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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Doxapram Hydrochloride
- **CAS Number**: 7081-53-0
- **Molecular Formula**: $C_{24}H_{30}N_2O_2 \cdot HCl$
- **Molecular Weight**: 414.97 g/mol
- **Chemical Source**: Synthetic fine chemical (synthesized from diphenyl ketone via cyclization, amination, morpholine modification and hydrochlorination; purified by recrystallization to ensure high purity and low impurity content; optimized process for excellent water solubility and formulation compatibility for injectable preparations).
- **Product Trait**: White crystalline powder, practically odorless, slightly hygroscopic; **freely soluble in water** (150 g/L at 25℃), freely soluble in ethanol/methanol, slightly soluble in organic solvents (acetone/ether); stable in dry, dark and weakly acidic environment, mild hydrolysis in alkaline/moist environment; no light sensitivity under normal storage conditions; good stability in pharmaceutical processing.
- **Core Properties**: Classic **central respiratory stimulant** with high selectivity for respiratory center; fast onset (1-3 minutes), short duration of action (30-60 minutes); potent excitation of medullary respiratory center, increases tidal volume and respiratory rate; no significant effect on cardiovascular system at clinical doses; the gold standard for treating post-anesthesia/postoperative respiratory depression and ICU mild respiratory failure.
- **Main Application**: Pharmaceutical intermediate for human injectable respiratory stimulant formulations (post-anesthesia respiratory depression, postoperative hypoventilation); ICU respiratory support pharmaceutical raw material for mild respiratory failure; pharmaceutical R&D reference reagent for respiratory center pharmacology and critical care medicine 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 (Doxapram Hydrochloride)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105℃ constant weight method (2h)
Residue on Ignition	≤ 0.1%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 5 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Chloride (Cl^-)	8.5-9.1%	Volumetric Method
Sulfate (SO_4^{2-})	≤ 0.05%	Turbidimetric Method
Melting Point	214-218℃	Melting Point Apparatus
pH Value (1% aqueous solution,25℃)	3.5-5.5	Digital pH Meter
Total Bacterial Count	≤ 10 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	Plate Count Method
Particle Size	95% passing 80 mesh	Standard Sieve Method
Water Solubility (25℃)	≥ 140 g/L	Solubility Test
Bulk Density	1.25-1.29 g/cm³	Pycnometer Method
Hydrolysis Stability	≤ 0.3% related substances after 7 days (25℃, 60% RH)	HPLC

3. Product Advantages

1. **High Respiratory Center Selectivity**: Specific excitation of medullary respiratory center, no significant effect on cerebral cortex or spinal cord; increases tidal volume and respiratory rate without causing convulsions at clinical doses; the most selective central respiratory stimulant for clinical use.
2. **Rapid Onset & Short Duration**: Onset in 1-3 minutes after intravenous injection, peak effect at 5-10 minutes, duration of action 30-60 minutes; short half-life facilitates clinical dose adjustment, no cumulative toxicity with repeated administration.
3. **Excellent Water Solubility**: Freely soluble in water (150 g/L at 25℃), suitable for preparing high-concentration injectable formulations (20 mg/mL); no organic solvent required, reduces formulation irritation to blood vessels and tissues.
4. **Low Cardiovascular Adverse Effects**: No significant tachycardia, hypertension or arrhythmia at clinical therapeutic doses; safe for use in patients with mild cardiovascular disease, expands clinical application scope.

4. Application Fields

4.1 Pharmaceutical Industry (Post-Anesthesia/Postoperative Respiratory Stimulant)

- **Post-Anesthesia Respiratory Depression**: Core raw material for 20 mg/mL injectable formulations; used for reversing respiratory depression caused by general anesthetics (halothane, isoflurane); intravenous bolus administration, rapid recovery of spontaneous breathing.
- **Postoperative Hypoventilation**: Formulations for treating postoperative respiratory hypoventilation caused by opioid analgesics; reduces the risk of respiratory failure, shortens postoperative mechanical ventilation time.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Adult Post-Anesthesia Respiratory Depression**: 20 mg/mL injectable formulation, intravenous bolus 0.5-1 mg/kg (single dose); repeat every 5-10 minutes if necessary, maximum total dose 2 mg/kg.
- **Adult Postoperative Hypoventilation**: 10 mg/mL dilute formulation, continuous intravenous infusion 1-3 mg/min; adjust infusion rate according to respiratory status, stop immediately when spontaneous breathing is stable.
- **ICU Mild Respiratory Failure**: 10 mg/mL formulation, continuous infusion 0.5-2 mg/min; combined with oxygen therapy, monitor blood gas indicators continuously.
- **Neonatal Respiratory Distress**: 5 mg/mL dilute formulation, intravenous bolus 0.5-1 mg/kg; slow injection over 1-2 minutes, avoid rapid administration to prevent tachycardia.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Anti-Hygroscopic)

- 100 g/bottle: Clear glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade drum with aluminum foil inner lining + sealed plastic cover + outer carton (bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs.

7. Safety & Protection

- The product is a central respiratory stimulant toxic pharmaceutical intermediate with respiratory/neurological effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant full face shield, 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.
- Monitor respiratory rate/heart rate for personnel with prolonged operation time (>4 hours); take a rest every 2 hours for continuous operation.