



NEWAY SINOPHC TECH. LIMITED

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Technical Data Sheet (TDS)

1. Product Overview

Product Name: Estradiol **English Name:** Estradiol **CAS Number:** 50-28-2 **Molecular Formula:**

$C_{18}H_{24}O_2$ **Molecular Weight:** 272.38 g/mol **Product Characteristics:** Endogenous steroidal estrogen, the primary and most potent natural estrogen in the human body. White to off-white crystalline powder, odorless, slightly soluble in water, soluble in ethanol, chloroform, ether and vegetable oils. Stable under recommended storage conditions, with strong physiological estrogenic activity, regulating the development and function of the female reproductive system, maintaining secondary sexual characteristics and bone metabolism balance. High purity, natural biological compatibility, core raw material for estrogen replacement therapy and gynecological drug formulation.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powder **Assay (HPLC):** $\geq 98.5\%$ **Melting Point:** 175-180°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, ethanol, 25°C):** +76° to +86° **Solubility:** Slightly soluble in water, soluble in ethanol/chloroform/ether, miscible in vegetable oils **Storage Stability:** Stable for 24 months at 2-8°C (sealed, dark condition) **pH Value:** Not applicable (slightly soluble in water)

3. Product Advantages

Natural Endogenous Structure: Consistent with the human body's natural estrogen, high biological compatibility, low side effect potential for clinical application.

High Purity and Potency: Assay $\geq 98.5\%$, low impurity content, stable and high estrogenic activity meeting pharmaceutical grade raw material standards.

Good Stability and Solubility: Long shelf life under recommended storage; soluble in common organic solvents and vegetable oils, suitable for various pharmaceutical formulation processes (oral, injectable, topical).

Diverse Biological Activity: Regulates female reproductive system, bone metabolism and cardiovascular function, with broad application prospects in pharmaceutical research and development.

Standardized Production: Manufactured in accordance with ISO 9001 quality management system and GMP guidelines, complete production and quality inspection records, reliable product quality.

4. Application Fields

- **Pharmaceutical Industry:** Core raw material for human pharmaceutical formulations (estrogen replacement therapy drugs, treatment of hypoestrogenism, menopause syndrome, osteoporosis and gynecological diseases such as ovarian insufficiency).
- **Research & Development:** Laboratory research on estrogen hormone mechanism, reproductive biology, endocrinology research, steroid hormone activity testing and new drug development for estrogen-related diseases.
- **Fine Chemicals:** Intermediate for the synthesis of other natural and synthetic estrogen derivatives, modified steroidal hormone products and pharmaceutical intermediates.
- **Cosmeceuticals:** Raw material for high-end cosmeceuticals with anti-aging and skin care effects (complies with relevant cosmeceutical regulations).

5. Usage Methods

- **Pharmaceutical Formulation:** Dissolve in appropriate organic solvent (ethanol/chloroform) or vegetable oil according to formulation requirements, prepare oral tablets, capsules, injectable formulations or topical creams; adjust the concentration and dosage based on clinical needs and drug specifications.



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- Research Use: Prepare standard solutions with ethanol (1-10 mg/mL) for laboratory tests and in vitro/in vivo experiments; the specific dosage is determined by the research protocol and experimental design.
- Cosmeceutical Use: Add to the formula at a low concentration (0.01-0.1%) after dissolving in vegetable oil or cosmetic solvent, in accordance with national cosmeceutical regulations and safety standards.
- Note: Strictly follow national pharmaceutical and relevant industry regulations for use; the clinical application must be under the guidance of a physician; only for industrial production, scientific research and qualified cosmeceutical formulation, 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 (for cosmeceutical and research use).

Storage Conditions:

- Store in a cool, dry, dark place at 2-8°C, keep the container tightly sealed with aluminum foil to avoid moisture, light and air contact.
- Keep away from heat, open flame, strong oxidizing agents, strong acids and strong bases; avoid storage in a humid environment to prevent hygroscopicity.
- Store separately from food, beverages, aquatic products, feed and raw materials for edible use; separate from other non-compatible chemicals in the warehouse. **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 (2-8°C) for long-distance shipping to maintain product activity and stability.

7. Safety & Protection

- The product is an endogenous estrogen, avoid direct skin contact and dust inhalation during handling, especially for long-term and large-scale operation.
- Wear nitrile rubber gloves, safety glasses and dust mask for powder operation, weighing and packaging; wear a face shield for large-scale spillage handling.
- In case of skin contact: Rinse the affected area with plenty of soap and running water for 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; consult a doctor if irritation, redness or discomfort persists.
- Do not ingest the product; if accidentally swallowed, rinse mouth with water immediately and seek professional medical advice if gastrointestinal discomfort occurs.

8. Quality Assurance

- The product is manufactured in accordance with ISO 9001 quality management system and pharmaceutical raw material production specifications, with strict quality control in each production process (raw material inspection, production process control, finished product testing).
- Each batch of product is fully tested by professional quality inspection personnel with advanced testing equipment, and accompanied by a Certificate of Analysis (COA) to ensure all indicators meet industrial standards and product specifications.
- Provide one-stop technical support for product application, including formulation optimization, solubility guidance, quality control suggestions and experimental scheme design for scientific research use.