

## Technical Data Sheet (TDS)

### 1. Product Overview

- **Product Name:** Recombinant Human Interferon  $\alpha$ -2b (重组人类干扰素  $\alpha$ -2b, rIFN  $\alpha$ -2b)
- **CAS Number:** 98530-12-2
- **Formula:**  $C_{148} H_{2344} N_{412} O_{46} S_{18}$
- **Formula Weight:** 31000 Da (approx)
- **Molecular Form:** Recombinant glycoprotein (165 amino acid residues, identical to native human interferon  $\alpha$ -2b)
- **Product Characteristics:** High-purity pharmaceutical GMP grade Recombinant Human Interferon  $\alpha$ -2b is produced via genetic engineering (E. coli/CHO cell expression), with identical amino acid sequence and biological activity to native human interferon  $\alpha$ -2b. White odorless lyophilized powder, soluble in neutral aqueous buffer, highly hygroscopic and stable only under ultra-low temperature vacuum storage. Potent antiviral, antitumor and immunomodulatory activity, FDA/EMA approved for clinical treatment of viral infections (hepatitis B/C) and malignant tumors; high biological potency, low immunogenicity (identical to native protein).

### 2. Technical Specifications (CP/USP/EP/FDA Compliant, GMP Grade)

Item	Specification (Pharmaceutical Grade)
Appearance	White to off-white lyophilized powder
Biological Activity (Assay)	$\geq 1.0 \times 10^8$ IU/mg (Vero Cell Viral Inhibition Method)
Protein Purity (Main Peak)	$\geq 99.0\%$ (RP-HPLC)
Loss on Drying (60°C, vacuum)	$\leq 2.0\%$
Residue on Ignition (600°C)	$\leq 0.5\%$
Heavy Metals (Pb)	$\leq 5$ ppm (AAS)
Heavy Metals (As)	$\leq 1$ ppm (AFS)
pH Value (1mg/mL aqueous, 25°C)	6.5-7.5
Water Content (Karl Fischer)	$\leq 2.0\%$
Bacterial Endotoxins	$\leq 0.1$ EU/ $\mu$ g (LAL Test)
Host Cell Protein Residue	$\leq 10$ ppm (ELISA)
Plasmid DNA Residue	$\leq 10$ pg/mg (RT-PCR)
Total Aerobic Count	$\leq 10$ CFU/g
Pathogens (E. coli/Salmonella)	Negative
Solubility	Soluble in water, dilute phosphate buffer (pH 6.5-7.5)
Particle Size	200-300 mesh
Hygroscopy	High (stable at RH $\leq 30\%$ )
Storage Stability	36 months (-20°C, unopened); 7 days (2-8°C, after opening)

### 3. Product Advantages

1. **Native Sequence Recombinant Protein:** Identical amino acid sequence to native human interferon  $\alpha$ -2b; no immunogenicity, high bioavailability and biological potency; consistent clinical efficacy with native protein.
2. **High Purity & Potency:**  $\geq 99.0\%$  RP-HPLC purity,  $\geq 1.0 \times 10^8$  IU/mg biological activity; ultra-low host cell protein/DNA residue ( $< 10$  ppm/ $< 10$  pg/mg); meets global pharmacopoeia (CP/USP/EP/FDA) and recombinant biological product standards.
3. **Multi-biological Activity:** Potent antiviral, antitumor and immunomodulatory activity; broad-spectrum antiviral effect (hepatitis B/C, HPV, influenza); inhibits tumor cell proliferation and induces apoptosis.
4. **GMP Compliant Production:** Manufactured in GMP-certified clean room; strict quality control throughout the production process; batch-to-batch consistency and product safety guaranteed.



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5. **Excellent Formulability:** Soluble in neutral aqueous buffer; compatible with various pharmaceutical excipients; suitable for injection, lyophilized powder and other formulation types.
6. **Proven Clinical Efficacy:** FDA/EMA approved for clinical use; well-documented safety and efficacy in viral hepatitis and tumor treatment; global clinical application for decades.

### 4. Application Fields

- **Pharmaceutical Industry:** Production of injectable formulations (intravenous/intramuscular/subcutaneous) for chronic hepatitis B/C, human papillomavirus (HPV) infection, melanoma, renal cell carcinoma and other viral infections/malignant tumors; clinical immunomodulatory adjuvant therapy.
- **Biomedical Research:** Research reagent for virology, oncology, immunology; antiviral drug development, tumor immunotherapy research, interferon signaling pathway research; cell culture supplement for virus-infected cell models.
- **Veterinary Medicine:** Livestock/poultry antiviral drug raw material; treatment of animal viral diseases (avian influenza, swine fever); improves animal immune function (limited clinical use).
- **Biotechnology:** Core material for interferon analog modification research; biological standard reference material for interferon activity assay; recombinant protein expression technology development.

### 5. Usage Methods

- **Pharmaceutical Formulation (Injection):** Dissolve in sterile water for injection/physiological saline to prepare  $1-10 \times 10^6$  IU/mL injectable solution; adjust pH to 6.5-7.5 with phosphate buffer; add stabilizers (mannitol, glycine) for lyophilized powder formulation; sterile filtration and aseptic filling under GMP conditions.
- **Research Use:**  $10-1000$  IU/mL concentration for in vitro cell experiments (antiviral/tumor inhibition);  $1 \times 10^5-1 \times 10^6$  IU/kg body weight for in vivo animal experiments; dissolve in sterile phosphate-buffered saline (PBS, pH 7.0) to prepare stock solution (store at  $-20^\circ\text{C}$ , avoid repeated freeze-thaw).
- **Cell Culture:** Add to virus-infected cell culture medium at  $10-100$  IU/mL concentration; inhibits viral replication and protects host cells; suitable for Vero, HepG2 and other cell lines.
- **Critical Notes:**
  1. Raw powder for pharmaceutical use only under GMP conditions; no direct human/animal use (unformulated); strict dosage control for clinical use (flu-like side effects at high doses).
  2. Avoid use in interferon-allergic individuals, autoimmune disease patients and severe liver/kidney dysfunction patients.
  3. Ultra-low temperature storage is mandatory; avoid high temperature/moisture/repeated freeze-thaw to prevent protein denaturation and activity loss.
  4. Monitor patients for flu-like symptoms (fever/fatigue) during clinical use; symptomatic treatment with antipyretics if needed.

### 6. Packaging & Storage

#### Packaging Specifications (Vacuum/Ultra-Low Temperature/Hygroscopic Protection)

- $1 \times 10^6$  IU/vial (pharmaceutical GMP grade, **vacuum-sealed** glass vial with rubber stopper + aluminum crimp seal, anhydrous desiccant inside)
- $1 \times 10^7$  IU/vial (research grade, vacuum-sealed glass vial)
- $1 \times 10^8$  IU/bottle (bulk pharmaceutical grade, vacuum-sealed HDPE plastic bottle with anhydrous desiccant)
- Custom packaging ( $1 \times 10^5$  IU/ $5 \times 10^6$  IU) for research/small-batch orders available on request (vacuum-sealed glass vials).

#### Storage Conditions (Ultra-Low Temperature Mandatory)

- **Long-term Storage:**  $-20^\circ\text{C} \pm 5^\circ\text{C}$  (**ultra-low temperature**), dry, dark, **vacuum-sealed**; low-humidity environment (RH  $\leq 30\%$ ); secondary packaging with anhydrous desiccant; store in original packaging; **avoid repeated freeze-thaw cycles** ( $\leq 3$  times).