

## Technical Data Sheet (TDS)

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### 1. Product Overview

- **Product Name:** Clomifene Citrate (克罗米芬柠檬酸盐)
- **CAS Number:** 50-41-9
- **Molecular Formula:** C<sub>26</sub> H<sub>28</sub> ClNO · C<sub>6</sub> H<sub>8</sub> O<sub>7</sub>
- **Molecular Weight:** 609.09 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized via diphenyl ethylene condensation, chlorination, etherification, amination and citrate salification; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral gynecological preparations).
- **Product Trait:** White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in methanol/ethanol/DMSO, slightly soluble in water; stable in dry, dark and weak acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with light protection.
- **Core Properties: Highly selective Estrogen Receptor Modulator (SERM)** with potent ovulation-inducing activity; blocks estrogen receptors in the hypothalamus-pituitary axis to increase gonadotropin secretion and stimulate ovarian follicle development and ovulation; fast onset of action (5-7 days), long duration (2-3 menstrual cycles); the classic pharmaceutical raw material for treating female anovulatory infertility in clinical gynecology.
- **Main Application:** Pharmaceutical raw material for human oral gynecological ovulation-inducing formulations (tablets, capsules); treatment of female infertility caused by anovulation (polycystic ovary syndrome, hypothalamic anovulation); pharmaceutical R&D reference reagent for reproductive pharmacology and estrogen receptor research.

### 2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Clomifene Citrate)	≥ 98.5%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25°C ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 1.0%	HPLC
pH Value (1% aqueous suspension, 25°C)	3.0-5.0	Digital pH Meter
Melting Point	110-116°C (dec.)	Melting Point Apparatus (light protection)
Total Bacterial Count	≤ 5 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method (light protection)
Solubility in Methanol	Freely soluble	Solubility Test
Bulk Density	1.24-1.28 g/cm <sup>3</sup>	Pycnometer Method
Photostability	≤ 0.5% related substances after 7 days (25°C, light exposure)	HPLC

### 3. Product Advantages



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1. **High SERM Selectivity:** Potent and highly selective binding to estrogen receptors (ER $\alpha$ /ER $\beta$ ); low affinity for other nuclear receptors, reducing adverse effects such as hot flashes and breast tenderness associated with non-selective SERMs.
2. **Potent Ovulation-Inducing Efficacy:** Targets the hypothalamus-pituitary-ovarian axis to effectively induce ovulation; ovulation rate up to 70-80% in anovulatory patients, pregnancy rate up to 30-40% with single course treatment; the first-line drug for clinical anovulatory infertility.
3. **Optimal Pharmacokinetics:** Good oral bioavailability ( $\approx$ 90%); rapid absorption in the gastrointestinal tract, peak plasma concentration at 2-6 hours; long half-life ( $\approx$ 5 days), once-daily administration, high patient compliance; good tissue penetration, effective for central estrogen receptor blockade.
4. **Pharmaceutical Grade Purity:** Meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits; high assay ( $\geq$ 98.5%) and low related substances; suitable for GMP production of clinical oral gynecological ovulation-inducing formulations.
5. **Excellent Formulation Compatibility:** Freely soluble in organic solvents, compatible with common oral pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol); easy to prepare tablets and capsules for clinical gynecological treatment; stable in granulation and tableting processes.

## 4. Application Fields

### 4.1 Pharmaceutical Industry (Oral Gynecological Ovulation-Inducing Formulations)

- **Anovulatory Infertility:** Core raw material for 50mg oral tablets/capsules; first-line treatment for female anovulatory infertility (polycystic ovary syndrome, hypothalamic dysfunction); 50mg once daily for 5 days (start on the 5th day of menstrual cycle), adjustable according to ovulation response.
- **Polycystic Ovary Syndrome (PCOS):** Formulation for treating PCOS-related anovulation; combined with metformin for synergistic efficacy, improving ovulation rate and pregnancy rate in PCOS patients.

## 5. Usage & Formulation Guidelines

### 5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets/Capsules (Adults):** 50mg per unit; standard dose: 50mg once daily for 5 consecutive days (start on day 5 of menstrual cycle); maximum dose: 150mg once daily for 5 days (for poor ovulation response).
- **Clinical Course:** 3 consecutive menstrual cycles as one course; evaluate ovulation status (B-ultrasound, luteinizing hormone test) after each course, adjust dosage according to response.

## 6. Packaging & Storage

### 6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, **light protection**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection and moisture-proof**).

## 7. Safety & Protection

- The product is a highly selective SERM gynecological pharmaceutical intermediate with irritant and mild reproductive/hepatic toxic effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **light protection**; monitor reproductive and hepatic function for personnel with prolonged handling exposure.