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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Ruxolitinib nitrate
- **CAS Number**: 941678-49-5
- **Molecular Formula**: $C_{17}H_{18}N_6O \cdot HNO_3$
- **Molecular Weight**: 385.38 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via pyrrolopyrimidine ring formation, pyrazole coupling, cyclopentyl substitution and nitrate salinization; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral hematology/oncology preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in methanol/ethanol/DMSO, sparingly soluble in water; stable in dry, dark and neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Highly selective JAK1/JAK2 inhibitor** with potent hematology/oncology activity; blocks JAK-STAT signaling pathway to inhibit abnormal cell proliferation and cytokine production; fast onset of action (1-2 hours), long duration (24 hours); the classic pharmaceutical raw material for treating myelofibrosis, polycythemia vera and essential thrombocythemia in adults.
- **Main Application**: Pharmaceutical intermediate for human oral hematology/oncology formulations (tablets, capsules); pharmaceutical R&D reference reagent for hematology/oncology pharmacology and JAK inhibitor research; analytical reference material for pharmaceutical quality inspection of hematology/oncology 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 (Ruxolitinib nitrate)	≥ 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% methanol 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 Methanol	Freely soluble	Solubility Test
Bulk Density	1.42-1.46 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	205-211℃	Melting Point Apparatus (light protection)

3. Product Advantages

1. **High JAK1/JAK2 Selectivity**: Potent and highly selective inhibition of JAK1 and JAK2 kinases; no significant affinity for other JAK family members (JAK3/TYK2), reducing adverse effects such as immunosuppression associated with non-selective JAK inhibitors.
2. **Broad Hematology Efficacy**: Effective for myelofibrosis, polycythemia vera and essential thrombocythemia; relieves splenomegaly and systemic symptoms, reduces abnormal blood cell proliferation, a single active ingredient for multiple myeloproliferative neoplasms.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈95%); long half-life (≈3 hours), twice-daily oral administration, high patient compliance; good hematopoietic tissue penetration, rapid inhibition of JAK-STAT signaling pathway for myeloproliferative neoplasm treatment.
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 hematology/oncology patients (including myelofibrosis and polycythemia vera).
5. **Excellent Formulation Compatibility**: Freely soluble in organic solvents; compatible with common oral pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol); easy to prepare tablets and capsules for clinical hematology/oncology treatment.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Hematology/Oncology Formulations)

- **Myelofibrosis**: Core raw material for 5mg/10mg/15mg oral tablets; first-line treatment for primary and secondary myelofibrosis; relieves splenomegaly, bone pain and fatigue, improves quality of life for patients.
- **Polycythemia Vera**: Formulation for treating polycythemia vera in adults; reduces red blood cell proliferation, lowers blood viscosity and the risk of thrombosis, an alternative to hydroxyurea for refractory patients.
- **Essential Thrombocythemia**: Formulation for treating essential thrombocythemia; inhibits platelet overproduction, reduces the risk of thrombotic and hemorrhagic events.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Myelofibrosis Oral Tablets**: 5mg/10mg/15mg per unit; adult starting dose 15mg twice daily (based on platelet count), titrated according to clinical response and safety.
- **Polycythemia Vera/Essential Thrombocythemia Oral Tablets**: 10mg per unit; adult starting dose 10mg twice daily, adjusted according to blood cell count and clinical response.

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 a highly selective JAK1/JAK2 inhibitor hematology/oncology pharmaceutical intermediate with irritant and mild hematological/hepatic 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**; monitor hematological and hepatic function for personnel with prolonged handling exposure.
- 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 (especially hematotoxic/hepatotoxic drugs) randomly.