

Technical Data Sheet (TDS) - Finerenone

Revision Date: 29 FEB 2026 **CAS Number:** 1050477-31-0 **Molecular Formula:** C₂₃H₂₂F₄N₄O₃S **Molecular Weight:** 512.51 g/mol

1. Product Overview

Finerenone is a high-purity pharmacopoeial-grade selective nonsteroidal mineralocorticoid receptor antagonist (MRA), a core pharmaceutical raw material for clinical treatment of chronic kidney disease (CKD) associated with type 2 diabetes and heart failure. It exerts its pharmacological effect by selectively binding to mineralocorticoid receptors (MR) in the kidney, heart and blood vessels, blocking the harmful effects of aldosterone-mediated MR overactivation, reducing renal fibrosis, myocardial hypertrophy and vascular damage. With high MR selectivity, low risk of hyperkalemia and good oral bioavailability, it is widely used in the production of clinical oral solid preparations for diabetic kidney disease and chronic heart failure.

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	235 ~ 239 °C
Optical Rotation (25 °C, c=1 in DMSO)	0° ± 2°
pH Value (0.1% DMSO solution, 25 °C)	6.0 ~ 8.0
Solubility	Sparingly soluble in water; freely soluble in DMSO, acetonitrile; soluble in ethanol, methanol
Stability	Stable at 2~8 °C, dark and sealed conditions; degraded by strong light/heat/acid
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)

3. Product Advantages

- High-Selectivity MR Antagonism:** Precisely targets mineralocorticoid receptors with no significant affinity for glucocorticoid, progesterone and androgen receptors, reducing off-target side effects (e.g., gynecomastia) and lowering the risk of hyperkalemia compared with traditional MRAs.
- Dual Organ Protection:** Simultaneously exerts renal and cardiac protective effects, delays the progression of chronic kidney disease in type 2 diabetes patients, and reduces the risk of cardiovascular events in heart failure patients, with proven clinical benefits.
- Good Oral Bioavailability:** Rapid absorption after oral administration, peak plasma concentration at 1~2 hours, oral bioavailability of approximately 60%, and long half-life (~18 hours), supporting once-daily administration.
- 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.
- Favorable Safety Profile:** Lower risk of hyperkalemia and volume depletion, suitable for long-term administration in patients with mild to moderate renal insufficiency, with a low incidence of adverse reactions.

4. Application Fields

Pharmaceutical Raw Material for Clinical Nephrology and Cardiology Therapy:

- **Chronic Kidney Disease:** CKD associated with type 2 diabetes (stages 2-4), reduces albuminuria and delays renal function deterioration.
- **Heart Failure:** Chronic heart failure with reduced ejection fraction (HFrEF) and preserved ejection fraction (HFpEF), reduces cardiovascular mortality and hospitalization risk.
- **Potential Indications:** Hypertensive nephropathy, diabetic cardiomyopathy (clinical research stage).
- **Dosage form production:** 10mg/20mg/40mg oral tablets (main dosage form), 5mg hard capsules (pediatric/elderly reduced dosage).

5. Usage Methods (for Pharmaceutical Formulation)

Oral Solid Formulation (Tablets/Capsules)

- **20mg Oral Tablet:** Mix Finerenone 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 and high temperature during the whole production process; control the moisture content of granules $\leq 0.5\%$ to prevent drug hydrolysis; tablet disintegration time ≤ 30 minutes (artificial gastric juice).
- **10mg Hard Capsule:** Mix the granulated Finerenone 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.

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 and moisture absorption; strict light protection to avoid photodegradation.
- **Incompatibilities:** Store separately from strong acids, oxidizing agents, heavy metal ions and photosensitizers.
- **Shelf Life:** 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated, used up as soon as possible with strict record).

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 gastrointestinal discomfort, hyperkalemia—seek emergency medical treatment at once and conduct symptomatic treatment.
- Operate in a well-ventilated GMP workshop with negative pressure dust collection and light-proof facilities; avoid strong light and high temperature during material transfer and processing.