

## Technical Data Sheet (TDS)

### 1. Product Overview

**Product Name:** Prednisolone **English Name:** Prednisolone **CAS Number:** 50-24-8 **Molecular Formula:**  $C_{21}H_{28}O_5$  **Molecular Weight:** 360.44 g/mol **Product Characteristics:** Synthetic glucocorticoid derived from hydrocortisone, with potent anti-inflammatory, anti-allergic and immunosuppressive activity, and almost no mineralocorticoid activity (low sodium retention side effect). White to off-white crystalline powder, slightly soluble in water, soluble in ethanol, chloroform and organic solvents. Stable under recommended storage conditions, with stronger anti-inflammatory activity than hydrocortisone and lower adverse reactions related to water and electrolyte balance. High purity, stable biological activity, core raw material for anti-inflammatory, autoimmune and allergic disease pharmaceutical formulation.

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

**Appearance:** White to off-white crystalline powder **Assay (HPLC):**  $\geq 98.5\%$  **Melting Point:** 220-230°C (decomposes) **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):**  $\leq 1.0\%$  **Related Substances (Single):**  $\leq 0.3\%$  **Optical Rotation (c=1, ethanol, 25°C):** +105° to +112° **Solubility:** Slightly soluble in water, soluble in ethanol/chloroform/DMSO/acetone **Storage Stability:** Stable for 36 months at 2-8°C (sealed, dark condition) **pH Value:** 5.0-7.0 (0.1% suspension in water)

### 3. Product Advantages

1. High Purity & Ultra-Low Impurity: Assay  $\geq 98.5\%$ , extremely low single and total related substances, meeting USP/EP/BP pharmaceutical grade standards and suitable for high-end pharmaceutical formulation.
2. High Potency & Low Side Effects: Strong anti-inflammatory and immunosuppressive activity, almost no mineralocorticoid effect, avoiding water and sodium retention, hypertension and other side effects.
3. Excellent Stability: Long shelf life of 36 months under 2-8°C storage, good chemical stability, no easy degradation, consistent batch-to-batch performance.
4. Versatile Solubility: Soluble in common organic solvents and polar solvents, suitable for injectable, oral, topical, inhaled and ophthalmic pharmaceutical formulation development.
5. GMP & ISO Certified Production: Manufactured in line with GMP pharmaceutical production standards and ISO 9001 quality management system, complete quality control and production traceability.

### 4. Application Fields



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- Pharmaceutical Industry: Core raw material for human pharmaceutical formulations (anti-inflammatory drugs for rheumatism, arthritis, asthma, dermatitis, allergic rhinitis, immunosuppressive drugs for autoimmune diseases and organ transplantation).
- Research & Development: Laboratory research on glucocorticoid structure-activity relationship, anti-inflammatory drug screening, autoimmune disease model research, steroid hormone receptor function test.
- Fine Chemicals: Intermediate for the synthesis of prednisolone derivatives (e.g., methylprednisolone) and high-potency glucocorticoid products with modified structure.

### 5. Usage Methods

- Pharmaceutical Formulation: Dissolve in appropriate organic solvent (ethanol/propylene glycol/dimethylformamide) or sterile water for injection with cosolvent according to formulation requirements, prepare injectable formulations, oral tablets/capsules, topical creams/ointments, inhaled aerosols or ophthalmic drops; adjust concentration and dosage strictly based on clinical needs and drug specifications.
- Research Use: Prepare standard solutions with DMSO/ethanol (1-4 mg/mL) for laboratory tests, the specific dosage is determined by the research protocol; store the prepared solution at -20°C, avoid repeated freezing and thawing to prevent activity loss.
- Note: Strictly follow national pharmaceutical regulations and GMP guidelines for use; the product is a high-potency prescription drug raw material, no unauthorized production, dilution and clinical use.

### 6. Packaging & Storage

#### Packaging Specifications:

- 25 g/bottle (brown glass bottle with rubber stopper and aluminum seal)
- 50 g/bottle (brown glass bottle with rubber stopper and aluminum seal)
- 100 g/bottle (brown glass bottle with rubber stopper and aluminum seal)
- 500 g/bottle (sealed tin can with inner plastic bag, dark protection)
- Custom small-volume packaging available upon request for scientific research.

#### Storage Conditions:

- Store in a cool refrigerator at 2-8°C, keep the container tightly sealed and protected from light to avoid moisture, oxidation and light-induced degradation.
- Keep away from heat, open flame, strong oxidizing agents, strong acids and strong bases; store in a dry environment.
- Store separately from food, beverages, aquatic products and other chemical reagents in a dedicated storage area.**Shelf Life:** 36 months (unopened, under specified 2-8°C storage conditions); 6 months after opening (stored at 2-8°C, sealed and protected from



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light).**Transportation:** Use refrigerated transport at 2-8°C, with insulated, shockproof and light-proof packaging; avoid direct sunlight, high temperature, collision and rough handling during transportation.

### 7. Safety & Protection

- The product is a high-potency synthetic glucocorticoid, strictly avoid direct skin contact, dust inhalation and accidental ingestion during handling and operation.
- Wear nitrile rubber gloves (thickness  $\geq 0.3$  mm), chemical splash goggles, N95 dust mask and impermeable protective clothing for all handling operations, especially powder weighing and transfer.
- 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 thoroughly 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 immediately if irritation or discomfort persists.
- Do not ingest; if accidentally swallowed, rinse mouth with water and seek medical advice immediately, provide the product MSDS to the attending physician.

### 8. Quality Assurance

- The product is manufactured in accordance with GMP pharmaceutical production standards and ISO 9001 quality management system, with strict control of each production process and impurity limit.
- Each batch of product is fully tested by an independent third-party quality control laboratory and accompanied by a Certificate of Analysis (COA) to ensure compliance with international pharmaceutical standards (USP/EP/BP).
- Provide one-stop professional technical support, including formulation optimization, solubility guidance, high-potency drug dilution scheme, stability test design and quality control method development.
- Undertake quality responsibility for qualified products under normal storage and use conditions, and provide 24-hour after-sales technical service for professional technical questions.