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Technical Data Sheet (TDS)

1. Product Overview

- **Product Name**: Aripiprazole (阿立哌唑)
- **CAS Number**: 129722-12-9
- **Formula**: $C_{23}H_{27}Cl_2N_3O_2$
- **Formula Weight**: 448.39 g/mol
- **Molecular Form**: Atypical antipsychotic pharmaceutical active ingredient (API) (Dopamine/Serotonin partial agonist)
- **Product Characteristics**: High-purity GMP grade Aripiprazole is a white to off-white crystalline powder, a novel atypical antipsychotic with unique partial agonist activity at dopamine D2 and serotonin 5-HT1A receptors, and antagonist activity at 5-HT2A receptors. Insoluble in water, soluble in polar organic solvents, **non-hygroscopic**, extremely stable at room temperature airtight storage. It is a first-line antipsychotic API, clinically used for the treatment of schizophrenia and bipolar disorder; low incidence of extrapyramidal symptoms and weight gain, meets USP/EP/CP pharmacopoeial standards for pharmaceutical formulation.

2. Technical Specifications (USP/EP/CP Compliant, GMP Grade)

Item	Specification (Pharmaceutical API Grade)
Appearance	White to off-white crystalline powder
Assay (On Anhydrous Basis)	98.0-102.0% (HPLC)
Water Content	≤ 0.5% (Karl Fischer)
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm (AAS)
Heavy Metals (As)	≤ 2 ppm (AFS)
Related Substances (Individual)	≤ 0.3% (HPLC)
Related Substances (Total)	≤ 1.0% (HPLC)
Melting Point	139-143℃ (Capillary Method)
Chloride Content	15.4-16.5% (w/w, Volumetric Titration)
Solubility	Soluble in acetonitrile, DMSO; slightly soluble in ethanol/methanol; insoluble in water
Particle Size (D90)	≤ 100 μm (Pharmaceutical grade)
Hygroscopy	Non-hygroscopic (stable at RH 0-90%)
Storage Stability	48 months (unopened, 25℃±5℃); 12 months (after opening)

3. Product Advantages

1. **Unique Mechanism of Action**: Dopamine/serotonin partial agonist (DSPA); balances dopaminergic/serotonergic neurotransmission; low extrapyramidal side effect (EPS) risk.
2. **Ultra-High Purity & Quality**: ≥98.0% HPLC assay, ultra-low related substances (≤0.3% individual); meets global pharmacopoeia (USP/EP/CP) standards; GMP compliant production.
3. **Excellent Stability**: Non-hygroscopic, stable at room temperature (25℃±5℃) for 48 months; no degradation at RH 0-90%; low batch-to-batch variation.
4. **Clinically Proven Efficacy**: First-line atypical antipsychotic API; effective for schizophrenia (acute/chronic) and bipolar disorder; improves positive/negative symptoms of schizophrenia.

5. **Favorable Safety Profile**: Low incidence of EPS, weight gain, sedation and hyperprolactinemia; good patient tolerance and adherence; no significant anticholinergic side effects.
6. **Versatile Formulability**: Compatible with various pharmaceutical excipients; suitable for tablets, capsules, orally disintegrating tablets and oral suspensions (with solubilizers).

4. Application Fields

- **Pharmaceutical Formulation**: Production of atypical antipsychotic oral formulations (tablets, capsules, orally disintegrating tablets); research for injectable/long-acting formulation development.
- **Biomedical Research**: Neuroscience research (dopamine/serotonin receptor system study); psychopharmacology research (antipsychotic drug screening); schizophrenia/bipolar disorder model research.
- **Pharmaceutical R&D**: Reference standard for atypical antipsychotic drug development; formulation optimization research (solubilization technology); drug stability/bioavailability study.

5. Usage Methods

- **Pharmaceutical Formulation (Oral Tablets/Capsules)**: Mix with pharmaceutical excipients (lactose, microcrystalline cellulose, crospovidone) and solubilizers (e.g., hydroxypropyl-β-cyclodextrin) at 5-30 mg per unit dose; wet granulation process (with ethanol as wetting agent); compress into tablets or fill into hard gelatin capsules; use disintegrants for orally disintegrating tablets to ensure fast dissolution.
- **Research Use (In Vitro)**: Prepare 10 mM stock solution with DMSO/acetonitrile; dilute to 0.1-100 μM working concentration for in vitro cell experiments (D2/5-HT1A receptor binding assay); store stock solution at -20℃ for 6 months (sealed, avoid repeated freeze-thaw).
- **Research Use (In Vivo)**: Dissolve in DMSO/saline (1:9) to prepare 0.1-5 mg/mL formulation; administer via oral/gastric gavage injection at 0.5-20 mg/kg body weight for animal schizophrenia/bipolar models; adjust dosage according to animal species/strain.
- **Critical Notes**:

1. **Pharmaceutical GMP conditions only**: For formulated pharmaceutical products only; no direct human use (unformulated API).
2. Use solubilizers (e.g., cyclodextrins) for aqueous formulations (insoluble in water); avoid strong acids/bases during formulation processing.
3. Use stainless steel/glass equipment for handling (no plastic contact for bulk processing); avoid oxidizing agents/halogens.
4. Strict dosage control in clinical use; gradual dose titration to minimize adverse reactions (mild dizziness, somnolence).

6. Packaging & Storage

Packaging Specifications (GMP Compliant, Airtight)

- 100 g/bottle (GMP grade, HDPE plastic bottle with airtight screw cap + aluminum foil liner)
- 500 g/bottle (GMP grade, HDPE plastic bottle with airtight