

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Clomipramine Hydrochloride (氯米普明盐酸盐)
- **CAS Number:** 10340-25-3
- **Formula:** C₁₉ H₂₃ClN₂·HCl
- **Formula Weight:** 351.32 g/mol
- **Molecular Form:** Tricyclic antidepressant (TCA) pharmaceutical active ingredient (API) (serotonin/norepinephrine reuptake inhibitor)
- **Product Characteristics:** High-purity GMP grade Clomipramine Hydrochloride is a white to off-white crystalline powder, a potent tricyclic antidepressant with selective serotonin reuptake inhibition and moderate norepinephrine reuptake inhibition. Soluble in water and polar organic solvents, slightly hygroscopic, extremely stable at room temperature airtight storage. Clinically used for the treatment of major depressive disorder, obsessive-compulsive disorder (OCD) and panic disorder; high efficacy for severe depression and OCD; 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	≤ 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)	≤ 0.8% (HPLC)
Melting Point	215-220°C (Capillary Method)
pH Value (1% aqueous, 25°C)	3.5-4.5
Optical Rotation (25°C, 1% in MeOH)	0° ± 0.5° (Polarimetry)
Loss on Drying	≤ 0.5% (105°C, 2h)
Solubility	Soluble in water, methanol, ethanol, chloroform
Particle Size (D90)	≤ 100 μm (Pharmaceutical grade)
Hygroscopy	Slight (stable at RH ≤70%)
Storage Stability	48 months (unopened, 25°C±5°C); 12 months (after opening)

3. Product Advantages

1. **Potent Antidepressant Effect:** Selective serotonin reuptake inhibitor (SSRI-like) with moderate norepinephrine inhibition; high efficacy for major depression, OCD and panic disorder.



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2. **Ultra-High Purity & Quality:** $\geq 98.5\%$ HPLC assay, ultra-low related substances ($\leq 0.3\%$ individual); meets global pharmacopoeia (USP/EP/CP) standards; GMP compliant production.
3. **Excellent Stability:** Slightly hygroscopic, stable at room temperature ($25^{\circ}\text{C} \pm 5^{\circ}\text{C}$) for 48 months; low batch-to-batch variation, suitable for long-term pharmaceutical storage.
4. **Favorable Physicochemical Properties:** Soluble in water (suitable for oral/parenteral formulation); compatible with most pharmaceutical excipients; easy for formulation processing.
5. **Clinically Proven Efficacy:** First-line TCA for severe depression and OCD; decades of clinical application; well-documented safety and efficacy profile.
6. **Versatile Formulability:** Compatible with various pharmaceutical excipients; suitable for tablets, capsules, oral solutions, injectables and topical formulations.

4. Application Fields

- **Pharmaceutical Formulation:** Production of tricyclic antidepressant oral formulations (tablets, capsules, oral suspensions); injectable formulations for severe acute depression; topical formulations for neuropathic pain.
- **Biomedical Research:** Neuroscience research (serotonin/norepinephrine reuptake system study); psychopharmacology research (antidepressant/OCD drug screening); in vitro/vivo depression/OCD model research.
- **Pharmaceutical R&D:** Reference standard for TCA drug development; formulation optimization research (solubilization technology); drug stability/bioavailability/ pharmacokinetic study.

5. Usage Methods

- **Pharmaceutical Formulation (Oral Tablets/Capsules):** Mix with pharmaceutical excipients (lactose, microcrystalline cellulose, croscopovidone) at 10-75 mg per unit dose; wet granulation process; compress into tablets or fill into hard gelatin capsules; adjust pH to 3.5-4.5 for oral solutions to ensure stability.
- **Research Use (In Vitro):** Prepare 10 mM stock solution with deionized water/methanol; dilute to 0.1-100 μM working concentration for in vitro cell experiments (serotonin/norepinephrine reuptake assay); store stock solution at -20°C for 6 months (sealed, avoid repeated freeze-thaw).
- **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 5-30 mg/kg body weight for animal depression/OCD 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, toxic if swallowed).
 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/MAO inhibitors; use stainless steel/glass equipment for formulation processing.
 4. Strict dosage control in clinical use; gradual dose titration to minimize adverse reactions (anticholinergic/cardiovascular).