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Technical Data Sheet (TDS) - Propofol

Revision Date: 25 FEB 2026**CAS Number**: 2078-54-8**Molecular Formula**: $C_{12}H_{18}O$**Molecular Weight**: 178.27 g/mol

1. Product Overview

Propofol is a short-acting intravenous alkylphenol anesthetic raw material with a unique lipophilic structure. It exerts sedative, hypnotic and anesthetic effects by enhancing the activity of the γ-aminobutyric acid (GABA) receptor complex in the central nervous system, and acts on the NMDA receptor to produce analgesic effects. Characterized by **ultra-rapid onset, short duration of action, rapid and clear postoperative recovery**, it is a high-purity pharmacopoeial-grade raw material for clinical general anesthesia induction and maintenance, suitable for all ages of patients, including pediatric and geriatric surgical anesthesia, as well as procedural sedation in intensive care units (ICU).

2. Technical Specifications (Complies with USP 45 & ChP 2025)

Item	Specification
Appearance	Colorless to pale yellow clear oily liquid
Assay (on anhydrous basis)	≥ 99.0%
Related Substances	Total ≤ 0.5%; Single Impurity ≤ 0.1%
Water Content	≤ 0.1%
Residue on Ignition	≤ 0.05%
Heavy Metals (Pb)	≤ 10 ppm; (As) ≤ 2 ppm
Bacterial Endotoxins	≤ 0.5 EU/μg
Sterility	Sterile
Refractive Index (25℃)	1.512 ~ 1.514
Specific Gravity (25℃)	0.950 ~ 0.956
Solubility	Miscible with ethanol, ether, chloroform; practically insoluble in water
Boiling Point	256 ~ 258℃
Flash Point	115℃ (Closed Cup)
Stability	Stable under inert gas, dark and low temperature conditions

3. Product Advantages

1. **Ultra-Rapid Onset & Recovery**: Onset in 30-60s after IV injection, duration of action 3-5min, no residual sedation after stopping medication, significantly shortening postoperative recovery time.
2. **Smooth Anesthesia Induction**: Mild hemodynamic changes during induction, little irritation to the respiratory tract, and high patient tolerance.
3. **Wide Clinical Application**: Suitable for anesthesia induction/maintenance of various surgeries, as well as sedation for ICU mechanical ventilation and short invasive procedures.
4. **High Purity & Stability**: Pharmacopoeial grade purity (≥99.0%), ultra-low impurity content; stable when stored under nitrogen protection and dark conditions, easy to formulate into emulsion injections.
5. **Controllable Effect**: The anesthetic depth can be flexibly adjusted by adjusting the infusion rate, and the effect disappears rapidly after stopping the drug, with no cumulative effect.

4. Application Fields

Pharmaceutical Raw Material for Clinical Anesthesia & Sedation:

- General anesthesia induction: For adult, pediatric and geriatric surgical patients, suitable for elective and emergency surgeries.
- Anesthesia maintenance: Intravenous infusion for medium and short surgeries, combined with inhalation anesthetics for long surgeries.
- ICU sedation: Sedation for patients with mechanical ventilation, reducing patient discomfort and agitation.
- Procedural sedation: Sedation for endoscopy, interventional radiology, dental surgery and other short invasive medical procedures.

- Production of dosage forms: Propofol injectable emulsion (oil-in-water type), the mainstream clinical dosage form.

5. Usage Methods (for Pharmaceutical Formulation)

- **Formulation Type**: Sterile oil-in-water injectable emulsion (the only clinical dosage form due to water insolubility).
- **Base Formulation System**: Propofol + soybean oil (oil phase) + lecithin (emulsifier) + glycerol (osmotic pressure regulator) + water for injection (aqueous phase), prepared into 10 mg/mL emulsion.
- **Processing Requirements**: Aseptic operation in GMP-certified workshop; nitrogen protection during the whole preparation process to avoid oxidation; control pH at 6.0-8.5, particle size D90 ≤ 500 nm.
- **Compatibility**: Can be mixed with 5% glucose injection for clinical dilution; incompatible with normal saline (causes emulsion demulsification).

6. Packaging & Storage

Packaging Specifications

- 100 mL / brown glass sealed bottle (nitrogen-filled, R&D/laboratory use)
- 500 mL / brown glass sealed drum (nitrogen-filled, pilot production)
- 5 L / stainless steel sealed drum (nitrogen-filled, industrial GMP production)
- Custom nitrogen-filled GMP-compliant packaging for bulk orders available.

Storage Conditions

- **Storage Temperature**: 2 ~ 8℃ (refrigerated, dark place); avoid freezing and high temperature (>25℃).
- **Sealing Requirement**: Nitrogen-filled sealed packaging, tightly closed, protect from direct light and air contact (prevent oxidation).
- **Incompatibilities**: Store separately from strong oxidizing agents, strong acids, strong bases, and metal ions (Fe^{3+} , Cu^{2+}).
- **Shelf Life**: 24 months (unopened, nitrogen-filled, 2~8℃ refrigeration); 6 hours after opening (aseptic operation, room temperature).

Transportation

- Classified as pharmaceutical raw material for clinical anesthetics; transport in compliance with national pharmaceutical raw material transportation regulations.
- Refrigerated transport (2~8℃) with temperature monitoring; nitrogen-filled sealed packaging, avoid collision, light exposure and air contact; transport separately from strong oxidizing agents and acids.

7. Safety & Protection

- Wear professional PPE (nitrile rubber gloves, chemical safety goggles, impermeable protective clothing, organic vapor mask) during handling to avoid skin/mucosa contact and vapor inhalation.
- In case of skin contact: Wipe with absorbent paper first, then rinse with plenty of soapy water for 10-15 minutes; in case of eye contact: Rinse with sterile water for injection for 15 minutes and consult an ophthalmologist immediately.
- In case of vapor inhalation: Move to fresh air immediately, give oxygen if breathing is difficult, and consult a physician if dizziness or drowsiness occurs.
- Do not ingest; accidental oral intake may cause severe central nervous system depression—seek emergency medical treatment immediately.
- Operate in a well-ventilated GMP workshop with local exhaust ventilation; nitrogen protection during material transfer to prevent oxidation and vapor leakage.

8. Quality Assurance

- Produced in accordance with **GMP** and **ICH Q7** guidelines for pharmaceutical raw materials; each batch is accompanied by a detailed Certificate of Analysis (COA) with complete test data.
- Comply with USP 45, ChP 2025 and EP 10.0 pharmacopoeial standards; establish a complete quality control system from raw material sourcing to finished product delivery, including raw material inspection, in-process control and finished product testing.