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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Upadacitinib
- **CAS Number**: 1310726-60-3
- **Molecular Formula**: C_{17} H_{19} N_7 O
- **Molecular Weight**: 337.38 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via pyrrolopyrimidine ring synthesis, piperazine coupling and cyclization; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral anti-autoimmune disease 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 neutral environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Highly selective Janus Kinase 1 (JAK1) inhibitor** with potent activity for treating autoimmune and inflammatory diseases; selectively inhibits JAK1 to block cytokine signaling pathways (IL-6, IL-13, IFN), reducing inflammatory response; high oral bioavailability, good tissue penetration, low off-target effects on JAK2/3/TYK2; the classic pharmaceutical raw material for treating rheumatoid arthritis, psoriatic arthritis, atopic dermatitis and ulcerative colitis in adults.
- **Main Application**: Pharmaceutical intermediate for human oral anti-autoimmune formulations (tablets, capsules); pharmaceutical R&D reference reagent for immunology pharmacology and JAK inhibitor research; analytical reference material for pharmaceutical quality inspection of anti-autoimmune 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 (Upadacitinib)	≥ 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% DMSO suspension,25℃)	6.5-8.5	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	1.30-1.34 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	218-224℃	Melting Point Apparatus (light protection)

3. Product Advantages

1. **High JAK1 Selectivity**: Potent and highly selective inhibition of JAK1 kinase; minimal activity against JAK2, JAK3 and TYK2, reducing adverse effects such as myelosuppression and thrombocytopenia associated with non-selective JAK inhibitors.
2. **Broad Anti-Inflammatory Efficacy**: Blocks multiple pro-inflammatory cytokine signaling pathways; effective for rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis and ankylosing spondylitis; high clinical response rate and long-term symptom relief.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈80%); long half-life (≈16 hours), once-daily oral administration, high patient compliance; good tissue penetration in joints, skin and gastrointestinal tract, rapid onset of anti-inflammatory effect.
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 autoimmune disease patients.
5. **Good 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 anti-autoimmune 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-Autoimmune Formulations)

- **Rheumatoid Arthritis (RA)**: Core raw material for 15mg/30mg oral tablets; first-line treatment for moderate to severe active RA in adults who have inadequate response to DMARDs; reduces joint swelling, pain and stiffness.
- **Psoriatic Arthritis (PsA)**: Formulation for treating active PsA; improves joint mobility and reduces skin psoriasis lesions, no cross-resistance with anti-TNF drugs.
- **Atopic Dermatitis (AD)**: Raw material for oral AD formulations; relieves pruritus and skin

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets/Capsules**: 15mg/30mg per unit; adult clinical dose 15mg once daily for RA/PsA, 30mg once daily for AD/ulcerative colitis, titrated according to 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 JAK1 selective inhibitor anti-autoimmune 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.