



# NEWAY SINOPHC TECH. LIMITED

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## Technical Data Sheet (TDS)

### 1. Product Overview

**Product Name:** Progesterone **English Name:** Progesterone **CAS Number:** 57-83-0 **Molecular Formula:**  $C_{21}H_{30}O_2$  **Molecular Weight:** 314.46 g/mol **Product Characteristics:** Endogenous progestogen hormone, the primary female sex hormone for pregnancy maintenance. White to creamy white crystalline powder, odorless, tasteless, insoluble in water, soluble in ethanol, chloroform and vegetable oils. Stable under recommended storage conditions, with strong progestational activity, promoting endometrial hyperplasia, maintaining pregnancy and regulating the menstrual cycle. High purity, stable biological activity, core raw material for gynecological and reproductive pharmaceutical formulation.

### 2. Technical Specifications (Complies with Industrial Standards)

**Appearance:** White to creamy white crystalline powder **Assay (HPLC):**  $\geq 98.0\%$  **Melting Point:** 128-131 °C **Loss on Drying:**  $\leq 0.5\%$  **Residue on Ignition:**  $\leq 0.1\%$  **Heavy Metals (Pb):**  $\leq 10$  ppm **Heavy Metals (As):**  $\leq 2$  ppm **Related Substances (Total):**  $\leq 1.5\%$  **Related Substances (Single):**  $\leq 0.5\%$  **Optical Rotation (c=1, ethanol, 25°C):**  $+186^\circ$  to  $+198^\circ$  **Solubility:** Insoluble in water, soluble in ethanol/chloroform, slightly soluble in vegetable oils **Storage Stability:** Stable for 24 months at 2-8°C (sealed, dark condition) **pH Value:** Not applicable (insoluble in water)

### 3. Product Advantages

1. High Purity & Low Impurity: Assay  $\geq 98.0\%$ , low single and total related substances, meeting pharmaceutical raw material standards.
2. Endogenous Bioactivity: Natural hormone structure, high biological potency and physiological compatibility.
3. Excellent Stability: Long shelf life under recommended storage, no easy degradation and activity loss.
4. Good Solubility: Soluble in common organic solvents, suitable for oral, injectable and topical formulation development.
5. Standardized Production: Manufactured in line with ISO 9001 and pharmaceutical GMP guidelines, complete testing data and reliable quality.

### 4. Application Fields

- Pharmaceutical Industry: Core raw material for human pharmaceutical formulations (oral contraceptives, progesterone supplements, pregnancy maintenance drugs, gynecological disease treatment).
- Research & Development: Laboratory research on progestogen hormone mechanism, reproductive system drug development, steroid hormone activity testing.
- Fine Chemicals: Intermediate for the synthesis of progesterone derivatives and modified progestogen products.

### 5. Usage Methods

- Pharmaceutical Formulation: Dissolve in appropriate organic solvent (ethanol/chloroform) or vegetable oil according to formulation requirements, prepare injectable formulations, oral tablets,



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capsules or topical creams; adjust concentration and dosage based on specific drug specifications.

- Research Use: Prepare standard solutions with ethanol (1-5 mg/mL) for laboratory tests, the specific dosage is determined by the research protocol.
- Note: Strictly follow national pharmaceutical regulations for use, only for industrial and 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.
- 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.**Shelf Life:** 24 months (unopened, under specified storage conditions).**Transportation:** Non-hazardous for transport under sealed condition; avoid high temperature, sunlight and collision during transportation; use refrigerated transport for long-distance shipping.

### 7. Safety & Protection

- The product is an endogenous hormone, avoid direct skin contact and dust inhalation during handling.
- Wear nitrile rubber gloves, safety glasses and dust mask for large-scale handling or prolonged contact.
- In case of skin contact: Rinse the affected area with plenty of soap and 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 persists.
- Do not ingest; if accidentally swallowed, rinse mouth with water and seek medical advice immediately.

### 8. Quality Assurance

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