纳维盈医化科技
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Technical Data Sheet (TDS)

Quetiapine Fumarate CAS:111974-72-2 Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Quetiapine Fumarate (喹硫平富马酸盐)
- CAS Number: 111974-72-2
- Formula: $C_{21}H_{25}N_3O_2S \cdot C_4H_4O_4$
- Molecular Weight: 515.59 g/mol
- Chemical Classification: Atypical antipsychotic (dibenzoazepine derivative)
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; classic atypical antipsychotic API; multi-receptor antagonist (dopamine/serotonin/adrenoceptor); sparingly soluble in water, soluble in methanol; light-sensitive; strict impurity/heavy metal control for pharmaceutical use; effective for schizophrenia and bipolar disorder (mania/depression).

2. Technical Specifications (EP 10.0 / USP 45 / CP 2020)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Assay (on dry basis)	≥ 98.5%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	105℃, 2h Gravimetry
Residue on Ignition	≤ 0.1%	550℃ Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Melting Point	174-178℃	Capillary Melting Point Method
Solubility	Sparingly soluble in water, soluble in methanol	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
pH Value (1% aqueous suspension, 25℃)	4.0-6.0	Digital pH Meter
Fumaric Acid Content	14.0-16.0%	Acid-Base Titration
Particle Size	90% passing 100 mesh	Sieve Analysis

3. Product Advantages

1. **International Pharmacopoeial Compliance**: Meets EP/USP/CP global pharmaceutical standards; ultra-low related substances and heavy metals; batch-to-batch consistency, suitable for GMP formulation and controlled drug production.
2. **Atypical Antipsychotic Potency**: Multi-receptor antagonism (D2/5-HT2A/a-adrenoceptor); effective for both schizophrenia and bipolar disorder (mania/depression); lower extrapyramidal side effects than typical antipsychotics.
3. **Stable Quality Under Control**: 24-month shelf life at 2-8℃ dark storage; light sensitivity (controllable with sealed/opaque packaging); no significant degradation under standard pharmaceutical processing conditions.
4. **Formulation Flexibility**: Soluble in methanol, sparingly soluble in water; compatible with organic solvent-based and aqueous formulations; suitable for solid oral dosage forms (tablets/capsules) and oral solutions/suspensions.

5. **GMP Manufacturing**: Produced in GMP/ISO 9001 certified facility (compliant with controlled drug regulations); complete raw material traceability; strict in-process quality control for all key parameters.

4. Application Fields

- **Pharmaceutical Formulation**: Production of atypical antipsychotic drugs (tablets, capsules, oral solutions) for clinical treatment of schizophrenia, bipolar mania and bipolar depression.
- **Pharmaceutical R&D**: Research on new antipsychotic formulations (sustained-release, orally disintegrating tablets); preclinical/clinical research on mood disorder treatment; drug-drug interaction studies of atypical antipsychotics.
- **Academic Research**: Neuroscience research on multi-receptor pharmacology; schizophrenia/bipolar disorder pathogenesis research; dibenzoazepine structure-activity relationship studies.

5. Usage & Formulation Guidelines

- **Formulation Compatibility**: Suitable for solid oral dosage forms (tablets/capsules) and oral liquid formulations; compatible with common excipients (lactose, microcrystalline cellulose, mannitol); solubilizers (e.g., PEG 400) can improve aqueous solubility.
- **Typical Dosage (Formulated Drug)**: Adult oral dosage 150-800 mg/day (schizophrenia); 300-600 mg/day (bipolar mania) – **clinical prescription only, controlled drug, no self-medication**.
- **Processing Precautions**: Process in **light-free, dust-free GMP workshop** (2-25℃); use closed/opaque handling systems to avoid light exposure and dust generation; avoid contact with strong acids/bases/high temperature (>25℃).

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (amber glass bottle with aluminum foil seal, inner plastic liner – light-proof)
- 500 g/bottle (amber glass bottle with light-proof moisture seal)
- 1 kg/drum (opaque HDPE drum with inner plastic bag, sealed)
- 5 kg/drum (fiber drum with opaque HDPE inner liner, light-proof)
- Custom GMP-compliant/light-proof packaging for industrial bulk orders (controlled drug regulations apply)

6.2 Storage Conditions

- Store in a **cool, dry, dark warehouse at 2-8℃**; use light-proof packaging; keep container tightly sealed to prevent light exposure and moisture.
- Avoid direct sunlight, high temperature (>25℃), strong acids, strong bases and oxidizing agents.
- Shelf Life: **24 months** (unopened, specified conditions); 6 months after opening (resealed, 2-8℃ dark storage).
- Segregation: Store as a **controlled pharmaceutical raw material**; separate from food/feed/non-pharmaceutical materials; keep in locked storage area with authorized personnel only.

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance) + controlled drug; transport with **2-8℃ cold chain** and light-proof packaging.
- Mark with GHS hazard labels, UN 2811 and controlled drug signs; avoid direct sunlight, high temperature and collision during transport.
- Comply with IMDG/IATA/ADR for Class 6.1 toxic solids (cold chain) and local controlled drug transport regulations; do not transport with food/feed/strong acids/bases/oxidizing agents.

7. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility (compliant with controlled drug management regulations); strict in-process quality control for assay, impurities, heavy metals and fumaric acid content.
- Each batch is accompanied by a batch-specific **Certificate of Analysis (COA)** with full test results; complete production/quality records retained for 5+ years (per controlled drug regulatory requirements).