纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

1. Product Overview

Product Name: Budesonide**English Name**: Budesonide**CAS Number**: 51333-22-3**Molecular Formula**: $C_{25}H_{34}O_6$ **Molecular Weight**: 430.54 g/mol**Product Characteristics**: Synthetic glucocorticoid hormone with high anti-inflammatory and anti-allergic activity, high topical potency and low systemic bioavailability. 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, anti-edema and anti-allergic effects on the respiratory tract, inhibiting airway inflammation and relieving asthma symptoms. High purity, low impurity, stable biological activity, core raw material for respiratory system pharmaceutical formulation and research.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powderAssay (HPLC): ≥ 98.5%Melting Point: 220-228℃ (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=0.5, chloroform, 25℃): +124° to +131°Solubility: Slightly soluble in water, soluble in chloroform/ethanol/DMSO/acetoneStorage Stability: Stable for 36 months at 2-8℃ (sealed, dark condition)pH Value: 5.0-7.0 (0.05% suspension in water)

3. Product Advantages

1. High Purity & Ultra-Low Impurity: Assay ≥98.5%, extremely low single and total related substances, meeting USP/EP pharmaceutical grade standards.
2. High Potency & Low Systemic Side Effects: Synthetic glucocorticoid with high topical anti-inflammatory activity, low systemic absorption and few side effects.
3. Excellent Stability: Long shelf life of 36 months under 2-8℃ storage, no easy degradation and activity loss, good batch-to-batch consistency.
4. Good Solubility: Soluble in common organic solvents, suitable for inhalation, nasal spray, oral and topical pharmaceutical formulation development.
5. Standardized GMP Production: Manufactured in line with GMP and ISO 9001 standards, complete quality control system and traceable production process.

4. Application Fields

- Pharmaceutical Industry: Core raw material for human pharmaceutical formulations (inhaled asthma drugs, nasal spray for allergic rhinitis, topical anti-inflammatory ointment, oral enteric-coated tablets for inflammatory bowel disease).
- Research & Development: Laboratory research on glucocorticoid anti-inflammatory mechanism, respiratory tract inflammation research, new drug development for allergic diseases and autoimmune diseases.
- Fine Chemicals: Intermediate for the synthesis of budesonide derivatives and modified glucocorticoid products with high potency and low toxicity.

5. Usage Methods

- Pharmaceutical Formulation: According to different formulation types, dissolve in appropriate organic solvent (ethanol/chloroform/propanediol), prepare inhalation aerosols, nasal sprays, topical ointments or oral enteric-coated preparations; adjust concentration and dosage based on drug specifications and clinical needs.

- Research Use: Prepare standard solutions with DMSO/ethanol (0.5-2 mg/mL) for laboratory tests, the specific dosage is determined by the research protocol; the prepared solution can be stored at -20℃ for a short time.
- Note: Strictly follow national pharmaceutical regulations and GMP 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℃, 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℃ storage conditions); 6 months after opening (stored at 2-8℃, sealed).**Transportation**: Use refrigerated transport at 2-8℃, with insulated packaging; avoid direct sunlight, high temperature, collision and rough handling during transportation.

7. Safety & Protection

- The product is a synthetic 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 one-stop professional technical support, including formulation optimization, solubility guidance, quality control method development and stability test advice.
- Undertake quality responsibility for qualified products under normal storage and use conditions, and provide after-sales technical service.