纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: MGL-3196
- **CAS Number**: 920509-32-6
- **Molecular Formula**: $C_{24}H_{25}F_3N_2O_2$
- **Molecular Weight**: 430.47 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via piperidine ring formation, fluorophenyl coupling, amidation and chiral resolution; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral hepatology/cardiovascular preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in methanol/ethanol/DMSO, sparingly soluble in water; 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**: **Highly selective liver X receptor (LXR) agonist** with potent hepatology and cardiovascular activity; activates LXRα/β to regulate lipid metabolism, reduce hepatic lipid accumulation and lower blood lipid levels; fast onset of action (2-4 hours), long duration (24 hours); the classic pharmaceutical raw material for treating dyslipidemia, non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) in adults.
- **Main Application**: Pharmaceutical intermediate for human oral hepatology/cardiovascular formulations (tablets, capsules); pharmaceutical R&D reference reagent for hepatology/cardiovascular pharmacology and LXR agonist research; analytical reference material for pharmaceutical quality inspection of hepatology/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 (MGL-3196)	≥ 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% methanol solution,25℃)	5.0-7.0	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 Methanol	Freely soluble	Solubility Test
Bulk Density	1.38-1.42 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	192-198℃	Melting Point Apparatus (light protection)

3. Product Advantages

1. **High LXR Selectivity**: Potent and highly selective activation of LXRα/β; no significant affinity for other nuclear receptors, reducing adverse effects such as hypertriglyceridemia associated with non-selective LXR agonists.
2. **Double Efficacy for Liver and Blood Lipid**: Simultaneously improves hepatic lipid metabolism and regulates blood lipid levels; effective for both NAFLD/NASH and dyslipidemia, a single active ingredient for multiple hepatology/cardiovascular indications.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈85%); long half-life (≈10 hours), once-daily oral administration, high patient compliance; good hepatic tissue penetration, rapid reduction of hepatic lipid accumulation and blood lipid levels.
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 oral use for adult hepatology/cardiovascular patients (including NAFLD and dyslipidemia).
5. **Excellent 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 hepatology/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; stable in pharmaceutical processing with low-temperature granulation.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Hepatology/Cardiovascular Formulations)

- **Non-alcoholic Fatty Liver Disease (NAFLD)/NASH**: Core raw material for 10mg/20mg/40mg oral tablets; first-line treatment for NAFLD and NASH; reduces hepatic steatosis and inflammation, delays the progression of liver fibrosis.
- **Dyslipidemia**: Formulation for treating hypercholesterolemia and mixed dyslipidemia in adults; lowers serum total cholesterol, low-density lipoprotein cholesterol (LDL-C) and triglycerides, raises high-density lipoprotein cholesterol (HDL-C).
- **Other Indications**: Formulation development for cardiovascular diseases such as atherosclerosis under clinical research; high potential for treating LXR-related metabolic and cardiovascular diseases.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **NAFLD/NASH Oral Tablets**: 10mg/20mg/40mg per unit; adult starting dose 20mg once daily, titrate up to 40mg once daily according to hepatic lipid response.
- **Dyslipidemia Oral Tablets**: 20mg/40mg per unit; adult starting dose 20mg once daily, adjusted according to blood lipid levels (target LDL-C < 2.6 mmol/L).

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 highly selective LXR agonist hepatology/cardiovascular pharmaceutical intermediate with irritant and mild hepatic/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 hepatic and cardiovascular function for personnel with prolonged handling exposure.