

Technical Data Sheet (TDS)

1. Product Overview

Product Name: Methylprednisolone **English Name:** Methylprednisolone **CAS Number:** 83-43-2 **Molecular Formula:** C₂₂H₃₀ O₅ **Molecular Weight:** 374.47 g/mol **Product Characteristics:** Synthetic glucocorticoid with potent anti-inflammatory, anti-allergic and immunosuppressive activity, higher potency and shorter half-life than prednisone. 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 various inflammatory reactions, inhibiting immune response and relieving allergic symptoms. 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):** ≥ 98.5% **Melting Point:** 220-230°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):** +79° to +86° **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 ≥98.5%, ultra-low single and total related substances, meeting USP/EP/BP pharmaceutical grade standards.
2. High Potency & Selective Activity: Strong anti-inflammatory and immunosuppressive effects, low mineralocorticoid activity, reducing water and sodium retention side effects.
3. Excellent Stability: Long shelf life of 36 months under 2-8°C storage, good batch-to-batch consistency, no easy degradation.
4. Versatile Solubility: Soluble in common organic solvents, suitable for injectable, oral, topical pharmaceutical formulation development.
5. GMP Standard Production: Manufactured in line with GMP and ISO 9001 quality management system, complete traceability and strict quality control.

4. Application Fields

- Pharmaceutical Industry: Core raw material for human pharmaceutical formulations (anti-inflammatory drugs for rheumatism, arthritis, asthma, allergic diseases, immunosuppressive drugs for organ transplantation).
- Research & Development: Laboratory research on glucocorticoid mechanism, anti-inflammatory drug screening, autoimmune disease model research, steroid hormone activity testing.
- Fine Chemicals: Intermediate for the synthesis of methylprednisolone derivatives and high-potency glucocorticoid products.

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 or topical creams; adjust concentration and dosage based on clinical needs and drug specifications.



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- Research Use: Prepare standard solutions with DMSO/ethanol (1-5 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.
- 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 a potent 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 professional technical support for product application, 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 comprehensive after-sales technical service.