Recombinant Human Interleukin-21 (rHu IL-21) Closed System Solutions (CSS)®

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).

The liquid rHu IL-21 CSS product is packaged in a sterile fluoropolymer bag with two different weldable tubing connection options, allowing for easy incorporation into modern closed-system cell culture bioprocessing protocols. rHu IL-21 CSS increases safety and ease of use by eliminating the reconstitution step during manufacture and allows for the introduction of cytokine material into culture media in a fully contained manner to maximize sterility. Sterile filtration and aseptic filling are followed by Endotoxin and Sterility testing performed per USP/EP on the final product.

Product Features:

Active Substance

- Type II eCTD MF (#026086) on file with FDA
- Carrier protein-free formulation
- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)

Manufacturing

- Multi-step downstream purification strategy excluding affinity tags
- Commercial-scale production capacity
- *E. coli* expression system
- Sterile filtration and aseptic filling

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Packaging

- Sterile bag chamber – 8-mil fluoropolymer film providing inert bio-compatibility, structural integrity, and minimal gas transmission
- Two-part tube weldable tube - proximal 6" portion made from weldable TPE AdvantaFlex® (1/8" ID x1/4" OD), and the distal 6" portion made from standard weldable PVC (3/32" ID x 5/32" OD)
- All primary packaging is plasticizer free
- Primary packaging materials extensively validated, controlled, and qualified to ensure a consistent experience
- Every bag packed in individual protective cassette and shipped in validated CSafe Parcel insulated shipper

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 20399:2022, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products and Gene Therapy Products

Release Testing:

- Appearance
- pH
- ID via SDS-PAGE
- Biological Activity
- Purity via Reducing SDS-PAGE
- Purity via Non-reducing SDS-PAGE
- Bacterial Endotoxin
- Sterility

Stability:

- Under long-term stability program
- Store at 2-8 °C
- Transport with cold packs
- Do not freeze

Methods of Use:

There are two different options available for connecting to and extracting the liquid solution from Akron's rHu IL-21 CSS product (for full instructions, see "Methods of Use" document):

1) Weldable connection via proximal TPE AdvantaFlex® section (1/8" ID x 1/4" OD)
2) Weldable connection via distal PVC section (3/32" ID x 5/32" OD)

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.

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Related Products:

Catalog Number	Product Name	Size
AR1045-0010	Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions (CSS)®	1 MIU
AR1050-0020	Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions (CSS)®	15 MIU
AR1013-0100	Recombinant Human Interleukin-7 (rHu IL-7) Closed System Solutions (CSS)®	100 µg
AR1003-0050	Recombinant Human Interleukin-15 (rHu IL-15) Closed System Solutions (CSS)®	50 µg
AR1048-0060	Human AB Serum, Converted from Octaplas®, Closed System Solutions (CSS)®	60 mL
AR1048-0100	Human AB Serum, Converted from Octaplas®, Closed System Solutions (CSS)®	100 mL
AR1037-0060	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)®	60 mL
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)®	100 mL
AK9988-1000	ImmunoCell Growth Medium® (ICGM) Phenol Red Free Closed System Solutions (CSS)®	1000 mL

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