PRODUCT PAGE

Human Fibronectin Solution, Virus Inactivated

Tubes (1 mg) Cat. # AK9930-0001 | Bottles (5 mg) Cat. # AK9930-0005 | Protein Concentration (1 mg/mL)

Product Description:

Akron Bio's Human Fibronectin Solution, Virus Inactivated is manufactured, tested, and released following relevant cGMP guidelines for ancillary materials and is specifically formulated for cell and gene therapy manufacturing applications. This product leverages pharmaceutically licensed virus and prion inactivated plasma as a raw material, offering greater batch-to-batch consistency and a unique safety profile. Akron's Human Fibronectin Solution, Virus Inactivated is purified from this raw material using a sterilized gelatin resin derived from a pharmaceutical-grade polygeline solution. Fibronectin is an important blood plasma and extracellular matrix (ECM) protein that facilitates attachment and cytoplasmic spreading during cell and tissue culture for all types of anchorage-dependent cells. Fibronectin has been shown to promote cell adhesion, spreading, proliferation, and differentiation for a variety of cell types and is considered a serum-free media supplement. *In vivo*, fibronectin is also responsible for cell adhesion and migration processes including embryogenesis, wound healing, blood coagulation, host defense, and metastasis.

Advantages:

Donor Eligibility

- Pharmaceutically licensed, pooled plasma from US-licensed plasma donation centers
- Donor screening and virus testing per 21 CFR 610.40
- Nucleic Acid Testing (NAT) conducted for HIV, B19V, HAV, HBV, HCV, & HEV

Raw Material

- Solvent Detergent (S/D) treatment for virus inactivation of enveloped viruses
- Immune Neutralization for inactivation of certain non-enveloped viruses
- Affinity Chromatography to reduce prion proteins
- Sterile microfiltration to minimize the presence of bacteria and parasites

Manufacturing

- Affinity chromatography ligand and sterilized gelatin resin derived from pharmaceutical-grade polygeline solution
- Sterile microfiltration followed by aseptic filling

Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- ISO 13485:2016, Medical devices - Quality Management Systems - Requirements for Regulatory Purposes
- ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products
- Mycoplasma, Endotoxin, and Sterility testing per USP/EP

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Release Testing:

- Appearance
- pH
- Purity
- Molecular Weight
- Protein Concentration
- Mycoplasma
- Bacterial Endotoxins
- Sterility

Stability:

- Currently on a long-term stability program
- Store at -20 °C
- Transport on dry ice
- Avoid repeated freeze-thaw cycles

For Use Statement:

For research or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

Related Products:

Catalog Number	Product Name	Size
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)	100 mL
AK8228-0100	Human Serum Albumin 25% Solution	100 mL
AR1010-0100	Human AB Serum, Converted from Octaplas®, Pooled Plasma (Human), Xeno-Free, Virus Inactivated	100 mL
AK9844-1000	Recombinant Human Insulin (rHu Insulin)	1 g

For more information on our available products or for technical assistance, see contact info below.
For contract orders under master supply agreement, please inquire.