Technical Data Sheet (TDS)

1. Product Overview

Product Name: Betamethasone**English Name**: Betamethasone**CAS Number**: 378-44-9**Molecular Formula**: $C_{22}H_{29}FO_5$ **Molecular Weight**: 392.46 g/mol**Product Characteristics**: Synthetic fluorinated glucocorticoid with ultra-potent anti-inflammatory, anti-allergic and immunosuppressive activity, higher potency and longer duration of action than methylprednisolone. White to off-white crystalline powder, slightly soluble in water, soluble in ethanol, chloroform and organic solvents. Stable under recommended storage conditions, with strong anti-inflammatory effects on severe inflammatory and allergic reactions, and significant immunosuppressive effects. High purity, stable biological activity, core raw material for severe anti-inflammatory, autoimmune and allergic disease pharmaceutical formulation.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powderAssay (HPLC): ≥ 98.5%Melting Point: 235-245℃ (decomposes)Loss on Drying: ≤ 0.5%Residue on Ignition: ≤ 0.1%Heavy Metals (Pb): ≤ 10 ppmHeavy Metals (As): ≤ 2 ppmRelated Substances (Total): ≤ 1.0%Related Substances (Single): ≤ 0.3%Optical Rotation (c=1, dioxane, 25℃): +115° to +122°Fluoride Content: 4.5-5.5%Solubility: Slightly soluble in water, soluble in ethanol/chloroform/DMSO/acetone/dioxaneStorage Stability: Stable for 36 months at 2-8℃ (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 & Long Duration: Fluorinated glucocorticoid with ultra-strong anti-inflammatory and immunosuppressive activity, long biological half-life and sustained therapeutic effect.
3. Excellent Stability: Long shelf life of 36 months under 2-8℃ storage, good batch-to-batch consistency, resistance to degradation under normal storage conditions.
4. Good Solubility: Soluble in common organic solvents and dioxane, suitable for injectable, oral, topical and ophthalmic pharmaceutical formulation development.
5. GMP & ISO Certified 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 arthritis, severe asthma, allergic shock, immunosuppressive drugs for organ transplantation, topical drugs for severe skin diseases).
- 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 betamethasone derivatives (e.g., betamethasone valerate, betamethasone dipropionate) 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; adjust concentration and dosage strictly based on clinical needs and drug specifications (low dosage due to high potency).

- 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℃ 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, use and dilution.

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℃, 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℃ storage conditions); 3 months after opening (stored at 2-8℃, sealed and protected from light).**Transportation**: Use refrigerated transport at 2-8℃, with insulated, shockproof and light-proof packaging; avoid direct sunlight, high temperature and collision during transportation.

7. Safety & Protection

- The product is a 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.

8. Quality Assurance

- The product is manufactured in accordance with GMP pharmaceutical production standards and ISO 9001 quality management system, with strict control of fluoride content and impurity limits.
- 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).