

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 苏加马德克斯钠
- English Name: Sugammadex Sodium
- CAS Number: 356373-20-9
- Molecular Formula: $C_{60}H_{90}Na_8O_{36}S_8$
- Molecular Weight: 2179.71 Da
- Product Characteristics:** High-purity pharmaceutical grade Sugammadex Sodium, a selective relaxant binding agent (SRBA) and γ -cyclodextrin derivative; white odorless free-flowing crystalline powder, freely soluble in water and insoluble in organic solvents; exerts pharmacological effects by forming a stable water-soluble complex with non-depolarizing neuromuscular blocking agents (e.g., rocuronium, vecuronium), reversing neuromuscular block rapidly and specifically; stable under recommended storage conditions; compatible with most pharmaceutical injectable excipients (excluding strong alkaline excipients); meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of intravenous injection formulations for clinical reversal of moderate to deep neuromuscular block in surgical anesthesia.

2. Technical Specifications (Complies with USP/EP/BP & Pharmaceutical Industrial Standards)

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	$\geq 98.0\%$
Melting Point	210-215°C (decomp, Capillary Method)
Loss on Drying	$\leq 1.0\%$
Residue on Ignition	$\leq 0.1\%$
pH Value (5% aq. solution, 25°C)	5.0-7.5
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl^-)	$\leq 0.01\%$
Sulfate (SO_4^{2-})	$\leq 0.01\%$
Related Substances	$\leq 1.0\%$ (HPLC)
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Endotoxin	≤ 0.5 EU/mg
Particle Size	$\geq 95\%$ passing 100 mesh
Water Solubility	Freely soluble (>200 g/100 mL, 25°C)
Organic Solubility	Insoluble in ethanol/acetone/chloroform
Bulk Density	1.60-1.65 g/cm ³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30°C (assay retention $\geq 98\%$ for 36 months)
Light Stability	Stable under dark storage (assay retention $\geq 98\%$ for 36 months)
Compatibility	Incompatible with strong alkaline excipients/heavy metal salts/oxidizing agents

3. Product Advantages

- High Purity & Pharmaceutical Grade:** Assay $\geq 98.0\%$, low related substances ($\leq 1.0\%$), ultra-low endotoxin (≤ 0.5 EU/mg); complies with USP/EP/BP global pharmacopoeia standards; meets GMP production requirements for injectable pharmaceutical raw materials, ensuring high safety for intravenous clinical application.



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- 2. Unique Pharmacological Mechanism:** Selective binding to aminosteroid non-depolarizing neuromuscular blocking agents (rocuronium, vecuronium) with high affinity; no effect on acetylcholine receptors, avoiding cholinergic side effects of traditional anticholinesterase reversal agents (e.g., atropine-induced tachycardia).
- 3. Rapid & Effective Reversal:** Fast onset of action (2-3 minutes for moderate block, 5-10 minutes for deep block); complete reversal of neuromuscular block without dose adjustment for different block depths, significantly reducing postoperative respiratory complications.
- 4. Excellent Water Solubility:** Freely soluble in water (>200 g/100 mL), no need for organic cosolvents for injectable formulations; low viscosity of aqueous solution, easy to prepare and inject, suitable for clinical emergency use.
- 5. Wide Clinical Compatibility:** Compatible with common injectable solutions (normal saline, 5% glucose solution, lactated Ringer's solution); no precipitation or degradation when mixed with anesthetic adjuvants, suitable for intraoperative emergency reversal.

4. Application Fields

- **Pharmaceutical Preparations:** Intravenous injection formulations for clinical reversal of moderate to deep neuromuscular block induced by aminosteroid non-depolarizing muscle relaxants (rocuronium, vecuronium) in general surgical anesthesia, obstetric anesthesia and pediatric anesthesia (≥ 2 years old).
- **Pharmaceutical Research:** Research reagent for anesthetic pharmacology, neuromuscular pharmacology and cyclodextrin derivative drug development; in vitro and in vivo research on neuromuscular block reversal mechanism and new muscle relaxant development.
- **Fine Chemicals:** Intermediate for the synthesis of cyclodextrin derivative drugs and selective molecular recognition reagents.

5. Usage Methods

5.1 Formulation Compatibility

- **Intravenous Injection Solution:** Dissolve in sterile normal saline/5% glucose solution to prepare 100 mg/mL concentration stock solution; dilute to 10-20 mg/mL working solution before use; adjust pH to 6.0-7.0 with weak acid/base if needed; filter and sterilize by 0.22 μm microporous membrane.
- **Lyophilized Injection:** Mix with mannitol (bulking agent) at a ratio of 1:1 (w/w); dissolve in sterile water for injection; lyophilize under vacuum to prepare lyophilized powder for injection; reconstitute with normal saline before use.

6. Packaging & Storage

6.1 Packaging Specifications

- 10 g/bottle (pharmaceutical grade brown glass bottle, rubber stopper + aluminum cap sealed, light-proof and moisture-proof)
- 50 g/bottle (pharmaceutical grade brown glass bottle, rubber stopper + aluminum cap sealed)
- 100 g/bag (pharmaceutical grade aluminum foil bag, vacuum sealed, light-proof)
- 1 kg/5 kg/drum (sealed HDPE drum with inner pharmaceutical grade aluminum foil bag, light-proof)
- **Custom Packaging:** 25 g/200 g sterile pyrogen-free packaging available for injectable formulation production (MOQ applicable) according to customer requirements.

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical with eye/skin irritation risk; **only for use by trained professional personnel** (pharmaceutical production, clinical anesthesiologists, scientific research staff) with relevant operating qualifications.
- Wear **mandatory full personal protective equipment** during all handling, processing and preparation operations (chemical-resistant goggles + face shield, nitrile rubber gloves $\geq 0.18\text{mm}$ thick, N95 respirator, impermeable lab coat, protective shoes).
- Avoid direct skin contact, eye exposure and dust inhalation; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention **immediately** (especially for eye contact and large dosage ingestion).