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

Technical Data Sheet (TDS)

Issue Date: 20 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Timolol Maleate
- **CAS Number**: 26839-75-8
- **Molecular Formula**: $C_{17}H_{24}N_4O_3 \cdot C_4H_4O_4$
- **Molecular Weight**: 432.45 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via morpholine coupling, thiadiazole ring formation and maleic acid salinization; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for ophthalmic and oral cardiovascular preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in water/methanol/ethanol, slightly soluble in acetonitrile; stable in dry, dark and neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with light protection.
- **Core Properties**: **Non-selective beta-adrenergic receptor blocker** with potent cardiovascular and ophthalmic activity; blocks beta-1 and beta-2 receptors to reduce cardiac output, lower blood pressure and decrease intraocular pressure (by reducing aqueous humor production); fast onset of action (15-30 minutes), long duration (24 hours); the classic pharmaceutical raw material for treating open-angle glaucoma, ocular hypertension, hypertension, angina pectoris and cardiac arrhythmias in adults.
- **Main Application**: Pharmaceutical intermediate for human ophthalmic eye drops and oral cardiovascular formulations (tablets, capsules); pharmaceutical R&D reference reagent for cardiovascular/ophthalmology pharmacology and beta-blocker research; analytical reference material for pharmaceutical quality inspection of cardiovascular/ophthalmic 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 (Timolol Maleate)	≥ 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% aqueous solution,25℃)	3.8-5.5	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 Water	Freely soluble	Solubility Test
Bulk Density	1.35-1.39 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	197-203℃	Melting Point Apparatus (light protection)

3. Product Advantages

1. **Potent Beta-Blocking Activity**: Non-selective beta-1/beta-2 receptor blockade; high potency for lowering blood pressure and intraocular pressure; effective for both cardiovascular and ophthalmic clinical indications with a single active ingredient.
2. **Dual Clinical Application**: Core raw material for both ophthalmic eye drops (glaucoma) and oral cardiovascular formulations (hypertension/angina); reduces pharmaceutical R&D and production costs for multi-indication drug manufacturers.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈90%); long half-life (≈4 hours), twice-daily oral administration, high patient compliance; good ocular tissue penetration, rapid intraocular pressure reduction (15 minutes) for ophthalmic use.
4. **Pharmaceutical Grade Purity**: Assay ≥99.0%, related substances ≤0.5%, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical ophthalmic (sterile) and oral use for adult patients.
5. **Excellent Formulation Compatibility**: Freely soluble in water; compatible with common ophthalmic (benzalkonium chloride, boric acid) and oral (lactose, microcrystalline cellulose) pharmaceutical excipients; easy to prepare sterile eye drops and oral tablets/capsules.
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; stable in sterile aqueous eye drop formulations for 24 months.

4. Application Fields

4.1 Pharmaceutical Industry

- **Ophthalmic Formulations**: 0.25%/0.5% sterile eye drops for open-angle glaucoma and ocular hypertension; reduces aqueous humor production to lower intraocular pressure, first-line treatment for primary glaucoma.
- **Cardiovascular Formulations**: 5mg/10mg oral tablets/capsules for essential hypertension, stable angina pectoris and supraventricular cardiac arrhythmias; reduces cardiac output and peripheral vascular resistance to lower blood pressure and relieve angina.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Ophthalmic Eye Drops**: 0.25%/0.5% sterile aqueous solution; 1 drop per eye, twice daily; titrate concentration according to intraocular pressure response.
- **Oral Tablets/Capsules**: 5mg/10mg per unit; adult clinical starting dose 10mg daily (divided into two doses), titrated according to blood pressure/angina response (maximum 60mg 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 non-selective beta-blocker cardiovascular/ophthalmic pharmaceutical intermediate with irritant and mild cardiovascular 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**; monitor blood pressure/heart rate for prolonged handling.
- 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 (especially beta-agonists) randomly.