

Technical Data Sheet (TDS) - Manidipine

Revision Date: 20 FEB 2026 **CAS Number:** 89226-50-6 **Molecular Formula:** C₃₅ H₃₈ N₄O₆ **Molecular Weight:** 602.70 g/mol

1. Product Overview

Manidipine is a high-purity pharmacopoeial-grade dihydropyridine calcium channel blocker (CCB), a core pharmaceutical raw material for clinical antihypertensive therapy. It exerts a selective blocking effect on vascular smooth muscle L-type and T-type calcium ion channels, dilating peripheral arterioles and coronary arteries, reducing peripheral vascular resistance, and achieving a stable and long-acting antihypertensive effect without obvious negative inotropic effect. With high target selectivity, long half-life, mild adverse reactions and good oral bioavailability, it is widely used in the production of clinical oral solid preparations for essential hypertension and combined hypertension.

2. Technical Specifications (Complies with USP 45 & ChP 2025)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (on dry basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Melting Point	124 ~ 128°C
Optical Rotation (25°C, c=1 in CHCl ₃)	+42° ~ +48°
pH Value (0.1% methanol solution, 25°C)	6.0 ~ 8.0
Solubility	Sparingly soluble in water; freely soluble in chloroform/methanol; soluble in ethanol/acetonitrile
Stability	Stable at 2~8°C, dark and sealed conditions; degraded by strong light/heat/humidity
Microbial Limit	Total bacterial count ≤ 100 CFU/g; E. coli negative; Mold & yeast ≤ 10 CFU/g
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)
Plasma Protein Binding Rate	≥ 98% (in vitro test)

3. Product Advantages

- Double Calcium Channel Blockade:** Selectively blocks L-type and T-type calcium channels, dilates both large and small blood vessels, achieves smooth and sustained blood pressure reduction, and reduces the risk of reflex tachycardia compared with single L-type channel blockers.
- Long-Acting Antihypertensive Effect:** Long half-life (≈24 hours), once-daily administration can maintain 24-hour blood pressure control, conform to the circadian rhythm of blood pressure, and reduce the risk of morning blood pressure surge.
- Good Organ Protection:** While lowering blood pressure, it dilates coronary arteries and renal arterioles, has protective effects on the heart and kidneys, and is suitable for hypertensive patients with mild coronary heart disease or early renal damage.
- High Purity & Stable Quality:** Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; good chemical stability under recommended storage conditions, compatible with common pharmaceutical excipients for oral solid formulations.

5. **Mild Adverse Reactions:** Low incidence of common CCB adverse reactions such as ankle edema, flushing and headache; no obvious effect on cardiac contractility and atrioventricular conduction, suitable for long-term clinical administration.

4. Application Fields

Pharmaceutical Raw Material for Clinical Cardiology & Hypertension Therapy:

- **Hypertension:** Essential hypertension, mild to moderate combined hypertension, isolated systolic hypertension (especially in the elderly).
- **Associated Indications:** Hypertensive patients with mild coronary heart disease, early renal damage or cerebral arteriosclerosis (adjuvant vascular protection).
- **Dosage form production:** 5mg/10mg/20mg oral tablets (main dosage form), 5mg hard capsules (pediatric/elderly reduced dosage), 10mg sustained-release tablets (long-acting formulation).

5. Usage Methods (for Pharmaceutical Formulation)

Oral Solid Formulation (Tablets/Capsules)

- **10mg Oral Tablet:** Mix Manidipine with microcrystalline cellulose (filler), croscarmellose sodium (disintegrant), hypromellose (binder) and magnesium stearate (lubricant), adopt wet granulation process (ethanol-water as wetting agent), granulate at low temperature (<60°C), compress and coat with film coating to prepare oral tablets.
- **Processing Requirements:** Avoid strong light, high temperature and high humidity during the whole production process; control the moisture content of granules ≤ 0.5% to prevent drug hydrolysis and crystallization; tablet disintegration time ≤ 30 minutes (artificial gastric juice).
- **5mg Hard Capsule:** Mix the granulated Manidipine with lactose monohydrate (diluent) evenly, fill into hard gelatin capsules of appropriate size; the capsule shell uses light-proof medical grade material to avoid photodegradation.

Sustained-Release Tablet Formulation

- **20mg Sustained-Release Tablet:** Use hypromellose as the sustained-release matrix, mix with Manidipine and other excipients, adopt direct powder compression process, and coat with water-insoluble film to prepare sustained-release tablets; the drug release rate is controlled at 20-30% in 2h, 50-60% in 6h, and ≥80% in 24h.

6. Packaging & Storage

Packaging Specifications

- 1 g / brown glass sealed bottle (nitrogen-filled, R&D/laboratory use)
- 5 g / aluminum foil vacuum-sealed brown glass bottle (pilot production)
- 25 g / stainless steel sealed drum (nitrogen-filled, industrial GMP production)
- 100 g / HDPE light-proof sealed drum (for oral formulation raw material)
- Custom GMP-compliant nitrogen-filled light-proof packaging for bulk orders available.

Storage Conditions

- **Storage Temperature:** 2 ~ 8°C (refrigerated, dark place); avoid freezing and high temperature (>25°C).
- **Sealing Requirement:** Nitrogen-filled tight sealing to prevent oxidation, moisture absorption and photodegradation; strict light protection (UV-proof packaging).
- **Incompatibilities:** Store separately from strong acids, strong bases, oxidizing agents, high-humidity substances and photosensitizers.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable light-proof protective clothing) during handling to avoid skin/mucosa contact and dust inhalation.
- In case of skin contact: Rinse with plenty of running water and soap for 10-15 minutes; apply mild emollient if irritation occurs.
- In case of eye contact: Rinse with sterile water for injection for 15 minutes; consult a physician immediately if irritation persists.
- Do not ingest; accidental oral intake may cause hypotension, dizziness, nausea—seek emergency medical treatment at once and conduct symptomatic treatment (e.g., fluid replacement, blood pressure support).