

CytoPak GMP Human IL-2 Protein

Catalog # GMP-L02H14GB01



For Closed System Manufacturing

Product Description

CytoPak GMP Recombinant Human IL-2 Protein is packaged in sterile closed containers that can be readily incorporated into ex vivo clinical production processes. The bag utilizes medical grade multilayer film with two weldable options. The outlet weldable tube contains proximal TPE section (1/8" ID x 1/4" OD) and distal PVC section (3/32" ID x 5/32" OD). The liquid state and closed-system packaging of CytoPak GMP Recombinant Human IL-2 Protein can be directly welded to GMP media bags resulting in safety and user-friendliness by bypassing the reconstitution step during manufacture.

Source

CytoPak GMP Recombinant Human IL-2 Protein (GMP-L02H14GB01) is expressed from E. coli cells. It contains AA Ala 21 - Thr 153 (Accession # P60568-1). Predicted N-terminus: Met

Molecular Characterization

IL-2(Ala 21 - Thr 153)
P60568-1

This protein carries no "tag".

The protein has a calculated MW of 15.4 kDa. The protein migrates as 16 kDa \pm 2 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

Features

1. Closed System Process
2. Minimized Manual Touchpoints
3. Ready-to-Use Format
4. Enhanced Efficiency
5. Weldable Tubing
6. Designed under ISO 9001:2015 and ISO 13485:2016
7. Manufactured and QC tested under a GMP compliance factory
8. Animal-Free materials
9. Beta-lactam materials free
10. Batch-to-batch consistency
11. Stringent quality control tests

Endotoxin

Less than 5.0 EU/ mL by the LAL method.

Host Cell Protein

<0.5 ng/ μ g of protein tested by ELISA.

Host Cell DNA

<0.1 ng/ μ g of protein tested by qPCR.

Sterility

The sterility testing was performed by membrane filtration method described in USP<71> and Ph. Eur. 2.6.1.

Contact us for customized product form or formulation.

Mycoplasma

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Supplied as 0.2 μ m filtered solution in phosphate with protectants.

Shipping and Storage

This product is supplied and shipped as sterile liquid solution with dry ice, please inquire the shipping cost.

Upon receipt, store it immediately at -70°C or lower for long term storage. Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

-70°C for 24 months

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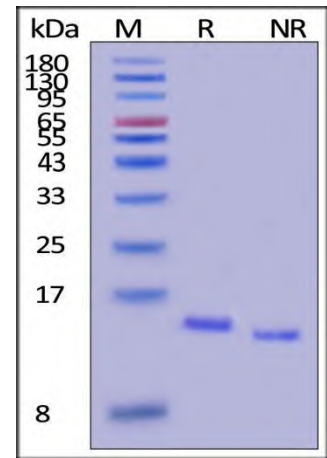
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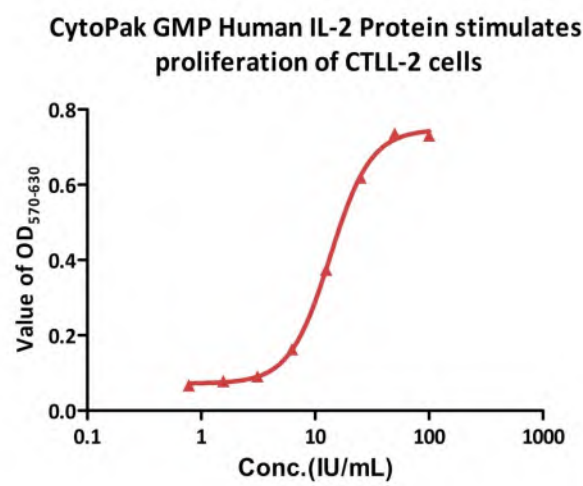
Can be stored up to 1 month at -20 °C
Can be stored up to 1 week at 2 - 8 °C

SDS-PAGE



CytoPak GMP Human IL-2 Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity - CELL BASE



CytoPak GMP Human IL-2 Protein (Cat. No. GMP-L02H14GB01) stimulates proliferation of CTLL-2 cells. The specific activity of CytoPak GMP Human IL-2 Protein is $\geq 1.20 \times 10^7$ IU/mg, which is calibrated against human Interleukin-2 China National Standard (NIFDC code: 270008) (QC tested). China National Institutes for Food and Drug Control (NIFDC) Standard was prepared and calibrated against human IL-2 WHO International Standard (NIBSC code: 86/500) by NIFDC.

Bag design

The long outlet tube affixed to the bag consists of two distinct segments that are joined together with an in-line barb connector. Both sections are made from weldable materials. The section closer to the bag is made of weldable TPE (1/8" ID x 1/4" OD), while the section farther from the bag is made of weldable PVC (3/32" ID x 5/32" OD). Both sections are about 6 inch long. The TPE section has a pinch clamp, which users can slide to the desired position and clamp the tube securely.

The other shorter tube attached to the bag is the inlet tube, which is not recommended for liquid exchange. To make a weldable connection to CytoPak, please refer to the user manual below.

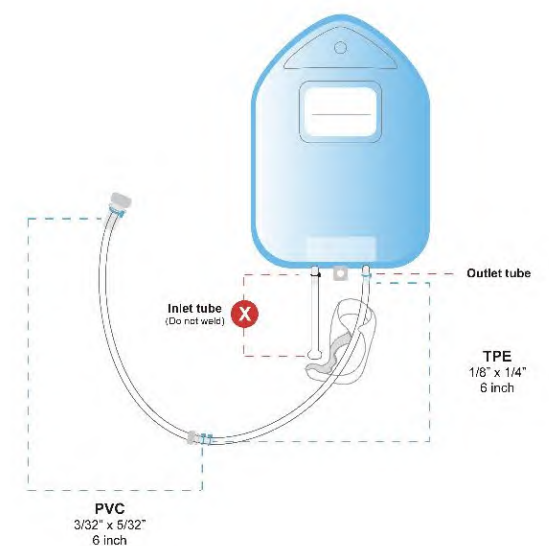
General Guidelines

● Equipment Needed

1. Tube Welder
2. Tube Sealer

● Caution

3. Avoid placing heavy objects directly on top of the bag, as excessive pressure can jeopardize the integrity of the packaging.
4. Ensure the pinch-clamp on the outlet tube is not released before a sealed connection is made. If the pinch-clamp does not work before connection, you could use vessel clamp to clamp the closer section of the bag.
5. The PVC tubing may become fragile during transit when packed with dry ice. For immediate use, let the bag thaw for approximately 1 hour before taking it out of the box.



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● Connection Method

Prepare

6. Take out CytoPak from -70 °C storage and thaw at room temperature 1 hour or 4°C overnight.
7. As the PVC line may turn brittle during transportation on dry ice. Let CytoPak remain in the box for 5 minutes at room temperature prior to removing.
8. Remove the CytoPak from the plastic bag and ensure it is completely thawed. Mix gently several times.
9. Make sure the pinch clamp is securely engaged on the outlet line.

Add CytoPak to Media Bag

10. Weld the CytoPak bag to a media bag using aseptic welding protocol.

There are two options for connecting to the CytoPak bags: weldable connection via proximal TPE section (1/8" ID x 1/4" OD) and distal PVC section (3/32" ID x 5/32" OD). Both of the tubes are about 6 inch long (15cm).

11. Once the welding process is finished, release the pinch clamps in the outlet tubing line, then allow the solution from CytoPak bag flow into media bag. You can tilt the bag a bit to make solution in the CytoPak bag drain through the outlet tubing as much as possible.
12. We have conducted extensive testing and validation to eliminate the residual volume in the tubing and the bag, a single squeeze can meet the requirement for cell culture.
 - a. User can squeeze the CytoPak cytokine into the culture media bag in one go, without the need to rinse with the culture media (Recommended).
 - b. User can also repeatedly transfer the media between the media bag and the CytoPak bag 2 to 5 times to fully recover the cytokines to media bag. (Optional).
13. Clamp the tube between the CytoPak bag and the media bag.
 - a. Confirm the clamp on the media bag side is closed to media bag and engage clamp.
 - b. Confirm the clamp on the CytoPak side is close to CytoPak bag and engage clamp.
14. Seal and disconnect the tubing between the media bag and CytoPak bag.

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology – Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents:

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

Animal-Free materials

Materials purchased from the approved suppliers by QA

ISO 5 clean rooms and automatic filling equipment

Qualified personnel

Quality-related documents review and approve by QA

Fully batch production and control records

Equipment maintenance and calibration

Validation of analytical procedures

Stability studies conducted

Comprehensive regulatory support files

Request For Regulatory Support Files (RSF)

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

SDS-PAGE

Protein content



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Endotoxin level

Residual Host Cell DNA content

Residual Host Cell Protein content

Biological activity analysis

Microbial testing

Mycoplasma testing

In vitro virus assay

Residual moisture

Batch-to-batch consistency

BACKGROUND

Interleukin-2 (IL-2) is an interleukin, a type of cytokine immune system signaling molecule, which is a leukocytotropic hormone that is instrumental in the body's natural response to microbial infection and in discriminating between foreign (non-self) and self. IL-2 mediates its effects by binding to IL-2 receptors, which are expressed by lymphocytes, the cells that are responsible for immunity. Mature human IL-2 shares 56% and 66% aa sequence identity with mouse and rat IL-2, respectively. Human and mouse IL-2 exhibit cross species activity. The receptor for IL-2 consists of three subunits that are present on the cell surface in varying preformed complexes. IL-2 is also necessary during T cell development in the thymus for the maturation of a unique subset of T cells that are termed regulatory T cells (Tregs). After exiting from the thymus, Tregs function to prevent other T cells from recognizing and reacting against "self antigens", which could result in "autoimmunity". Tregs do so by preventing the responding cells from producing IL-2. Thus, IL-2 is required to discriminate between self and non-self, another one of the unique characteristics of the immune system.

DISCLAIMER

ACROBiosystems GMP grade products are designed for research, manufacturing use or ex vivo use.

CAUTION: Not intended for direct human use.

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