



Recombinant Human Erythropoietin (rHu EPO) Solution

Vials (2,000 IU) Cat. # AK9941-0002 | Vials (40,000 IU) Cat. # AK9941-0040 | Volume: 1 mL/vial

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Product Description:

Akron's Recombinant Human Erythropoietin (rHu EPO) Solution is manufactured following all relevant cGMP guidelines for ancillary materials and is supported by a Type II Master File (MF), which can be referenced by the FDA during your drug or biologic application process. Akron's rHu EPO, expressed in Chinese Hamster Ovary (CHO) cells, is a heavily glycosylated, ~30.4 kDa, glycoprotein containing 165 amino acids, with an identical sequence to natural erythropoietin. This recombinant form is known as epoetin alfa, which has an average glycosylation pattern and the same biological effects as endogenous erythropoietin *in vivo*.

It is purified in a pharmaceutical facility without the use of affinity columns such as histidine tag resins, which eliminate the use of nickel or other metals. Sterile filtration with aseptic filling are performed with Endotoxin and Sterility testing performed per USP/EP on the final product. The liquid product is packaged in vials and available in various aliquots as listed above according to activity, similar to the dosage forms of Procrit® and Epogen®.

In vivo, erythropoietin is largely responsible for erythropoiesis, controlling the differentiation and maintenance of red blood cells with their progenitors and precursors from hematopoietic stem cells (HSCs). Erythropoietin is also essential for angiogenesis in the embryo and adult human¹, and plays a protective role in many tissues, with anti-apoptotic effects having been shown in the brain, heart, and small intestines². Akron's cGMP-compliant rHu EPO can be used to stimulate cell proliferation and differentiation of erythroid progenitor cells and stimulate expansion of Tregs and CD34+ cells.

Product Features:

Active Substance

- Amino acid sequence identical to Procrit® and Epogen® (epoetin alfa)
- Expressed in CHO cells
- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)

Manufacturing

- Type II eCTD MF (#027160) on file with FDA
- Animal-free media components
- Formulated with a carrier protein, HSA (injectable)
- Tag-free pharmaceutical biosimilar processing
- Sterile filtration and aseptic filling



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Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- Master Cell Bank characterized according to EMEA – Note for Guidance on Virus Validation Studies CPMP/BWP/268/95; 29.2. 1996
- 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 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
- High Purity, Low Endotoxin - Endotoxin and Sterility testing per USP/EP

Release Testing:

- Appearance
- pH
- Biological Activity
- Western Blot
- Non-Reducing SDS-PAGE
- Peptide Mapping
- N-terminal Sequence Analysis
- Host Cell Derived Proteins
- Host Cell DNA
- Bacterial Endotoxins
- Sterility

Stability:

- 24-month shelf life
- Store at 2-8 °C
- Transport with cold packs

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy applications only. 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
AK9879-0100	Recombinant Human Stem Cell Factor (rHu SCF)	100 µg
AK9836-0100	Recombinant Human Interleukin-3 (rHu IL-3)	100 µg
AK9841-0100	Recombinant Human Interleukin-6 (rHu IL-6)	100 µg
AK8248-0300	Recombinant Human Granulocyte-Colony Stimulating Factor (rHu G-CSF) Solution	300 µg
AK8341-0150	Recombinant Human Granulocyte Macrophage-Colony Stimulating Factor (rHu GM-CSF)	150 µg

References:

- Müller-Ehmsen J, Schmidt A, Krausgrill B, Schwinger RHG, Bloch W. Role of erythropoietin for angiogenesis and vasculogenesis: from embryonic development through adulthood. *Am J Physiol Heart Circ Physiol.* 2006 Jan;290(1):H331-340.
- Yu Y, Shiou S-R, Guo Y, Lu L, Westerhoff M, Sun J, et al. Erythropoietin protects epithelial cells from excessive autophagy and apoptosis in experimental neonatal necrotizing enterocolitis. *PLoS One.* 2013;8(7):e69620.

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