

Technical Data Sheet (TDS)

1. Product Overview

Product Name: Hydrocortisone **English Name:** Hydrocortisone **CAS Number:** 50-23-7 **Molecular Formula:** $C_{21}H_{30}O_5$ **Molecular Weight:** 362.46 g/mol **Product Characteristics:** Endogenous glucocorticoid with natural anti-inflammatory, anti-allergic, anti-shock and immunosuppressive activity, the primary glucocorticoid secreted by the adrenal cortex. White to off-white crystalline powder, slightly soluble in water, soluble in ethanol, chloroform and organic solvents. Stable under recommended storage conditions, with balanced glucocorticoid and mineralocorticoid activity, regulating carbohydrate, fat and protein metabolism while maintaining water and electrolyte balance. High purity, stable biological activity, core raw material for endocrine, anti-inflammatory and allergic disease pharmaceutical formulation and research.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powder **Assay (HPLC):** $\geq 98.5\%$ **Melting Point:** 214-220°C (decomposes) **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):** $\leq 1.0\%$ **Related Substances (Single):** $\leq 0.3\%$ **Optical Rotation (c=1, ethanol, 25°C):** +162° to +169° **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 & Low Impurity: Assay $\geq 98.5\%$, ultra-low single and total related substances, meeting USP/EP/BP pharmaceutical grade standards.
2. Natural Structure & Balanced Activity: Consistent with endogenous human hormone structure, balanced glucocorticoid and mineralocorticoid activity, low side effect risk in rational use.
3. Excellent Stability: Long shelf life of 36 months under 2-8°C storage, no easy degradation, good batch-to-batch consistency.
4. Versatile Solubility: Soluble in common organic solvents, suitable for injectable, oral, topical and ophthalmic pharmaceutical formulation development.
5. GMP Standard Production: Manufactured in line with GMP and ISO 9001 quality management system, complete production traceability and strict quality control.

4. Application Fields

- Pharmaceutical Industry: Core raw material for human pharmaceutical formulations (adrenal cortex insufficiency replacement therapy, anti-inflammatory drugs for rheumatism, asthma, allergic diseases, anti-shock drugs for critical illness).
- Research & Development: Laboratory research on endogenous glucocorticoid mechanism, adrenal gland function research, steroid hormone receptor binding test, new drug screening for endocrine diseases.
- Fine Chemicals: Intermediate for the synthesis of hydrocortisone derivatives and modified glucocorticoid products with high potency.

5. Usage Methods

- Pharmaceutical Formulation: Dissolve in appropriate organic solvent (ethanol/propylene glycol) or sterile water for injection with cosolvent according to formulation requirements, prepare

injectable formulations, oral tablets/capsules, topical creams/ointments or ophthalmic preparations; adjust concentration and dosage based on clinical needs and drug specifications.

- Research Use: Prepare standard solutions with DMSO/ethanol (1-3 mg/mL) for laboratory tests, the specific dosage is determined by the research protocol; store the prepared solution at -20°C for short-term use and avoid repeated freezing and thawing.
- Note: Strictly follow national pharmaceutical regulations and professional medical guidelines for use; the product is a prescription drug raw material, no unauthorized production and use.

6. Packaging & Storage

Packaging Specifications:

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

Storage Conditions:

- Store in a cool refrigerator at 2-8°C, keep the container tightly sealed and protected from light to avoid moisture and oxidation.
- Keep away from heat, open flame, strong oxidizing agents, strong acids and strong bases.
- Store separately from food, beverages, aquatic products and other chemical reagents.**Shelf Life:** 36 months (unopened, under specified 2-8°C storage conditions); 6 months after opening (stored at 2-8°C, sealed).**Transportation:** Use refrigerated transport at 2-8°C, with insulated and shockproof packaging; avoid direct sunlight, high temperature and collision during transportation.

7. Safety & Protection

- The product is an endogenous glucocorticoid, avoid direct skin contact, dust inhalation and accidental ingestion during handling.
- Wear nitrile rubber gloves, safety glasses and dust mask for large-scale handling or prolonged contact; wear protective clothing for powder handling.
- 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 GMP pharmaceutical production standards and ISO 9001 quality management system.
- Each batch of product is fully tested by an independent quality control laboratory and accompanied by a Certificate of Analysis (COA) to ensure compliance with international pharmaceutical standards.
- Provide professional technical support for product application, including formulation optimization, solubility guidance, quality control method development and stability test advice.