



Recombinant Human Granulocyte-Colony Stimulating Factor (rHu G-CSF) Solution

Vials (300 µg) Cat # AK8248-0300 | Protein Concentration (300 µg/mL)

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Product Description:

Akron's Recombinant Human Granulocyte-Colony Stimulating Factor (rHu G-CSF) Solution product is manufactured following all relevant cGMP guidelines for ancillary materials. Akron's rHu G-CSF is a single-chain, approximately 18 kDa, non-glycosylated cytokine analog expressed in *E. coli*. It is purified in a pharmaceutical facility without the use of histidine tags and nickel columns. Sterile filtration with aseptic filling and lyophilization are performed in-house with Endotoxin and Sterility testing performed per USP/EP on the final product; the lyophilized product is packaged in sterile vials.

In vivo, G-CSF stimulates the production of granulocytes and hematopoietic stem cells (HSCs) from bone marrow and stimulates the proliferation, differentiation, and activation of neutrophils. Akron's cGMP-compliant rHu G-CSF can be used to promote the *ex vivo* expansion of neutrophils and HSCs.

Product Features:

Active Substance

- No animal materials were used in the manufacture of this product
- High Purity (≥ 98%)

Manufacturing

- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)
- *E. coli* expression system
- Endotoxin and Sterility per USP/EP

Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- USP <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- EP 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal 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

Release Testing:

- Appearance
- pH
- Protein Concentration (HPLC)
- Biological Activity
- Molecular Weight
- Western Blot
- Purity (Non-Reducing SDS-PAGE)
- Purity (Reducing SDS-PAGE)
- Host Cell Derived Proteins
- Host Cell DNA
- Bacterial Endotoxins
- Sterility



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Stability:

- 24-month shelf life
- Store at 2-8 °C
- Transport on cold packs
- Avoid freeze-thaw cycles

For Use Statement:

For research use 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
AK8341-0150	Recombinant Human Granulocyte Macrophage-Colony Stimulating Factor (rHu GM-CSF)	150 µg
AK9839-0100	Recombinant Human Interleukin-4 (rHu IL-4)	100 µg
AK9841-0100	Recombinant Human Interleukin-6 (rHu IL-6)	100 µg
AK9887-0050	Recombinant Human Tumor Necrosis Factor-alpha (rHu TNF-α)	50 µg

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