxil
- **CAS Number**: 1985606-14-1
- **Molecular Formula**: $C_{27}H_{23}F_2N_5O_7S$
- **Molecular Weight**: 601.56 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via chiral synthesis and esterification of cyclopentane derivatives; purified by recrystallization and chiral separation to ensure high optical purity and low impurity content; optimized process for good formulation compatibility for oral anti-influenza preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; practically insoluble in water, freely soluble in DMSO/acetonitrile, slightly soluble in methanol/ethanol; stable in dry, dark and weakly acidic environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Anti-influenza virus prodrug, cap-dependent endonuclease inhibitor** with potent antiviral activity against influenza A (including H1N1, H3N2) and influenza B viruses; inhibits viral RNA replication by targeting the influenza virus cap-dependent endonuclease; single-dose oral administration, high bioavailability (≈70%), fast onset of action, effective against oseltamivir-resistant influenza strains; the classic oral anti-influenza raw material for treating acute uncomplicated influenza in adults and pediatric patients (≥12 years old).
- **Main Application**: Pharmaceutical intermediate for human oral anti-influenza formulations (tablets, dispersible tablets); pharmaceutical R&D reference reagent for anti-influenza pharmacology and antiviral drug research; analytical reference material for pharmaceutical quality inspection of anti-influenza products.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Baloxavir Marboxil)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
pH Value (1% aqueous suspension,25℃)	5.0-7.0	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method (light protection)
Solubility in DMSO	Freely soluble	Solubility Test
Bulk Density	1.45-1.50 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Optical Purity (ee)	≥ 99.5%	Chiral HPLC

3. Product Advantages

1. **Potent Anti-Influenza Activity**: Effective against influenza A (H1N1, H3N2) and influenza B viruses; active against oseltamivir-resistant and zanamivir-resistant influenza strains, no cross-resistance with neuraminidase inhibitors.
2. **Novel Mechanism of Action**: Targets influenza virus cap-dependent endonuclease (PA subunit); inhibits viral RNA replication at the early stage of infection, fast onset of action (symptom relief within 24h).
3. **Optimal Pharmacokinetics**: Prodrug design with high oral bioavailability (≈70%); long half-life (≈12 hours), single-dose oral administration for a full course of treatment, high patient compliance.
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, optical purity ≥99.5%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical oral use for adults and adolescents.
5. **Good Formulation Compatibility**: Freely soluble in organic solvents; compatible with common oral pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol); easy to prepare tablets and dispersible tablets for different clinical needs.
6. **Stable Storage Property**: 36-month shelf life under sealed, dark and dry conditions; slightly hygroscopic with no significant impact on quality; light protection only required for long-term storage.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Anti-Influenza Formulations)

- **Adult & Adolescent Influenza**: Core raw material for 20mg/40mg oral tablets; single-dose administration for treating acute uncomplicated influenza A and B in patients ≥12 years old; effective for post-exposure prophylaxis of influenza in high-risk populations.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets (Adult/Adolescent ≥12 years, ≥40kg)**: 40 mg per unit; single oral dose for acute influenza treatment.
- **Oral Tablets (Adolescent ≥12 years, <40kg)**: 20 mg per unit; single oral dose for acute influenza treatment.
- **Dispersible Tablets (Pediatric R&D)**: 10mg/20mg per unit; oral administration after dispersion in water, dosage adjusted according to body weight.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, **light protection**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection and moisture-proof**).

7. Safety & Protection

- The product is an anti-influenza virus pharmaceutical intermediate with irritant and mild toxic effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **light protection**.
- Avoid direct sunlight and high humidity in the work area; keep the operation tools clean and dry; do not mix with other pharmaceutical raw materials randomly.
- In case of eye contact, **immediately rinse with plenty of running water for at least 20 minutes** and call a POISON CENTER/ophthalmologist for professional treatment (severe irritation may occur).