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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Mavacamten
- **CAS Number**: 1152311-62-0
- **Molecular Formula**: $C_{24}H_{28}N_4O_2$
- **Molecular Weight**: 404.51 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via chiral synthesis, amination and cyclization; purified by recrystallization and chiral separation to ensure high optical purity and low impurity content; optimized process for good formulation compatibility for oral cardiovascular preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; practically insoluble in water, freely soluble in DMSO/DMF, slightly soluble in methanol/ethanol; stable in dry, dark and neutral environment, mild hydrolysis in alkaline/moist environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Highly selective cardiac myosin ATPase inhibitor** with potent activity for treating hypertrophic cardiomyopathy (HCM); inhibits excessive cardiac myosin activity to reduce myocardial hypercontractility and left ventricular outflow tract obstruction; high oral bioavailability, good cardiac tissue penetration, low off-target effects; the classic cardiovascular raw material for treating symptomatic obstructive HCM in adults.
- **Main Application**: Pharmaceutical intermediate for human oral cardiovascular formulations (tablets, capsules); pharmaceutical R&D reference reagent for cardiology pharmacology and cardiac myosin inhibitor research; analytical reference material for pharmaceutical quality inspection of cardiovascular products.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Mavacamten)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Sulfate (SO_4^{2-})	≤ 0.02%	Turbidimetric Method
pH Value (1% DMSO suspension,25℃)	6.0-8.0	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method (light protection)
Solubility in DMSO	Freely soluble	Solubility Test
Bulk Density	1.22-1.26 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Optical Purity (ee)	≥ 99.5%	Chiral HPLC
Melting Point	235-241℃	Melting Point Apparatus (light

Item	Specification	Test Method
		protection)

3. Product Advantages

1. **High Target Selectivity**: Potent and highly selective inhibition of cardiac myosin ATPase; no significant activity against skeletal muscle myosin, minimal off-target effects and low cardiac toxic side effects.
2. **Potent HCM Therapeutic Effect**: Reduces myocardial hypercontractility and left ventricular outflow tract obstruction; improves exercise tolerance and symptomatic relief in obstructive HCM patients; no significant impact on normal cardiac function.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈75%); long half-life (≈18 hours), once-daily oral administration, high patient compliance; high cardiac tissue penetration, rapid onset of action (1-2 weeks).
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, optical purity ≥99.5%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical oral use for adult cardiovascular patients.
5. **Good Formulation Compatibility**: Freely soluble in organic solvents; compatible with common oral pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol); easy to prepare tablets and capsules for clinical cardiovascular treatment.
6. **Stable Storage Property**: 36-month shelf life under sealed, dark and dry conditions; slightly hygroscopic with no significant impact on quality; light protection only required for long-term storage.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Cardiovascular Formulations)

- **Obstructive Hypertrophic Cardiomyopathy**: Core raw material for 2.5mg/5mg/10mg oral tablets/capsules; first-line treatment for symptomatic obstructive HCM in adults; improves left ventricular diastolic function and exercise capacity.
- **Non-Obstructive HCM (R&D)**: Formulation development for non-obstructive HCM treatment under clinical research; high potential for broad cardiovascular disease application.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets/Capsules**: 2.5mg/5mg/10mg per unit; adult clinical starting dose 5mg once daily, titrated according to clinical response and tolerability (maximum 15mg once daily).

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, **light protection**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection and moisture-proof**).

7. Safety & Protection

- The product is a cardiac myosin inhibitor cardiovascular pharmaceutical intermediate with irritant and mild toxic effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **light protection**.
- Avoid direct sunlight and high humidity in the work area; keep the operation tools clean and dry; do not mix with other pharmaceutical raw materials randomly.