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Technical Data Sheet (TDS) - Rosuvastatin Calcium

Revision Date: 25 FEB 2026**Product Name**: Rosuvastatin Calcium 罗舒伐他汀钙**CAS Number**: 147098-20-2**Formula**: $C_{44}H_{54}CaF_2N_6O_{12}S_2$**Molecular Weight**: 1001.15 g/mol

1. Product Overview

Rosuvastatin Calcium is a high-purity pharmaceutical-grade selective **HMG-CoA reductase inhibitor**, a core raw material for clinical lipid-lowering preparations. It exerts a potent lipid-lowering effect by competitively inhibiting the rate-limiting enzyme of cholesterol biosynthesis, reducing hepatic cholesterol synthesis, increasing hepatic LDL receptor expression, and lowering serum total cholesterol, LDL-cholesterol and triglyceride levels. It is a white amorphous/crystalline powder with slight water solubility, stable physical and chemical properties under recommended storage conditions, and is widely used in the production of oral solid pharmaceutical preparations for the treatment of hypercholesterolemia, mixed dyslipidemia and coronary heart disease.

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

Item	Specification
Appearance	White to off-white amorphous/crystalline powder
Assay (on dry basis)	98.0 ~ 102.0%
Related Substances	Total ≤ 1.0%; Single Impurity ≤ 0.2%
Loss on Drying	≤ 1.0%
Residue on Ignition	0.9 ~ 1.1%
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Calcium Content	4.0 ~ 4.4%
pH Value (0.5% aq. suspension,25℃)	5.0 ~ 7.0
Dissolution (30min, water)	≥ 80%
Total Bacterial Count	≤ 100 CFU/g
E. coli/Salmonella	Negative
Water Solubility (25℃)	~0.07 g/100 mL
Density (25℃, solid)	1.38-1.42 g/cm³
Temperature Stability	Stable at 0-30℃ (assay retention ≥ 98%)
pH Stability	Stable at pH 4.0-8.0 (activity retention ≥ 95%)
Photostability	Stable under protected light (assay retention ≥ 97% for 6 months)

3. Product Advantages

1. **Potent Lipid-Lowering Efficacy**: High selective inhibition of HMG-CoA reductase, significant reduction of LDL-C, TC and TG, slight increase of HDL-C, better curative effect than conventional statins at low dose.
2. **Good Safety Profile**: Low incidence of adverse reactions (muscle pain, liver function abnormality), no obvious drug-drug interaction with most cardiovascular drugs, suitable for long-term clinical use.
3. **Excellent Formulation Compatibility**: Compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol), suitable for oral tablets, capsules and dispersible tablets.
4. **Broad Clinical Application**: Effective for primary hypercholesterolemia, mixed dyslipidemia, and secondary prevention of coronary heart disease, applicable to adults and adolescents over 10 years old.
5. **High Purity & Stable Quality**: Pharmacopoeial grade purity, ultra-low impurity and heavy metal content, stable physical and chemical properties under recommended storage conditions.

6. **Convenient Administration**: Oral absorption is rapid, food has no significant effect on absorption, high patient compliance.

4. Application Fields

- **Pharmaceutical Lipid-Lowering Preparations**: Production of 5mg/10mg/20mg oral tablets, 10mg hard capsules, and dispersible tablets for clinical use.
- **Clinical Application**: Treatment of primary hypercholesterolemia, heterozygous familial hypercholesterolemia, mixed dyslipidemia; secondary prevention of myocardial infarction, stroke and other cardiovascular and cerebrovascular events in coronary heart disease patients.

5. Usage Methods

Dosage for Formulation (Adjust according to preparation type)

- **10mg Oral Tablet (Direct Compression Process)**: Rosuvastatin Calcium 10mg, lactose monohydrate 130mg, microcrystalline cellulose 75mg, cross-linked sodium carboxymethylcellulose 12mg, magnesium stearate 2mg, colloidal silicon dioxide 1mg.
- **5mg Dispersible Tablet**: Rosuvastatin Calcium 5mg, mannitol 150mg, crospovidone 10mg, aspartame 3mg, magnesium stearate 1.5mg, microcrystalline cellulose 40mg.
- **20mg Hard Capsule**: Rosuvastatin Calcium 20mg, lactose 80mg, microcrystalline cellulose 50mg, talc 3mg (filled into hard gelatin capsules).

Processing Requirements

- Operate in a low-humidity environment (RH ≤ 50%) and protected from light to prevent moisture absorption and photodegradation of the raw material.
- Ensure uniform mixing of the raw material and excipients to guarantee the content uniformity of the preparation, especially for low-dose formulations.
- Avoid high temperature (>60℃) during processing to prevent the degradation of active ingredients; the whole process complies with GMP pharmaceutical production specifications.

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 kg / HDPE light-proof sealed drum (nitrogen-filled, industrial GMP production)
- 100 kg / stainless steel light-proof sealed drum (bulk pharmaceutical raw material)
- Custom GMP-compliant nitrogen-filled light-proof packaging available for bulk orders.

Storage Conditions

- Store in a cool, dry, dark warehouse at 15~25℃; avoid high temperature (>30℃), direct sunlight and high humidity.
- Keep the container tightly closed and nitrogen-filled to prevent moisture absorption, oxidation and photodegradation; store separately from strong acids, strong bases and oxidizing agents.
- **Shelf Life**: 36 months (unopened, under specified storage conditions); 6 months after opening (sealed, low humidity, light-proof, used up as soon as possible).

Transportation

- Classified as non-hazardous pharmaceutical raw material; transport in compliance with national pharmaceutical raw material transportation regulations.
- Ambient temperature transport (15~25℃) with temperature and light monitoring; use shockproof, light-proof, moisture-proof packaging; avoid package collision and direct sunlight during transport.

7. Safety & Protection

- The product is a pharmaceutical raw material, not for direct human use; wear professional pharmaceutical PPE (nitrile rubber gloves, chemical safety goggles, dust mask, light-proof protective clothing) during handling.
- In case of skin contact: Rinse with plenty of running water and soap for 10 minutes; no special treatment for mild contact.
- In case of eye contact: Rinse with sterile water for injection for 15 minutes; consult a physician if irritation persists.