

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Paroxetine Hydrochloride (盐酸帕罗西汀)
- **CAS Number:** 78246-49-8
- **Formula:** C₁₉ H₂₁FNO₃·HCl
- **Formula Weight:** 365.84 g/mol
- **Molecular Form:** Selective Serotonin Reuptake Inhibitor (SSRI) pharmaceutical active ingredient (API)
- **Product Characteristics:** High-purity GMP grade Paroxetine Hydrochloride is a white to off-white crystalline powder, a potent and selective SSRI with high affinity for serotonin transporters. Soluble in water and polar organic solvents, slightly hygroscopic, stable at room temperature sealed storage. It is a first-line antidepressant API, clinically used for the treatment of major depressive disorder, obsessive-compulsive disorder, panic disorder and social anxiety disorder; high bioavailability, low side effect profile, 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)	98.5-101.0% (HPLC)
Water Content	≤ 5.0% (Karl Fischer)
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm (AAS)
Heavy Metals (As)	≤ 2 ppm (AFS)
Related Substances (Individual)	≤ 0.5% (HPLC)
Related Substances (Total)	≤ 1.0% (HPLC)
Optical Rotation (25°C, 1% in H ₂ O)	-88.0° to -95.0° (Polarimetry)
pH Value (1% aqueous, 25°C)	5.0-6.0
Melting Point	120-125°C (Capillary Method)
Solubility	Soluble in water, methanol, ethanol; slightly soluble in acetone
Particle Size (D90)	≤ 80 μm (Pharmaceutical grade)
Hygroscopy	Slight (stable at RH ≤70%)
Storage Stability	36 months (unopened, 25°C±5°C); 6 months (after opening)

3. Product Advantages

1. **High Selectivity & Potency:** Selective serotonin reuptake inhibitor with no significant affinity for norepinephrine/dopamine transporters; high antidepressant activity at therapeutic dosages.
2. **Ultra-High Purity:** ≥98.5% HPLC assay, low related substances (≤1.0% total); meets global pharmacopoeia (USP/EP/CP) standards; GMP compliant production.
3. **Favorable Physicochemical Properties:** Soluble in water (suitable for oral/parenteral formulation); slightly hygroscopic, stable at room temperature; low batch-to-batch variation.
4. **Clinically Proven Efficacy:** First-line antidepressant API with decades of clinical application; effective for major depression, OCD, panic disorder and social anxiety disorder.
5. **Low Side Effect Profile:** No significant anticholinergic/cardiovascular side effects; mild adverse reactions (nausea, headache) with low incidence; good patient tolerance.
6. **Versatile Formulability:** Compatible with various pharmaceutical excipients; suitable for tablets, capsules, oral solutions and injectable formulations.

4. Application Fields

- **Pharmaceutical Formulation:** Production of antidepressant oral formulations (tablets, capsules, oral suspensions); research for injectable formulation development.
- **Biomedical Research:** Neuroscience research (serotonin system study); psychopharmacology research (antidepressant drug screening); in vitro/vivo depression model research.



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- **Pharmaceutical R&D:** Reference standard for SSRI drug development; formulation optimization research for antidepressant products; drug stability/ bioavailability study.

5. Usage Methods

- **Pharmaceutical Formulation (Oral Tablets/Capsules):** Mix with pharmaceutical excipients (lactose, microcrystalline cellulose, magnesium stearate) at 5-40 mg per unit dose; wet/dry granulation process; compress into tablets or fill into hard gelatin capsules; adjust pH to 5.0-6.0 for oral solutions to ensure stability.
- **Research Use (In Vitro):** Prepare 10 mM stock solution with deionized water/methanol; dilute to 1-100 μ M working concentration for in vitro cell experiments (serotonin transporter binding assay); store stock solution at 4°C for 1 month (sealed).
- **Research Use (In Vivo):** Dissolve in normal saline/5% glucose solution to prepare 0.1-10 mg/mL formulation; administer via oral/gastric gavage injection at 1-10 mg/kg body weight for animal depression 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. Avoid high humidity (RH >70%) during formulation; use moisture-proof excipients for solid formulations.
 3. Do not mix with strong acids/bases/oxidizing agents; use stainless steel/plastic equipment for formulation processing.
 4. Strict dosage control in clinical use; gradual dose titration to minimize adverse reactions.

6. Packaging & Storage

Packaging Specifications (GMP Compliant, Moisture-Proof)

- 100 g/bottle (GMP grade, HDPE plastic bottle with moisture-proof cap + aluminum foil liner)
- 500 g/bottle (GMP grade, HDPE plastic bottle with moisture-proof cap + aluminum foil liner)
- 1 kg/drum (GMP grade, HDPE plastic drum with inner aluminum foil bag)
- 5 kg/drum (Bulk GMP grade, HDPE plastic drum with inner aluminum foil bag)
- Custom packaging (10 g/50 g) for research/small-batch orders available on request.

Storage Conditions (Room Temperature Mandatory)

- **Long-term Storage:** 25°C \pm 5°C, dry, dark, **sealed**; store in original GMP packaging; avoid temperature fluctuation (>5°C) and high humidity (RH >70%).
- **Short-term Storage:** 25°C, sealed, up to 6 months after opening; place in a desiccator with anhydrous silica gel if needed.
- **Avoid:** High temperature (>60°C), direct sunlight, high humidity, strong acids/bases, oxidizing/reducing agents, heavy metal ions.
- **Segregation:** Store in **locked dedicated GMP pharmaceutical API storage area**; separate from food/feed/cosmetics/other hazardous chemicals; no co-storage with strong acids/bases.

7. Safety & Protection

- The product is **harmful if swallowed**, causes **serious eye irritation** and may damage the nervous system via prolonged exposure; no skin irritation/sensitization.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, powder-free nitrile gloves (\geq 0.18mm), disposable clean lab coat.
- Operate in well-ventilated area; avoid dust generation/inhalation, skin/eye contact and accidental ingestion; wash hands thoroughly after handling.

8. Quality Assurance

- Manufactured in accordance with **GMP (Good Manufacturing Practice)**, **ISO 9001 (Quality)** and **ISO 14001 (Environment)** standards; full traceability of production process.
- Each batch is tested by an independent third-party GMP laboratory and accompanied by a **Certificate of Analysis (COA)** with full pharmacopoeial test data.
- Provide **USP/EP/CP compliance documents**, GMP certification and hazardous chemical safety certificates for pharmaceutical grade products.