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Technical Data Sheet (TDS)

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1. Product Overview

- Product Name: Donepezil Hydrochloride (多依哌齐盐酸盐)
- CAS Number: 103474-53-9
- Formula: $C_{24}H_{29}NO_3 \cdot HCl$
- Molecular Weight: 415.96 g/mol
- Chemical Classification: Cholinesterase inhibitor; indanone derivative
- Product Grade: Pharmaceutical Grade (EP/USP/CP Compliant)
- Product Characteristics: High-purity white crystalline powder; core API for anti-Alzheimer's disease drugs; reversible acetylcholinesterase inhibitor; improves cognitive function in Alzheimer's patients; good water solubility; stable under controlled storage conditions; strict impurity and heavy metal control for pharmaceutical use; low acute toxicity at occupational exposure levels.

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

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Assay (on dry basis)	≥ 98.5%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	≤ 0.5%	105℃, 2h Gravimetry
Residue on Ignition	≤ 0.1%	550℃ Ignition Method
Heavy Metals (Pb)	≤ 5 ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%	HPLC
Melting Point	210-214℃	Capillary Melting Point Method
pH Value (0.5% aq. solution, 25℃)	3.5-5.5	Digital pH Meter
Solubility	Soluble in water, freely soluble in methanol	Pharmacopoeial Solubility Test
Chloride Content	8.2-9.0%	Volumetric Titration
Sulfate Content	≤ 0.03%	Volumetric Titration
Particle Size	90% passing 100 mesh	Sieve Analysis
Optical Rotation	0° ±1° (1% in methanol)	Polarimetry

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-Alzheimer's drugs.
2. **Potent Cholinesterase Inhibition**: Reversible acetylcholinesterase inhibitor with high selectivity; improves cognitive function, memory and attention in Alzheimer's disease patients; first-line clinical drug for mild to moderate Alzheimer's disease; long half-life (24h) for once-daily oral dosage.
3. **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.
4. **Excellent Solubility & Stability**: Good water solubility (6.8 g/100 mL) suitable for oral solid and liquid dosage forms; 24-month shelf life under dry, cool storage; slight hygroscopy (controllable with

sealed packaging); no chemical degradation under normal pharmaceutical processing conditions.

5. **GMP Manufacturing**: Produced in GMP/ISO 9001 certified facility; complete raw material traceability; strict in-process quality control for all key parameters; compliant with international pharmaceutical quality standards for neurological drug production.

4. Application Fields

- **Pharmaceutical Formulation**: Production of oral anti-Alzheimer's disease drugs (tablets, capsules, oral dispersible tablets, oral solutions) for clinical treatment of mild to moderate Alzheimer's disease.
- **Pharmaceutical R&D**: Research on new anti-dementia formulations (sustained-release, sublingual); preclinical and clinical research on severe Alzheimer's disease; drug combination research for cognitive impairment; development of new cholinesterase inhibitors with improved efficacy.
- **Academic Research**: Neuroscience research on cholinergic system and Alzheimer's disease pathogenesis; research on acetylcholinesterase inhibitor pharmacology; development of new drugs for neurodegenerative diseases.

5. Usage & Formulation Guidelines

- **Formulation Compatibility**: Suitable for oral solid dosage forms (tablets, capsules) and liquid dosage forms (oral solutions); compatible with common pharmaceutical excipients (microcrystalline cellulose, lactose, mannitol, starch, magnesium stearate); no solubilizer required for aqueous formulations (good water solubility).
- **Typical Dosage (Formulated Drug)**: Adult oral dosage 5-10 mg/day (once daily); titrate dosage according to clinical response – **clinical prescription only, for neurological use only**.
- **Processing Precautions**: Process in dust-free, low-humidity (<60%) GMP workshop; use closed handling systems to avoid dust inhalation and hygroscopy; avoid contact with strong acids/bases and high temperature (>60℃); maintain normal temperature (15-25℃) during processing.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (HDPE bottle with aluminum foil moisture-proof seal, inner plastic liner)
- 500 g/bottle (HDPE bottle with moisture-proof seal)
- 1 kg/drum (sealed HDPE drum with inner plastic bag)
- 5 kg/drum (fiber drum with HDPE inner liner, moisture-proof)
- Custom GMP-compliant packaging for industrial bulk orders (per customer requirements)

6.2 Storage Conditions

- Store in a **cool, dry, well-ventilated warehouse** at ≤25℃; keep container tightly sealed to prevent moisture absorption and dust contamination; avoid direct sunlight and high humidity (>60%).
- Incompatibilities: Store separately from strong acids, strong bases, oxidizing agents, food and feed materials.
- Shelf Life: **24 months** (unopened, under specified storage conditions); 6 months after opening (resealed, dry, cool storage).

6.3 Transportation

- Classified as UN 2811 (Class 6.1 Toxic Substance); transport with sealed, moisture-proof packaging; maintain temperature ≤25℃ during transport.
- Mark with GHS hazard labels and UN 2811; avoid direct sunlight, high temperature, collision and vibration during transport; do not transport with strong acids/bases/oxidizing agents, food or feed.

7. 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.
- 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-Alzheimer's drug production.