Recombinant Human Interleukin-7 (rHu IL-7) Closed System Solutions™ (CSS)

Product Description:

Akron's Recombinant Human Interleukin-7 (rHu IL-7) Closed System Solutions™ (CSS) is manufactured following all relevant cGMP guidelines for ancillary materials. The rHu IL-7 active substance is supported by a Type II Master File (MF) on file with the FDA, which can be referenced during your drug or biologic application process.

Akron's rHu IL-7 is a single chain, 17.5 kDa, non-glycosylated cytokine analog expressed in E. coli, containing 153 amino acids. The downstream purification process uses a multi-step orthogonal approach, without the use of affinity tags, to minimize exogenous impurities and ensure the delivery of highly purified and active substance for further manufacturing applications.

IL-7 is primarily expressed by non-marrow-derived stromal and epithelial cells and is required for early T cell development inside the thymus and for T cell homeostasis and regeneration in the periphery. It promotes the differentiation of hematopoietic stem cells (HSCs) down the lymphoid cell lineage and optimizes T celldendritic cell interaction. The dimeric IL-7 receptor protein (IL-7R) shares an identical subunit with the IL-2, IL-15, and IL-21 receptor proteins and activates some of the same signal transduction mechanisms. IL-7 is currently being investigated as an immunotherapy agent for various malignancies as well as HIV infection. Akron's cGMP-compliant rHu IL-7 can be used to stimulate proliferation of cytotoxic T lymphocytes (CTLs), B lymphocyte cells, monocytes, NK cells, and LAK cells.

The liquid rHu IL-7 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-7 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. See product Packaging features below.

Product Features:

Active Substance

- Type II eCTD MF (#026084) 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 x 1/4" 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

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-7 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 Closed System Solutions™ (rHu IL-2 CSS)	1 MIU
AR1050-0020	Recombinant Human Interleukin-2 Closed System Solutions™ (rHu IL-2 CSS)	15 MIU
AR1003-0050	Recombinant Human Interleukin-15 Closed System Solutions™ (rHu IL-15 CSS)	50 µg
AR1037-0060	Human Serum Albumin 25% Closed System Solutions™ (HSA CSS)	60 mL
AR1037-0100	Human Serum Albumin 25% Closed System Solutions™ (HSA CSS)	100 mL
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

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