FREQUENTLY ASKED QUESTIONS

Recombinant Human Interleukin-12 (rHu IL-12)

1. Why use Akron's Recombinant Human Interleukin-12 (rHu IL-12)?

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. Each lot is tested for critical safety and quality aspects giving confidence in the performance of the material and the successful integration into drug products undergoing regulatory approval.

2. What are the recommended storage conditions for Akron's rHu IL-12?

We recommend storing this product at -20 ± 5 °C

3. What are the shipping conditions for Akron's rHu IL-12?

This product ships with dry ice.

4. What is the shelf-life for Akron's rHu IL-12?

This product is under a long-term stability program with a final target of 24 months.

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-12?

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

7. How long can I store Akron's rHu IL-12 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-12?

This product is expressed in yeast.

9. What is the molecular weight of Akron's rHu IL-12?

Akron's rHu IL-12 is a glycosylated heterodimer formed by two subunits, p40 and p35, for a total theoretical weight of 75 kDa. It has an apparent molecular weight of 70-100 kDa.

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

This product will be supported by a Type II eCTD MF on file with FDA, expected in 2023. At that time, 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.

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

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

12. 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.

13. 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).

14. Which cell types are suitable?

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.

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

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

16. How does Akron measure activity for rHu IL-12?

The activity assay is based on the detection of secreted alkaline phosphatase (SEAP) from HEK-Blue™ IL-12 reporter cells. The NIBSC standard for rHu IL-12 (95/544) is used to determine a relative activity for each lot.[1]

17. 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.

18. What packaging options are available?

Akron's lyophilized rHu IL-12 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 13 mm top. The vials are closed with a gray bromobutyl rubber stopper and sealed with a flip-top aluminum seal.

References

1. https://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.