

Technical Data Sheet (TDS)

1. Product Overview

Product Name: Ethinylestradiol **English Name:** Ethinylestradiol **CAS Number:** 57-63-6 **Molecular**

Formula: $C_{20}H_{24}O_2$ **Molecular Weight:** 296.40 g/mol **Product Characteristics:** Synthetic steroidal estrogen, a potent derivative of estradiol with an ethynyl group at the C17 position. White to off-white crystalline powder, odorless, insoluble in water, soluble in ethanol, chloroform and pyridine. Stable under recommended storage conditions, with strong estrogenic activity, able to regulate female reproductive system development and endocrine balance. High purity, stable biological potency, core raw material for oral contraceptives and estrogen replacement therapy drugs.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powder **Assay (HPLC):** $\geq 98.5\%$ **Melting Point:** 180-186°C **Loss on Drying:** $\leq 0.5\%$ **Residue on Ignition:** $\leq 0.1\%$ **Heavy Metals (Pb):** ≤ 10 ppm **Heavy Metals (As):** ≤ 2 ppm **Related Substances (Total):** $\leq 1.0\%$ **Optical Rotation (c=1, pyridine, 25°C):** +75° to +85° **Solubility:** Insoluble in water, soluble in ethanol/chloroform/pyridine, slightly soluble in ether **Storage Stability:** Stable for 24 months at 2-8°C (sealed, dark condition) **pH Value:** Not applicable (insoluble in water)

3. Product Advantages

High Purity: Assay $\geq 98.5\%$, low impurity content, batch-to-batch quality consistency meeting pharmaceutical grade standards.

Potent Estrogenic Activity: High biological potency, low effective dosage, suitable for various estrogen drug formulation.

Excellent Stability: Long shelf life under recommended storage, no easy degradation and activity loss.

Good Solubility: Soluble in common organic solvents, compatible with oral and pharmaceutical formulation processes.

Standardized Production: Manufactured in accordance with ISO 9001 quality management system, complete testing data and strict quality control.

4. Application Fields

- **Pharmaceutical Industry:** Core raw material for human pharmaceutical formulations (combined oral contraceptives, estrogen replacement therapy drugs, treatment of gynecological diseases such as hypoestrogenism).
- **Research & Development:** Laboratory research on estrogen hormone mechanism, reproductive system drug development, steroid hormone activity testing and new drug screening.
- **Fine Chemicals:** Intermediate for the synthesis of other estrogen derivatives and modified steroidal hormone products.

5. Usage Methods

- **Pharmaceutical Formulation:** Dissolve in appropriate organic solvent (ethanol/chloroform) according to formulation requirements, prepare oral tablets, capsules or compound preparations; adjust the concentration and dosage based on specific drug specifications and clinical needs.
- **Research Use:** Prepare standard solutions with ethanol (1-5 mg/mL) for laboratory tests, the specific dosage is determined by the research protocol and experimental design.



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- Note: Strictly follow national pharmaceutical regulations and relevant industry standards for use, only for industrial production and scientific research purposes, no unauthorized use.

6. Packaging & Storage

Packaging Specifications:

- 100 g/bottle (HDPE bottle with aluminum foil seal)
- 500 g/bottle (HDPE bottle with aluminum foil seal)
- 1 kg/tin can (sealed tin can with inner plastic bag)
- 5 kg/fiber drum (sealed fiber drum with inner plastic bag)
- Custom packaging available upon request.

Storage Conditions:

- Store in a cool, dry, dark place at 2-8°C, keep the container tightly sealed to avoid moisture and light exposure.
- Keep away from heat, open flame, strong oxidizing agents, strong acids and strong bases.
- Store separately from food, beverages, aquatic products and raw materials for edible use, and keep away from other non-compatible chemicals.**Shelf Life:** 24 months (unopened, under specified storage conditions).**Transportation:** Non-hazardous for transport under sealed condition; avoid high temperature, sunlight, collision and rough handling during transportation; use refrigerated transport for long-distance shipping to ensure product stability.

7. Safety & Protection

- The product is a synthetic steroidal estrogen, avoid direct skin contact and dust inhalation during handling and operation.
- Wear nitrile rubber gloves, safety glasses and dust mask for large-scale handling, prolonged contact or powder operation.
- In case of skin contact: Rinse the affected area with plenty of soap and running water for at least 5 minutes; remove contaminated clothing and wash before reuse.
- In case of eye contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes, lifting the upper and lower eyelids occasionally; consult a doctor if irritation or discomfort persists.
- Do not ingest the product; if accidentally swallowed, rinse mouth with water immediately and seek medical advice from a professional physician at once.

8. Quality Assurance

- The product is manufactured in accordance with ISO 9001 quality management system and pharmaceutical raw material production specifications, with complete production process records and quality inspection data.
- Each batch of product is fully tested by professional quality inspection personnel and accompanied by a Certificate of Analysis (COA) to ensure compliance with industrial standards and product specifications.
- Provide professional technical support and after-sales service for product application, including formulation optimization, solubility guidance and quality control suggestions.
- Undertake quality responsibility for qualified products under normal storage, transportation and use conditions.