

Recombinant Human Interleukin-21 (rHu IL-21)

Lyophilized (40 µg) Cat. # AK9833-0040

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Product Description:

Akron's Recombinant Human Interleukin-21 (rHu IL-21) is manufactured following all relevant cGMP guidelines for ancillary materials and is supported by a Type II Master File (MF), which can be referenced by the FDA during your drug or biologic application process. Akron's rHu IL-21 is a single chain, 15.4 kDa, non-glycosylated cytokine analog expressed in *E. coli*, containing 132 amino acids. 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.

IL-21 is expressed by activated helper T cells and NKT cells and is shown to enhance and sustain the populations and activity levels of NK cells and cytotoxic T cells. It is important for the proliferation and differentiation of T cells, B cells, and NK cells. The dimeric IL-21 receptor protein (IL-21R) shares an identical subunit with the IL-2, IL-7, and IL-15 receptor proteins and activates some of the same signal transduction mechanisms. IL-21 has significant structural homology with IL-2 and, like IL-2, has been used in the therapeutic treatment of cancer to suppress tumor growth. Akron's cGMP-compliant rHu IL-21 can be used to promote the activation and proliferation of a range of cell types, including, but not limited to, CD4+ and CD8+ T cells, B cells, macrophages, monocytes, and dendritic cells (DCs).

Product Features:

Active Substance

- Carrier protein-free formulation
- *E. coli* expression system
- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)

Manufacturing

- Type II eCTD DMF (#026086) on file with FDA
- Tag-free pharmaceutical processing
- Gram-scale production capacity
- In-house sterile filtration with aseptic filling and lyophilization

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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
- High Purity, Low Endotoxin - Endotoxin and Sterility testing per USP/EP

Release Testing:

- Appearance (Visual)
- pH (Potentiometric)
- Residual Moisture (Karl Fischer)
- Specific Activity (Hybridoma B9 Proliferation)
- Biological Activity (Hybridoma B9 Proliferation)
- Molecular Weight (SDS-PAGE)
- Western Blot
- Purity (Non-reducing SDS-PAGE)
- Host cell-derived Proteins (ELISA)
- Bacterial Endotoxins (USP <85> / EP 2.6.14)
- Sterility (USP <71> / EP 2.6.1)

Stability:

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

Reconstitution:

Reconstitute with water for injection (WFI). Product is fully soluble in aqueous solution at 0.1 mg/mL

For Use Statement:

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

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Related Products:

Catalog Number	Product Name	Size
AK8223-0100	Recombinant Human Interleukin-2 (rHu IL-2)	100 µg
AK9842-0040	Recombinant Human Interleukin-7 (rHu IL-7)	40 µg
AK9823-0040	Recombinant Human Interleukin-15 (rHu IL-15)	40 µg
AK9823-0020	Recombinant Human Interleukin-12 (rHu IL-12)	20 µg
AK9999-0025	Recombinant Human Interleukin-18 (rHu IL-18)	25 µg

Purity Data:

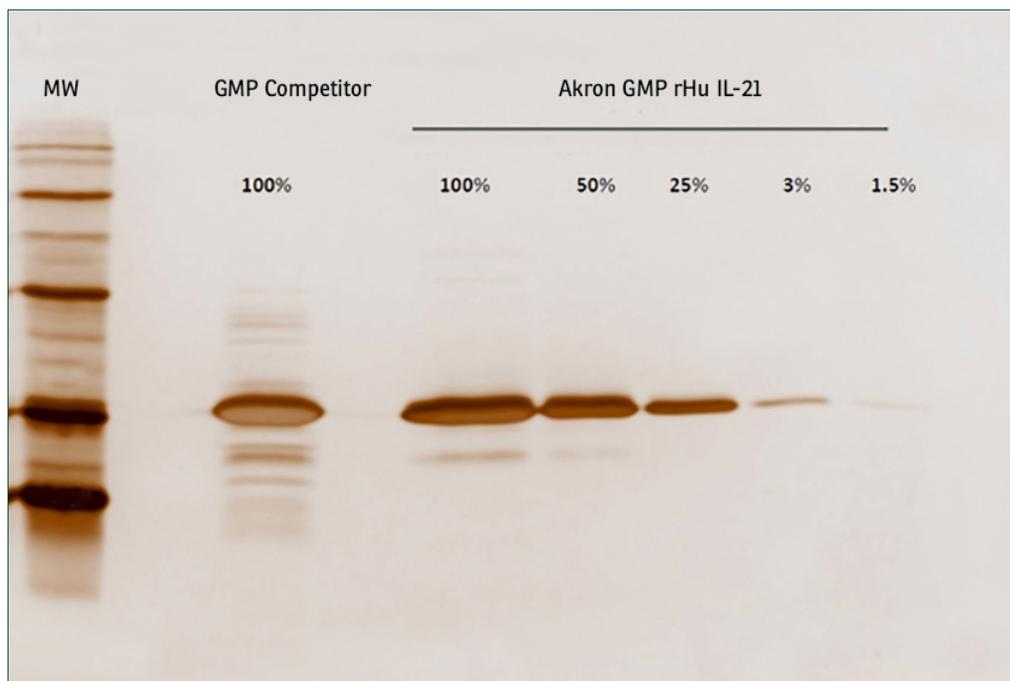


Fig.1 Non-reducing SDS-PAGE, Silver Stained

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