Recombinant Human Fibronectin GMP

Catalog Number: 4305-GMP

DESCRIPTION

Source	*Spodoptera frugiperda*, *Sf* 9 (baculovirus)-derived Gln32-Pro1908, with a C-terminal 6-His tag Accession # CAE45932 Produced in an animal component free process (ACFP). Manufactured and tested under current Good Manufacturing Practice (GMP) guidelines.
N-terminal Sequence Analysis	Amino acid sequencing was blocked, suggesting it is consistent with Gln32 as the first N-terminal amino acid. Predicted N-terminal sequence: Gln_{32}-Ala-Gln-Gln-Met-Val-Gln-Pro-Gln-Ser
Predicted Molecular Mass	207 kDa

SPECIFICATIONS

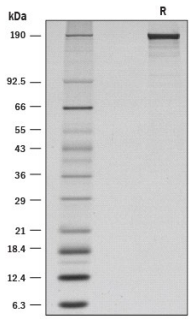
SDS-PAGE	190-210 kDa, reducing conditions
Activity	Measured by its ability to support cell attachment and spreading when used as a substratum for cell culture.
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>90%, by SDS-PAGE with silver staining.
Formulation	Lyophilized from a 0.2 µm filtered solution in PBS and Tween® 20. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 100 µg/mL in sterile PBS.
Shipping	The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	**Use a manual defrost freezer and avoid repeated freeze-thaw cycles.** ● 12 months, -20 to -70 °C as supplied. ● 1 month, 2 to 8 °C under sterile conditions after reconstitution. ● 3 months, -20 to -70 °C under sterile conditions after reconstitution.

DATA

SDS-PAGE



1 µg/lane of GMP-grade Recombinant Human Fibronectin (Catalog # 4305-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 187 kDa.

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BACKGROUND

R&D Systems' GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.

R&D Systems' quality focus includes:

- Manufacturing and testing under an ISO 9001:2008 and ISO 13485:2003 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP sterility testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells its GMP grade recombinant protein products for research use or further manufacturing use in ex vivo cell therapy applications. They are not for in vivo use or for use as therapeutic or other drugs, biologic products or devices. Please read the following End User Terms prior to using this product.

Animal Component-Free Process (ACFP) Manufacturing Conditions
R&D Systems Animal Component-Free Process (ACFP) recombinant proteins are expressed in an animal-free certified *Sf* 9 insect cell line using dedicated animal-free raw materials and labware. Production and purification procedures use equipment and media that are confirmed animal-free but performed outside our dedicated animal-free laboratories. Every stage of the manufacturing process follows R&D Systems' stringent Standard Operating Procedures (SOPs). The certified *Sf* 9 insect cell bank has undergone extensive testing to certify the lack of cytopathogens by screening for various viruses, Mycoplasma, and Spiroplasmas using both in vitro and in vivo testing methods. For *ex vivo* research or bioproduction, additional documentation can be provided.

Please read our complete ACFP Statement

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