Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Alectinib Hydrochloride
- **CAS Number**: 1256589-74-8
- **Molecular Formula**: C_{30} $H_{34}ClN_5$ O_2
- **Molecular Weight**: 519.08 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via multi-step organic synthesis including amination, coupling and salification; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral anti-tumor preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; practically insoluble in water, freely soluble in DMSO/DMF, 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**: **Highly selective anaplastic lymphoma kinase (ALK) inhibitor** with potent anti-tumor activity against ALK-positive non-small cell lung cancer (NSCLC); inhibits ALK tyrosine kinase activity to block tumor cell proliferation and induce apoptosis; high selectivity for ALK, low off-target effects; good oral bioavailability, high tissue penetration, especially in lung tissue; the classic anti-tumor raw material for treating ALK-positive advanced NSCLC.
- **Main Application**: Pharmaceutical intermediate for human oral anti-tumor formulations (capsules, tablets); pharmaceutical R&D reference reagent for oncology pharmacology and ALK inhibitor research; analytical reference material for pharmaceutical quality inspection of anti-tumor 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 (Alectinib Hydrochloride)	≥ 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℃)	5.5-7.5	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	1.28-1.32 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	216-222℃	Melting Point Apparatus (light

Item	Specification	Test Method
		protection)

3. Product Advantages

1. **High ALK Selectivity**: Potent and highly selective inhibition of ALK tyrosine kinase; low affinity for other kinases (EGFR, HER2, c-Kit), minimal off-target effects and low toxic side effects.
2. **Potent Anti-Tumor Activity**: Effective against ALK-positive non-small cell lung cancer (NSCLC), including crizotinib-resistant strains; induces tumor cell apoptosis and inhibits tumor metastasis, high clinical response rate.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈80%); long half-life (≈32 hours), once-daily oral administration, high patient compliance; high tissue penetration, especially in lung tissue and central nervous system (CNS).
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical oral use for adult tumor patients.
5. **Good Formulation Compatibility**: Freely soluble in organic solvents; compatible with common oral pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol); easy to prepare capsules and tablets for clinical anti-tumor treatment.
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-Tumor Formulations)

- **ALK-Positive NSCLC**: Core raw material for 150mg hard capsules/tablets; first-line and second-line treatment for ALK-positive advanced non-small cell lung cancer; effective for crizotinib-resistant NSCLC and CNS metastases.
- **ALK-Rearranged Tumors**: Formulation development for other ALK-rearranged malignant tumors (lymphoma, neuroblastoma) under clinical research; high potential for broad anti-tumor application.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Capsules/Tablets**: 150 mg per unit; adult clinical dose 600 mg twice daily (4 capsules/tablets), oral administration with food for better absorption.

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 ALK inhibitor anti-tumor 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.