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Technical Data Sheet (TDS)

Issue Date: 20 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Metoclopramide
- **CAS Number**: 364-62-5
- **Molecular Formula**: $C_{14}H_{22}ClN_3O_2$
- **Molecular Weight**: 299.80 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized via benzamide acylation, chlorination, amination and purification; prepared by chiral synthesis and recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral/injection gastroenterology preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in water/methanol/ethanol, soluble in DMSO; 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 dopamine D2 receptor antagonist** with potent antiemetic and gastrointestinal prokinetic activity; blocks central and peripheral dopamine D2 receptors to inhibit vomiting center and promote gastrointestinal peristalsis; fast onset of action (15-30 minutes), long duration (4-6 hours); the classic pharmaceutical raw material for treating nausea/vomiting and gastrointestinal motility disorders in adults and children (≥6 years old).
- **Main Application**: Pharmaceutical raw material for human oral/injection gastroenterology formulations (tablets, injections, syrups); treatment of chemotherapy/radiotherapy-induced nausea/vomiting, postoperative nausea/vomiting and functional dyspepsia; pharmaceutical R&D reference reagent for gastroenterology pharmacology and dopamine receptor research.

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 (Metoclopramide)	≥ 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
Chloride Content	11.8-12.5%	Volumetric Titration
pH Value (1% aqueous solution,25℃)	4.5-6.0	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 Water	Freely soluble	Solubility Test
Bulk Density	1.28-1.32 g/cm³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)	HPLC
Melting Point	147-151℃	Melting Point Apparatus (light protection)

3. Product Advantages

1. **High Dopamine D2 Selectivity**: Potent and highly selective inhibition of dopamine D2 receptors; low affinity for 5-HT3, muscarinic and adrenergic receptors, reducing adverse effects such as sedation and hypotension associated with non-selective antiemetics.
2. **Dual Antiemetic & Prokinetic Efficacy**: Simultaneously exerts central antiemetic and peripheral gastrointestinal prokinetic effects; effective for both nausea/vomiting and gastrointestinal motility disorders, a single active ingredient for multiple gastroenterology indications.
3. **Optimal Pharmacokinetics**: Good oral bioavailability (≈80%); rapid absorption in the gastrointestinal tract, peak plasma concentration at 1-2 hours; long half-life (≈5 hours), 3-4 times daily administration, high patient compliance; good tissue penetration, effective for both central and peripheral dopamine D2 receptor blockade.
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/injection use for adult and pediatric gastroenterology patients (≥6 years old).

4. Application Fields

4.1 Pharmaceutical Industry (Oral/Injection Gastroenterology Formulations)

- **Antiemetic Preparations**: Core raw material for 5mg/10mg oral tablets and 10mg/2mL injections; first-line treatment for chemotherapy/radiotherapy-induced nausea/vomiting, postoperative nausea/vomiting and morning sickness (pregnancy trimester 2-3); rapid relief of vomiting symptoms with high safety.
- **Gastrointestinal Prokinetic Preparations**: Formulation for treating functional dyspepsia, gastroparesis and gastroesophageal reflux disease (GERD); promotes gastrointestinal peristalsis, improves gastric emptying, relieves bloating, epigastric pain and regurgitation.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets (Adults)**: 5mg/10mg per unit; antiemetic: 10mg 3 times daily; prokinetic: 5mg 3 times daily (30 minutes before meals).
- **Injections (Adults)**: 10mg/2mL per ampoule; intravenous/intramuscular injection: 10mg once every 8 hours (maximum 30mg daily) for severe nausea/vomiting.
- **Pediatric Syrups (≥6 years old)**: 0.5mg/mL; 0.1mg/kg per dose 3 times daily (maximum 10mg 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 highly selective dopamine D2 receptor antagonist gastroenterology pharmaceutical intermediate with irritant and mild neurotoxic/gastrotoxic 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 nervous system and gastrointestinal function for personnel with prolonged handling exposure.
- 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 neurotoxic/gastrotoxic drugs) randomly.