

#### **PRODUCT PAGE**

# Recombinant Human Interleukin-18 (rHu IL-18)

Lyophilized (50 µg) Cat. # AR1052-0050 | Lyophilized (100 µg) Cat. # AR1052-0100

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# **Product Description:**

Akron's Recombinant Human Interleukin-18 (rHu IL-18) 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-18 is a single chain, 18.3 kDa, glycosylated cytokine analog expressed in Yeast, containing 157 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 50 µg and 100 µg aliquots.

In vivo, IL-18 is a proinflammatory cytokine with varied effects, influencing both innate and adaptive immunity and implicated in the mechanisms responsible for autoimmune disease. IL-18 was originally known as 'IFN- $\gamma$  inducing factor' and is widely known for its ability to co-stimulate the production of IFN- $\gamma$  in T cells and Natural Killer (NK) cells alongside IL-12 and IL-15. IL-18 is one of the 11 members of the Interleukin-1 superfamily, which all share structural homology and signal via a similar pathway. Akron's cGMP-compliant rHu IL-18 can be used to help differentiate, proliferate, and stimulate T cells, NK cells, Dendritic Cells (DCs), and macrophages.

#### **Product Features:**

#### **Active Substance**

- Carrier protein-free formulation
- Accurate mass and activity control
- High Purity via RP-HPLC (≥ 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 KG-1 cells against NIBSC standard)
- Specific Activity (Secretion of IFN-γ from KG-1 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 - 0.2 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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Lyophilized (50  $\mu$ g) Cat. # AR1052-0050 | Lyophilized (100  $\mu$ g) Cat. # AR1052-0100

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## **Related Products:**

Catalog Number	Product Name	Size
AR1051-0100	Recombinant Human Interleukin-12 (rHu IL-12)	100 µg
AR1051-0200	Recombinant Human Interleukin-12 (rHu IL-12)	200 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.