

Technical Data Sheet (TDS)

1. Product Overview

- **Product Name:** Follicle-Stimulating Hormone (FSH)
- **English Name:** Follicle-Stimulating Hormone
- **CAS Number:** 9002-68-0
- **Formula:** α/β Heterodimer Glycoprotein Hormone
- **Molecular Weight:** 32000-38000 Da (glycosylation variable)
- **Product Characteristics:** High-purity natural-sourced glycoprotein hormone, white lyophilized powder, odorless, soluble in PBS/saline buffer. Ultra-high biological activity (≥ 1500 IU/mg), ultra-low endotoxin and heavy metal content, suitable for biopharmaceutical R&D and reproductive biology research. Exceptional stability at 2-8°C (36 months shelf life), degrades at high temperature and freeze-thaw cycles. No flammable/explosive properties, biodegradable, non-toxic to the environment. Allergic reaction may occur in sensitive individuals; strict PPE required for handling.

2. Technical Specifications (Biopharmaceutical Grade)

Item	Specification
Appearance	White to off-white lyophilized powder
Purity (SDS-PAGE)	$\geq 95.0\%$
Biological Activity	≥ 1500 IU/mg
pH Value (100 μ g/mL in PBS, 25°C)	6.0-8.0
Moisture Content	$\leq 5.0\%$
Bacterial Endotoxin	≤ 2 EU/mg
Sterility	Negative
Heavy Metals (Pb)	≤ 5 ppm
Protein Content	$\geq 90.0\%$
Glycosylation Content	25-35%
Aggregation (SEC-HPLC)	$\leq 2.0\%$
Solubility	Soluble in PBS/0.9% saline buffer
Storage Stability	36 months (2-8°C, sealed, protected from light)
Reconstituted Stability	48 hours (2-8°C, 100 μ g/mL PBS solution)

3. Product Advantages

1. **Ultra-High Activity & Purity:** $\geq 95\%$ SDS-PAGE purity and ≥ 1500 IU/mg biological activity; high glycosylation content (25-35%) ensures native biological function.
2. **Ultra-Low Impurities:** ≤ 2 EU/mg bacterial endotoxin, ultra-low heavy metal and aggregation content; meets GMP requirements for biopharmaceutical R&D.
3. **Long-Term Stability:** 36-month shelf life at 2-8°C (the longest among similar products); sucrose as lyoprotectant to prevent protein denaturation/degradation.
4. **Sterile & Apyrogenic:** Sterile (negative) and apyrogenic; no additional sterilization required for in vitro experiments/cell culture/reproductive biology research.
5. **Biodegradable & Enviro-Friendly:** Fully biodegradable via protein hydrolysis; non-toxic to aquatic/soil organisms; no environmental pollution risk.
6. **Native Glycosylation:** Natural glycosylation pattern ensures consistent biological activity with endogenous FSH; no loss of function due to incomplete glycosylation.

4. Application Fields

- **Biopharmaceutical R&D:** FSH drug development (follitropin alfa/beta), formulation research, potency testing and quality control of gonadotropin products.
- **In Vitro Diagnostics:** Raw material for FSH immunoassay kits (ELISA, chemiluminescence); clinical diagnostic reagent for reproductive disease detection (infertility, ovarian dysfunction).
- **Reproductive Biology Research:** Ovarian follicle development study, spermatogenesis research, gonad function study and assisted reproductive technology (ART) R&D.



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- **Animal Breeding Experiment:** Superovulation induction in laboratory animals (mouse/rat/rabbit); livestock breeding research (cow/sheep) to improve ovulation rate.
 - **Academic Research:** Glycoprotein hormone structure-activity relationship study, reproductive endocrinology research, hormone receptor interaction experiment.
- ### 5. Usage Methods
- **Reconstitution:** Add sterile PBS/0.9% physiological saline buffer to the lyophilized powder to prepare 100µg/mL stock solution; gently swirl (do not vortex) to dissolve completely (avoid foam/denaturation).
 - **Stock Solution Storage:** Prepare 100µg/mL stock solution at 2-8°C for ≤48 hours; aliquot and freeze at -20°C for long-term use (avoid repeated freeze-thaw cycles).
 - **Working Concentration:** Dilute stock solution with appropriate buffer (PBS, HEPES) to working concentration (0.001-1 µg/mL, adjust according to experiment/animal model).
 - **Optimal Conditions:** Use sterile technique for all operations; perform experiments at 25±2°C; avoid high temperature (>37°C) and extreme pH for reaction systems; discard unused reconstituted solution after 48 hours.
- ### 6. Packaging & Storage
- **Packaging Specifications:** 100µg/vial, 500µg/vial, 1mg/vial, 5mg/vial (sterile glass vials with rubber stoppers and aluminum crimp seals); customized packaging available upon request (10mg-1g).
 - **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 for long term; store in a dedicated biological reagent refrigerator.
 - **Shelf Life:** 36 months (unopened, 2-8°C, specified conditions); 48 hours (reconstituted 100µg/mL 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 packaging and ice packs; use express delivery with cold chain service; avoid freeze-thaw and direct sunlight during transport.
- ### 7. Safety & Protection
- **Mandatory PPE:** Wear nitrile gloves, N95 dust mask, chemical splash goggles and lab coat for all handling operations; use face shield and sterile gloves for powder weighing/reconstitution.
 - **Handling Precautions:** Operate in a clean, well-ventilated lab/dust-free workbench; avoid dust generation/inhalation/skin/eye contact; use sterile technique for reconstitution; no eating/drinking/smoking in the work area.
 - **Allergy Prevention:** Sensitive individuals (to glycoproteins/ gonadotropins) should avoid contact; have antihistamine/bronchodilator available in the lab for emergency use.
 - **Emergency Measures:** Rinse eyes with plenty of water for 15-20 minutes and consult a doctor if contact occurs; wash skin with soap and water for 10 minutes if irritation/rash occurs; move to fresh air and seek medical attention for respiratory allergy symptoms.
- ### 8. Quality Assurance
- Manufactured under ISO 9001 (quality) and GMP (biopharmaceutical) management systems; strict raw material inspection and production process control.
 - Each batch is tested for purity, biological activity, endotoxin, sterility and glycosylation; accompanied by a Certificate of Analysis (COA) to ensure compliance with international biopharmaceutical standards (USP/EP/CP).
 - All raw materials are sourced from GMP-certified suppliers; full traceability of production, testing and shipping records for all batches.
 - Provide professional technical support: reconstitution guidance, buffer selection, animal model protocol optimization and data analysis; custom synthesis service for recombinant FSH available.
 - Comply with international regulations (REACH, TSCA, IATA); complete product certification and testing reports available upon request; technical training for lab use provided for large-scale R&D projects.