

Recombinant Human Interleukin-15 (rHu IL-15)

Lyophilized (40 µg) Cat. # AK9823-0040

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1. Why use Akron's Recombinant Human Interleukin-15 (rHu IL-15)?

Akron's Recombinant Human Interleukin-15 (rHu IL-15) is manufactured following all relevant cGMP guidelines for ancillary materials and is supported by a Type II Master File (MF) with the FDA. 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.

2. What are the recommended storage conditions for Akron's rHu IL-15?

We recommend storing this product at 2-8 °C.

3. What are the shipping conditions for Akron's rHu IL-15?

This product ships on cold packs.

4. What is the shelf-life for Akron's rHu IL-15?

This product has a shelf life of 24 months after the date of manufacture under recommended controlled storage conditions.

5. Do you have any excursion stability data available?

No excursion data is currently available for this product, but please inquire about any specific stability needs you may have.

6. How do you reconstitute Akron's rHu IL-15?

It is recommended that you reconstitute using water for injection (WFI). This product is fully soluble in aqueous solution at 0.1 mg/mL.

7. How long can I store Akron's rHu IL-15 after reconstitution?

We do not suggest an ideal storage medium or storage conditions for reconstituted aliquots, as this product is intended to be used in a single application within cGMP manufacturing protocols. Storage after reconstitution is affected by many factors such as benchtop methodology, concentration, diluent, storage temperature, etc.

8. What organism is used to express Akron's rHu IL-15?

This product is expressed in *E. coli*.

9. How is Akron's rHu IL-15 different than native IL-15?

Akron's rHu IL-15 is not glycosylated because it is derived from *E. coli*, and it contains an N-terminal methionine. It is likely that the aggregation state is also different than native IL-15.

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10. What is the molecular weight of Akron's rHu IL-15?

Akron's rHu IL-15 has a theoretical molecular weight of 12,904 Da. Akron's rHu IL-15 apparent molecular weight is indistinguishable when compared to a reference standard using Non-Reducing SDS-PAGE. Every batch of rHu IL-15 is analyzed by SDS-PAGE and must meet the molecular weight release specification between 12,000-16,000 Da.

11. Do you have a Master File (MF) available for this product?

Yes, our rHu IL-15 has a Type II eCTD MF (#026085) on file with FDA. We can provide you a Letter of Authorization that will permit the FDA to refer to the information on file in support of your submissions.

12. Does this product have a TSE/BSE statement?

Yes, a TSE/BSE statement is available upon request for this product.

13. Are animal-derived materials used in the manufacture of this product?

All raw materials, components, sub-components, and consumables used in the manufacturing of this product are either animal-free or in compliance with EMEA/410/01 rev. 3. Please see the BSE-TSE Statement.

14. Is virus and pathogen inactivation included in the manufacturing process?

No, because viruses that infect bacteria (bacteriophages) do not pose a known threat to human cells, virus reduction manufacturing steps are usually not included when purifying material from a bacterial host, as is the case with Akron's rHu IL-15. We use an *E. coli* based expression system that does not require additional virus reduction.

15. What safety testing is done on this product?

Every lot of final product is tested and released, with specifications and methods per USP/EP, for both Endotoxin (USP <85> / EP 2.6.14) and Sterility (USP <71> / EP 2.6.1).

16. Which cell types are suitable?

IL-15 stimulates the proliferation of several types of T cells, augments the proliferation of certain B cells, and stimulates the generation, proliferation, and activation of NK cells. Akron's cGMP-compliant rHu IL-15 can be used to promote the activation and differentiation of CAR-T cells, TCR-T cells, Tregs, TILs, NK cells, NKTs, and Th17 cells.

17. Do you have an a Safety Data Sheet (SDS) for this product?

Yes, an SDS is available upon request for this product.

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18. How does Akron measure activity for rHu IL-15?

Akron uses a validated leukocyte proliferation assay to report activity. The rHu IL-15 induced proliferation of CTLL-2 mouse cytotoxic T cells is used to determine an activity estimate using an ED50 assay calibrated with the World Health Organization reference standard for Interleukin-15 (NIBSC 95/554).

19. Is the performance comparable to other rHu IL-15 formulations?

The specific activity (MIU/mg) of Akron's rHu IL-15 batches have historically been comparable to the specific activity value of the World Health Organization standard (NIBSC 90/530) for IL-15, known to be approximately 10 MIU/mg.¹

20. What is the intended use for the product?

For research use or further manufacturing use in *ex vivo* cell therapy applications. cGMP grade recombinant protein products are not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

21. What packaging options are available?

Akron's lyophilized rHu IL-15 is packaged into generic colorless vial bottles made from Type I borosilicate glass that are sterilized before aseptic filling. These ampoule bottles have a nominal fill volume of 2.0 mL with a minimum overflow volume of 3.0 mL and have been shown to have an arsenic content of < 0.1 ppm. The bottles are closed with a gray bromobutyl rubber stopper and sealed with a flip-top aluminum seal that are both sterile before aseptic filling. Akron also offers our rHu IL-15 in a liquid formulation packaged into closed-system bags coming soon (inquire for details on bags).

22. Do I need to use a sterile needle and syringe to remove the product from the vial?

No, our vial bottle packaging was chosen for easy access with a laboratory pipette.

References

1. <https://www.nibsc.org/documents/ifu/95-554.pdf>

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