

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: Insulin Aspart
- English Name: Insulin Aspart
- CAS Number: 133107-64-9
- Formula: Fast-Acting Recombinant Insulin Analogue (51 Amino Acids, Asp³ human insulin variant)
- Molecular Weight: 5825.8 Da
- Product Characteristics: High-purity fast-acting recombinant insulin analogue, white lyophilized powder, odorless, soluble in PBS/neutral buffer. Ultra-high biological activity (≥ 28.0 IU/mg) and HPLC purity ($\geq 99.0\%$), ultra-low endotoxin/heavy metal/aggregation content. Exceptional stability at 2-8°C for 36 months, degrades at high temperature/freeze-thaw cycles. Non-combustible, fully biodegradable, non-toxic to the environment. May cause allergic reactions in sensitive individuals; strict GMP-compliant handling required. Suitable for biopharmaceutical R&D and fast-acting diabetes drug development.

2. Technical Specifications (Biopharmaceutical Grade)

Item	Specification
Appearance	White to off-white lyophilized powder
Purity (HPLC)	$\geq 99.0\%$
Biological Activity	≥ 28.0 IU/mg
pH Value (1mg/mL in PBS, 25°C)	6.5-7.5
Moisture Content	$\leq 3.0\%$
Bacterial Endotoxin	≤ 0.5 EU/mg
Sterility	Negative
Heavy Metals (Pb)	≤ 5 ppm
Protein Content	$\geq 98.0\%$
Amino Acid Sequence	Conforms to insulin aspart sequence
Aggregation (SEC-HPLC)	$\leq 0.5\%$
Solubility	Soluble in PBS/neutral buffer (pH6.5-7.5)
Storage Stability	36 months (2-8°C, sealed, protected from light)
Reconstituted Stability	48 hours (2-8°C, 1mg/mL PBS solution)

3. Product Advantages

1. Fast-Acting Analogue & High Activity: Exact standard insulin aspart amino acid sequence; ≥ 28.0 IU/mg biological activity ensures rapid and consistent blood glucose regulation function for acute diabetes management.
2. Ultra-High Purity & Ultra-Low Impurities: $\geq 99\%$ HPLC purity, ≤ 0.5 EU/mg endotoxin, trace heavy metals and aggregation ($< 0.1\%$); meets USP/EP/ICH strict standards for human biopharmaceutical development.
3. Long-Term GMP Stability: 36-month shelf life at 2-8°C; mannitol as dual lyoprotectant/stabilizer prevents protein denaturation, aggregation and activity loss during storage and reconstitution.
4. Sterile & Apyrogenic: Sterile (negative) and apyrogenic; no additional sterilization required for in vitro experiments/cell culture and pre-clinical diabetes research.
5. Biodegradable & Eco-Friendly: Fully biodegradable via protein hydrolysis; non-toxic to aquatic/soil organisms; no environmental pollution risk, complying with global environmental standards.
6. GMP-Compliant Production: Manufactured under GMP and ISO 9001 management systems; full traceability of all production steps; consistent batch-to-batch quality for reliable drug development and experimental results.

4. Application Fields

- Biopharmaceutical R&D: Fast-acting insulin drug development, formulation research, potency testing and quality control of insulin aspart products.



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- In Vitro Diagnostics: Raw material for insulin immunoassay kits (ELISA, chemiluminescence); clinical diagnostic reagent for diabetes and insulin resistance detection.
- Diabetes Research: Fast-acting blood glucose regulation study, insulin receptor interaction research, animal model experiment for type 1/2 diabetes acute blood glucose control.
- Pharmaceutical Formulation: Pre-formulation research for injectable insulin aspart preparations; excipient compatibility and stability testing for fast-acting formulations.
- Academic Research: Peptide hormone analogue structure-activity relationship study, recombinant fast-acting insulin expression/purification research, diabetes acute treatment mechanism study.

5. Usage Methods

- Reconstitution: Add sterile PBS/0.9% saline buffer (pH6.5-7.5) to the lyophilized powder to prepare 1mg/mL stock solution; gently swirl (do not vortex) to dissolve completely (avoid foam/protein denaturation that affects activity).
- Stock Solution Storage: 1mg/mL stock solution stored at 2-8°C for ≤48h; aliquot and freeze at -20°C for long-term use (avoid repeated freeze-thaw cycles to prevent aggregation).
- Working Concentration: Dilute stock solution with appropriate buffer (PBS, HEPES) to working concentration (0.001-2 µg/mL, adjust according to experiment/cell model and research purpose).
- Optimal Conditions: Use sterile GMP-compliant technique for all operations; perform cell culture experiments at 37°C/5% CO₂; use neutral buffer (pH6.5-7.5) to maintain protein stability; discard unused reconstituted solution after 48h.

6. Packaging & Storage

- Packaging Specifications: 1mg/vial, 5mg/vial, 10mg/vial, 50mg/vial (sterile GMP-compliant glass vials with rubber stoppers and aluminum crimp seals); customized packaging (100mg-1g) available upon request for large-scale R&D projects.
- Storage Conditions: **2-8°C (refrigerated)**, dark, sealed, protected from light and moisture; avoid freeze-thaw cycles, high temperature (>37°C) and room temperature storage; store in a dedicated GMP-compliant biological reagent refrigerator with temperature monitoring.
- Shelf Life: 36 months (unopened, 2-8°C); 48 hours (reconstituted 1mg/mL PBS solution, 2-8°C); 12 months (aliquoted stock solution, -20°C, avoid repeated freeze-thaw).
- Transportation: UN 3373 (Biological Substance, Category B); **refrigerated transport (2-8°C)** with insulated GMP-compliant packaging and ice packs; use cold chain express delivery with real-time temperature monitoring; avoid freeze-thaw, direct sunlight and violent collision during transport.

7. Safety & Protection

- Mandatory PPE: Wear sterile nitrile gloves, N95 dust mask, chemical splash goggles and GMP lab coat for all handling; use face shield and sterile latex gloves for powder weighing/reconstitution to prevent direct contact.
- Handling Precautions: Operate in a clean, GMP-compliant, well-ventilated lab/dust-free workbench; avoid dust generation/inhalation/skin/eye contact; use sterile technique for reconstitution; no eating/drinking/smoking in GMP work area to prevent contamination.
- Allergy Prevention: Sensitive individuals (to recombinant insulin/proteins) should avoid contact with the product; keep antihistamine/bronchodilator available in the lab for emergency use in case of allergic reactions.

8. Quality Assurance

- Manufactured under ISO 9001, GMP and ICH Q7 management systems; strict raw material inspection, recombinant expression control and multi-step purification process validation to ensure product purity and activity.
- Each batch is fully tested for purity, biological activity, endotoxin, sterility, amino acid sequence and identity; accompanied by a Certificate of Analysis (COA) complying with USP/EP/ICH international standards.
- All raw materials are sourced from GMP/ISO-certified suppliers; full traceability of production, testing, packaging and shipping records for all batches for quality tracking and accountability.