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: Opicapone (奥皮卡朋)
- CAS Number: 130929-57-6
- Formula: $C_{19}H_{21}N_3O_4$
- Molecular Weight: 355.39 g/mol
- Chemical Classification: Catechol-O-Methyltransferase (COMT) inhibitor; benzothiadiazinone derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity pale yellow crystalline powder; core API for adjuvant treatment of Parkinson's disease; potent, selective and long-acting COMT inhibitor; enhances the efficacy of levodopa by inhibiting its metabolic degradation; low systemic exposure with high peripheral selectivity; strict impurity and heavy metal control for pharmaceutical use; stable under controlled storage conditions; suitable for GMP pharmaceutical formulation of anti-Parkinson's drugs.

2. Technical Specifications (Complies with EP 10.0 / USP 45 / CP 2020)

Item	Specification
Appearance	Pale yellow to off-white crystalline powder
Assay (on dry basis)	≥ 98.5%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Melting Point	238-242℃
pH Value (1% aq. suspension, 25℃)	5.5-7.5
Solubility	Sparingly soluble in water, soluble in dimethylformamide
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%
Optical Rotation	+108° to +118° (1% in DMSO)
Particle Size	90% passing 100 mesh (pharmaceutical grade)
Temperature Stability	Stable at 0-30℃ (assay retention ≥ 98% for 24 months)

3. Product Advantages

1. **International Pharmacopoeial Compliance**: Meets EP/USP/CP global pharmaceutical standards; ultra-low related substances and heavy metal content; batch-to-batch consistency, suitable for GMP pharmaceutical formulation and commercial production of anti-Parkinson's disease drugs.
2. **Potent & Selective COMT Inhibition**: Long-acting, reversible peripheral COMT inhibitor with high selectivity; prolongs the half-life and bioavailability of levodopa; reduces motor fluctuations in Parkinson's disease patients; no direct central nervous system effects, low risk of central side effects.
3. **Superior Clinical Efficacy**: Adjuvant therapy for levodopa/carbidopa-treated Parkinson's disease; significantly improves motor function and daily activity ability; reduces off-time and increases on-time in patients with motor fluctuations; once-daily oral dosage for patient compliance.
4. **High Purity & Safety**: Pharmaceutical grade with ≥98.5% assay; strict control of toxic impurities and heavy metals; good clinical tolerability; low acute toxicity at occupational exposure levels; no significant chronic toxic effects or sensitization.
5. **Stable Quality & Formulability**: 24-month shelf life under dry, cool, dark storage (≤25℃); no hygroscopy, excellent chemical stability; compatible with common pharmaceutical excipients for oral solid dosage forms; suitable for tablet and capsule formulation.

4. Application Fields

- **Pharmaceutical Formulation**: Production of oral anti-Parkinson's disease drugs (tablets, capsules) as adjuvant therapy with levodopa/carbidopa for the treatment of idiopathic Parkinson's disease with motor fluctuations.
- **Pharmaceutical R&D**: Research on new anti-Parkinson's formulations (sustained-release, orally disintegrating tablets); preclinical/clinical research on early and advanced Parkinson's disease; drug combination research for motor symptom management; development of new COMT inhibitors with improved efficacy and safety.
- **Academic Research**: Neuroscience research on Parkinson's disease pathogenesis and dopamine metabolism; pharmacology research on COMT inhibitors; development of new drugs for neurodegenerative movement disorders.

5. Usage Methods

- **Formulation Compatibility**: Suitable for **oral solid dosage forms** (tablets, capsules); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, mannitol, croscarmellose sodium, magnesium stearate); optimal formulation pH 5.5-7.5; process with anhydrous excipients for low-water formulation systems.
- **Typical Dosage (Formulated Drug)**: Adult oral dosage 50 mg once daily, administered with levodopa/carbidopa; dosage adjustment based on clinical response and tolerability – **clinical prescription only, for neurological use only**.
- **Processing Precautions**: Process in dust-free, low-humidity (<60%) GMP clean room; use closed handling systems to avoid dust inhalation and light exposure; avoid contact with strong acids/bases and high temperature (>70℃); maintain processing temperature at 15-25℃; protect from direct sunlight during all production steps.

6. Packaging & Storage

- **Packaging Specifications**:
  - 100 g/bottle (amber HDPE bottle with aluminum foil moisture-proof seal, inner plastic liner)
  - 500 g/bottle (amber HDPE bottle with moisture-proof seal)
  - 1 kg/drum (sealed amber HDPE drum with inner plastic bag)
  - 5 kg/drum (fiber drum with amber HDPE inner liner, light-proof and moisture-proof)
  - Custom GMP-compliant light-proof packaging for industrial bulk orders (per customer requirements).
- **Storage Conditions**: Store in a **cool, dry, dark, well-ventilated warehouse** at ≤25℃; keep container tightly sealed to prevent light exposure, dust contamination and moisture absorption; avoid direct sunlight and high humidity (>60%); store separately from strong acids, strong bases, oxidizing agents and food/feed materials.

7. Safety & Protection

- The product is a pharmaceutical raw material with acute oral toxicity and severe eye irritation; strict GMP operation is required for all handling.
- Wear full PPE (nitrile gloves, chemical safety goggles, face shield, N95 dust mask, chemical-resistant lab coat) during handling; no bare hand contact and avoid dust inhalation/eye contact.
- Operate in a well-ventilated dust-free area with light protection; wash hands and face thoroughly after handling; no eating/drinking/smoking in the work area.
- In case of accidental contact/ingestion, follow the emergency measures in the MSDS and seek medical attention immediately.

8. Quality Assurance

- Manufactured in **GMP and ISO 9001 certified** production facility; strict in-process quality control (IPC) for all production steps; all test parameters meet EP/USP/CP pharmacopoeial standards; light-proof production process to ensure product stability.
- Each batch is accompanied by a batch-specific **Certificate of Analysis (COA)** with full test results; quality records retained for 5 years (per GMP requirements).
- Complete raw material and production traceability system; professional technical support for pharmaceutical formulation development, process optimization and quality control guidance for anti-Parkinson's drug production.