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) - Ruxolitinib Phosphate

Revision Date: 28 FEB 2026**CAS Number**: 1092939-17-7**Molecular Formula**: $C_{18}H_{22}N_4O_2 \cdot H_3PO_4$**Molecular Weight**: 404.38 g/mol

1. Product Overview

Ruxolitinib Phosphate is a high-purity pharmacopoeial-grade oral Janus-associated kinase (JAK) 1/2 inhibitor, a core pharmaceutical raw material for clinical treatment of myeloproliferative neoplasms and inflammatory skin diseases. It exerts its therapeutic effect by selectively inhibiting the activity of JAK1 and JAK2, blocking the JAK-STAT signaling pathway, thereby inhibiting abnormal cell proliferation and excessive inflammatory factor release. As a first-line therapeutic drug for myelofibrosis, it features high target selectivity, potent anti-proliferative and anti-inflammatory activity, and good oral bioavailability, and is widely used in the production of clinical oral solid preparations for myelofibrosis, polycythemia vera, and moderate to severe plaque psoriasis.

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 H_2O)	0° ± 2°
pH Value (1% aqueous solution, 25℃)	4.0 ~ 6.0
Solubility	Freely soluble in water; soluble in methanol/ethanol; slightly soluble in acetone/DMSO
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
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)

3. Product Advantages

1. **High-Selectivity JAK1/2 Inhibition**: Precisely targets JAK1 and JAK2 kinases, blocks abnormal JAK-STAT signaling; no significant inhibition of other JAK family members, reducing off-target side effects.
2. **Broad Therapeutic Spectrum**: First-line treatment for myelofibrosis (primary/secondary); effective for polycythemia vera resistant to hydroxyurea; also indicated for moderate to severe plaque psoriasis, with dual anti-proliferative and anti-inflammatory effects.
3. **Excellent Pharmacokinetic Properties**: Rapid absorption after oral administration, high bioavailability (≈95%), long half-life (≈3h), twice-daily administration; good tissue penetration, effective for both systemic and local diseases.
4. **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 for oral solid formulations.
5. **Proven Clinical Efficacy**: Significantly reduces splenomegaly and relieves constitutional symptoms in myelofibrosis patients; improves skin lesions in psoriasis patients with a good safety profile.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anti-tumor and Anti-inflammatory Therapy:

- **Myeloproliferative Neoplasms**: Primary myelofibrosis, post-polycythemia vera myelofibrosis, post-essential thrombocythemia myelofibrosis.
- **Hematologic Malignancies**: Hydroxyurea-resistant polycythemia vera, essential thrombocythemia.
- **Inflammatory Skin Diseases**: Moderate to severe plaque psoriasis (adults).
- **Dosage form production**: 5mg/10mg/15mg/20mg oral tablets (main dosage form), 2.5mg hard capsules (pediatric/elderly reduced dosage).

5. Usage Methods (for Pharmaceutical Formulation)

Oral Solid Formulation (Tablets/Capsules)

- **15mg Oral Tablet**: Mix ruxolitinib phosphate with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), hypromellose (binder) and magnesium stearate (lubricant), adopt wet granulation process (purified water as wetting agent), granulate at low temperature (<60℃), compress and coat with film coating to prepare oral tablets.
- **Processing Requirements**: Avoid strong light and high temperature during the whole production process; control the moisture content of granules ≤ 0.5% to prevent drug hydrolysis; tablet disintegration time ≤ 15 minutes (water).
- **2.5mg Hard Capsule**: Mix the granulated ruxolitinib phosphate with lactose monohydrate (diluent) evenly, fill into hard gelatin capsules of appropriate size; the capsule shell uses neutral medical grade material to avoid drug adsorption.

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 light-proof sealed drum (for oral formulation raw material)
- Custom GMP-compliant nitrogen-filled light-proof 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; strict light protection to avoid photodegradation.
- **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, used up as soon as possible with strict record).

Transportation

- Classified as pharmaceutical raw material for clinical anti-tumor and anti-inflammatory 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 (brown glass/stainless steel); avoid package collision and light exposure during transport.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable light-proof 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.