

Technical Data Sheet (TDS)

1. Product Overview

Product Name: Dexamethasone **English Name:** Dexamethasone **CAS Number:** 50-02-2 **Molecular Formula:** C₂₂H₂₉ FO₅ **Molecular Weight:** 392.46 g/mol **Product Characteristics:** High-potency synthetic fluorinated glucocorticoid with ultra-strong anti-inflammatory, anti-allergic, immunosuppressive and anti-shock activity. Far higher potency than hydrocortisone and prednisolone, with almost no mineralocorticoid activity. White to off-white crystalline powder, slightly soluble in water, soluble in ethanol, chloroform and organic solvents. Stable under recommended storage conditions, with long-lasting biological effects, core raw material for severe inflammatory, autoimmune and critical illness treatment.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powder **Assay (HPLC):** ≥ 98.5% **Melting Point:** 254-264°C (decomposes) **Loss on Drying:** ≤ 0.5% **Residue on Ignition:** ≤ 0.1% **Heavy Metals (Pb):** ≤ 10 ppm **Heavy Metals (As):** ≤ 2 ppm **Related Substances (Total):** ≤ 1.0% **Related Substances (Single):** ≤ 0.3% **Optical Rotation (c=1, dioxane, 25°C):** +72° to +80° **Fluoride Content:** 4.5-5.5% **Solubility:** Slightly soluble in water, soluble in ethanol/chloroform/DMSO/acetone/dioxane **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. Ultra-High Purity & Low Impurity: Assay ≥98.5%, ultra-low single and total related substances, precise fluoride content, meeting USP/EP/BP pharmaceutical grade standards.
2. Super Potency & Low Side Effects: Ultra-strong anti-inflammatory and immunosuppressive activity, almost no mineralocorticoid effect, avoiding water and sodium retention, hypertension and other adverse reactions.
3. Long-Lasting Effect: Long biological half-life, sustained therapeutic effect, reducing administration frequency for clinical use.
4. Excellent Stability: 36-month shelf life under 2-8°C storage, good batch-to-batch consistency, no easy degradation under normal conditions.
5. GMP Standard Production: Manufactured in line with GMP and ISO 9001 quality management system, complete production traceability and strict quality control at all stages.

4. Application Fields

- Pharmaceutical Industry: Core raw material for human pharmaceutical formulations (severe anti-inflammatory drugs for rheumatism, severe asthma, allergic shock, immunosuppressive drugs for organ transplantation, topical drugs for severe skin diseases, anti-shock drugs for critical illness).
- Research & Development: Laboratory research on high-potency glucocorticoid mechanism, severe inflammatory disease model research, new drug development for autoimmune diseases, steroid hormone potency testing.
- Fine Chemicals: Intermediate for the synthesis of dexamethasone derivatives (e.g., dexamethasone sodium phosphate) and ultra-high potency glucocorticoid products.

5. Usage Methods

- Pharmaceutical Formulation: Dissolve in appropriate organic solvent (ethanol/propylene glycol/dioxane) or sterile water for injection with cosolvent according to formulation requirements, prepare injectable formulations, oral tablets/capsules, topical creams/ointments or ophthalmic preparations; strictly control dosage due to ultra-high potency, adjust concentration based on clinical needs.

- Research Use: Prepare dilute standard solutions with DMSO/ethanol (0.1-1 mg/mL) for laboratory tests, the specific dosage is determined by the research protocol; store the prepared solution at -20°C and avoid repeated freezing and thawing.
- Note: Strictly follow national pharmaceutical regulations and professional medical guidelines for use; the product is a high-potency prescription drug raw material, no unauthorized production and 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 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 degradation.
- 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 in a dedicated locked storage area.**Shelf Life:** 36 months (unopened, under specified 2-8°C storage conditions); 3 months after opening (stored at 2-8°C, sealed and protected from light).**Transportation:** Use refrigerated transport at 2-8°C, with insulated, shockproof and light-proof packaging; avoid direct sunlight, high temperature and collision during transportation.

7. Safety & Protection

- The product is an ultra-high potency fluorinated glucocorticoid, strictly avoid direct skin contact, dust inhalation and accidental ingestion during handling.
- Wear nitrile rubber gloves (thickness ≥ 0.5 mm), chemical splash goggles, N95 dust mask and impermeable protective clothing for all handling operations.
- In case of skin contact: Rinse the affected area with plenty of soap and water for at least 10 minutes; remove contaminated clothing and wash thoroughly before reuse.
- In case of eye contact: Rinse eyes thoroughly with plenty of running water for 15 minutes; consult a doctor immediately 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, with strict control of raw materials, production processes and finished products.
- 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.
- Provide one-stop professional technical support, including formulation optimization, solubility guidance, high-potency drug dilution advice and stability test scheme design.
- Undertake quality responsibility for qualified products under normal storage and use conditions, and provide 24-hour after-sales technical service.