

Technical Data Sheet (TDS)

Penfluridol CAS:2269-15-4 Version Date: 28 FEB 2026

1. Product Overview

- Product Name: Penfluridol (戊氟里多)
- CAS Number: 2269-15-4
- Formula: C₂₈ H₂₇ ClF₂NO
- Molecular Weight: 467.97 g/mol
- Chemical Classification: Diphenylbutylpiperidine antipsychotic
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; long-acting oral antipsychotic API; potent dopamine D2 receptor antagonist; non-hygroscopic; sparingly soluble in ethanol, slightly soluble in water; light-sensitive; stable under cold chain storage; strict impurity/heavy metal control for pharmaceutical use, suitable for GMP formulation.

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°C, 2h Gravimetry
Residue on Ignition	≤ 0.1%	550°C 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	250-256°C	Capillary Melting Point Method
Solubility	Sparingly soluble in ethanol, slightly soluble in water	Pharmacopoeial Solubility Test
Chloride Content	≤ 0.01%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
Acidity/Alkalinity	pH 6.0-8.0 (0.1% in ethanol)	Digital pH Meter
Particle Size	90% passing 100 mesh	Sieve Analysis

3. Product Advantages

1. **International Pharmacopoeial Compliance:** Meets EP/USP/CP global standards; ultra-low related substances and heavy metal content; batch-to-batch consistency, suitable for GMP pharmaceutical formulation and controlled drug production.
2. **Long-Acting Antipsychotic Efficacy:** Potent D2 receptor antagonist; long oral half-life (up to 21 days); single weekly dosage for schizophrenia treatment; effective for positive symptoms (hallucinations, delusions) and maintains clinical remission.
3. **Stable Quality Under Control:** 24-month shelf life at 2-8°C dark storage; non-hygroscopic; no chemical degradation under recommended conditions; light-sensitive but stable with opaque/sealed packaging.
4. **Pharmaceutical Formulation Flexibility:** Compatible with solid oral dosage forms (tablets, capsules); suitable for immediate-release formulations; miscible with common pharmaceutical organic excipients (ethanol, PEG 400).
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



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- **Pharmaceutical Formulation:** Production of long-acting oral antipsychotic drugs (tablets, capsules) for clinical treatment of schizophrenia and other psychotic disorders; management of positive symptoms (hallucinations, delusions, disorganized thinking).
- **Pharmaceutical R&D:** Research on new long-acting antipsychotic formulations; preclinical/clinical research on schizophrenia treatment; drug combination research for refractory psychosis; diphenylbutylpiperidine derivative development.
- **Academic Research:** Neuroscience research on dopamine receptor pharmacology; schizophrenia pathogenesis research; antipsychotic structure-activity relationship studies.

5. Usage & Formulation Guidelines

- **Formulation Compatibility:** Suitable for solid oral dosage forms (tablets, hard capsules); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, starch, magnesium stearate); solubilizers (PEG 400/600) recommended for liquid formulations.
- **Typical Dosage (Formulated Drug):** Adult oral dosage 20-80 mg once weekly (schizophrenia treatment) – **clinical prescription only; controlled drug; no self-medication or dosage adjustment.**
- **Processing Precautions:** Process in **light-free, dust-free GMP workshop** (2-25°C); use closed/opaque handling systems to avoid light exposure and dust generation; avoid contact with strong acids/bases/high temperature (>100°C); maintain low humidity (<60%) during processing.

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 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°C**; use light-proof, airtight packaging; keep container tightly sealed to prevent light exposure and minor moisture contamination.
- Avoid direct sunlight, high temperature (>100°C), strong acids, strong bases, oxidizing agents and mechanical collision.
- Shelf Life: **24 months** (unopened, under specified cold chain conditions); 6 months after opening (resealed, 2-8°C dark storage).
- Segregation: Store as a **controlled pharmaceutical raw material**; keep in a locked, restricted-access storage area; separate from food, feed, non-pharmaceutical materials and aquatic environment sources.

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance) + controlled drug; transport with **2-8°C cold chain** and light-proof packaging.
- Mark with GHS hazard labels, UN 2811 and controlled drug warning signs; avoid direct sunlight, high temperature, collision and vibration during transport.
- Comply with IMDG/IATA/ADR regulations 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 national controlled drug management regulations); strict in-process quality control for all key parameters (assay, impurities, heavy metals).
- 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 and GMP requirements).