

Recombinant Human Granulocyte Macrophage-Colony Stimulating Factor (rHu GM-CSF)

Vials (150 µg) Cat # AK8341-0150

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Product Description:

Akron's Recombinant Human Granulocyte Macrophage-Colony Stimulating Factor (rHu GM-CSF) product is manufactured following all relevant cGMP guidelines for ancillary materials. Akron's rHu GM-CSF is a single chain, approximately 15 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, GM-CSF is produced by many cell types. It stimulates the development of neutrophils and macrophages and stimulates proliferation and development of megakaryocytic and eosinophilic progenitor cells. Akron's cGMP-compliant rHu GM-CSF can be used to promote the *ex vivo* expansion of dendritic cells (DCs), hematopoietic stem cells (HSCs), and monocytes.

Product Features:

Manufacturing

- No animal materials were used in the manufacture of this product
- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)
- *E. coli* expression system
- Endotoxin and Sterility per USP

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
- Biological Activity
- Molecular Weight
- Western Blot
- Host Cell Derived Protein
- Host Cell DNA
- Bacterial Endotoxins
- Sterility



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Stability:

- 24-month shelf life
- Store at 2-8 °C
- Transport on cold packs

Reconstitution:

Reconstitute the lyophilized product with 1 mL of sterile water for injection (WFI).

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
AK8248-0300	Recombinant Human Granulocyte-Colony Stimulating Factor (rHu G-CSF) Solution	300 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.