

Recombinant Human Interleukin-12 (rHu IL-12)

Lyophilized (100 µg) Cat. # AR1051-0100 | Lyophilized (200 µg) Cat. # AR1051-0200

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Product Description:

Akron's Recombinant Human Interleukin-12 (rHu IL-12) products are manufactured following relevant cGMP guidelines for ancillary materials. 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. Sterile filtration occurs immediately before aseptic filling and lyophilization of the final product. Endotoxin and sterility testing per USP/EP, along with a host of other critical quality tests, are performed on each final lot, giving confidence in the performance of the material and the successful integration into cell therapy drug products undergoing regulatory approval.

Akron's rHu IL-12 is a 75 kDa, glycosylated, heterogeneous dimer cytokine analog expressed in yeast. The p40 chain contains 306 amino acids and the p35 chain contains 197 amino acids, for a total of 503 amino acids. It uses a chemically defined carrier protein-free formulation to reduce matrix interference. The total protein specification is 100-125% of the labeled mass, constraining mass variability within a tight range and ensuring the customer always receives at least the intended aliquot. The lyophilized product is packaged in vials and offered in 100 µg and 200 µg aliquots.

The dimeric nature of IL-12 is only shared by three other cytokines, all of which comprise the IL-12 family. *In vivo*, IL-12 is well known for stimulating the production of IFN- γ in T cells and Natural Killer (NK) cells. It also enhances the effectiveness of cytotoxic T cells and NK cells, helps generate lymphokine-activated killer (LAK) cells, and induces proliferation of activated T cells and NK cells. Akron's cGMP-compliant rHu IL-12 can be used to help differentiate, proliferate, and stimulate helper T cells, cytotoxic T cells, NK cells, LAK cells, Dendritic Cells (DCs), and macrophages.

Product Features:

Active Substance

- Carrier protein-free formulation
- Accurate mass and activity control
- High Purity via RP-HPLC ($\geq 95\%$)

Manufacturing

- Multi-step downstream purification strategy excluding affinity tags
- Sterile microfiltration and aseptic filling/lyophilization
- Animal free expression system with yeast host

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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
- 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 (visual inspection)
- pH (USP <791>)
- Residual Moisture (USP <921>)
- Total Protein (USP <1057>)
- Purity (RP-HPLC)
- Biological Activity (Secretion of IFN- γ from PBMC cells against NIBSC standard)
- Specific Activity (Secretion of IFN- γ from PBMC cells against NIBSC standard)
- Bacterial Endotoxins (USP <85>)
- Sterility (USP <71>)

Stability:

- Under long-term stability
- Store at -20 °C
- Transport on dry ice

Reconstitution:

Reconstitute the lyophilized product with sterile water to a concentration of 0.1 - 0.5 mg/mL. Avoid repeated freeze-thaw cycles.

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy application. 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
AR1052-0050	Recombinant Human Interleukin-18 (rHu IL-18)	50 µg
AR1052-0100	Recombinant Human Interleukin-18 (rHu IL-18)	100 µg
AK9823-0040	Recombinant Human Interleukin-15 (rHu IL-15)	40 µg
AK8223-0100	Recombinant Human Interleukin-2 (rHu IL-2)	100 µg
AK9842-0040	Recombinant Human Interleukin-7 (rHu IL-7)	40 µg
AK9833-0040	Recombinant Human Interleukin-21 (rHu IL-21)	40 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.