CytoPak GMP Human IL-7 Protein *(E. coli)*

Catalog # GMP-L07H15GB01

For Closed System Manufacturing

Product Description

CytoPak GMP Human IL-7 Protein *(E. coli)* 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 a proximal TPE section (1/8'' ID x 1/4'' OD) and a distal PVC section (3/32'' ID x 5/32'' OD). The liquid state and closed-system packaging of CytoPak GMP Human IL-7 Protein *(E. coli)* can be directly welded to GMP media bags resulting in safety and user-friendliness by bypassing the reconstitution step during manufacture.

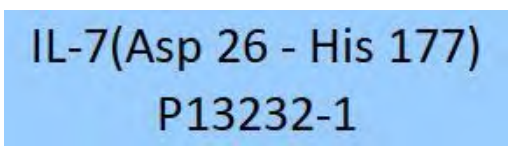
Features

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

Source

CytoPak GMP Human IL-7 Protein *(E. coli)* (GMP-L07H15GB01) is expressed from E. coli cells. It contains AA Asp 26 - His 177 (Accession # P13232-1).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 17.5 kDa. The protein migrates as 17 kDa±3 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

Met-Asp-Cys-Asp-Ile-Glu-Gly-Lys-Asp-Gly-Lys-Gln-Tyr-Glu-Ser (Routinely tested)

Endotoxin

Less than 1.0 EU/mL, tested by the rFC method in compliance with USP <86> and Ph. Eur. 2.6.32.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Sterility

Sterility testing was performed using the membrane filtration method in compliance with USP <71> and Ph. Eur. 2.6.1..

Mycoplasma

Negative

Purity

>95% as determined by SDS-PAGE.

Formulation

Supplied as 0.2 μm filtered solution in PBS, rHSA, pH7.4 with protectants.

Shipping and Storage

Upon receipt, store it immediately at -20°C or lower for long term storage.

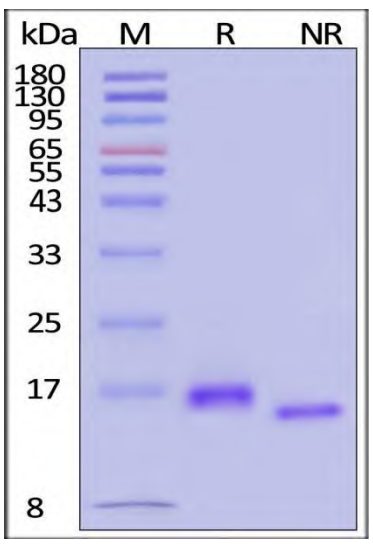
Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

Can be stored up to 24 months at -20°C;

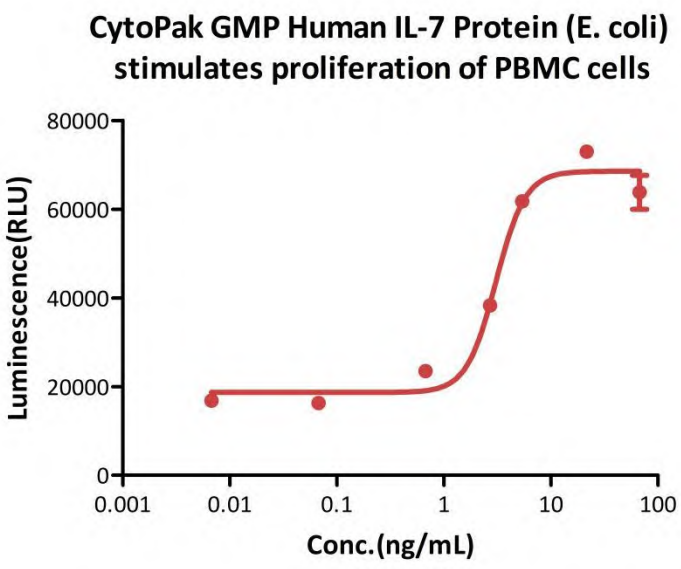
Can be stored up to 2 weeks at 2-8°C.

SDS-PAGE



CytoPak GMP Human IL-7 Protein *(E. coli)* 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

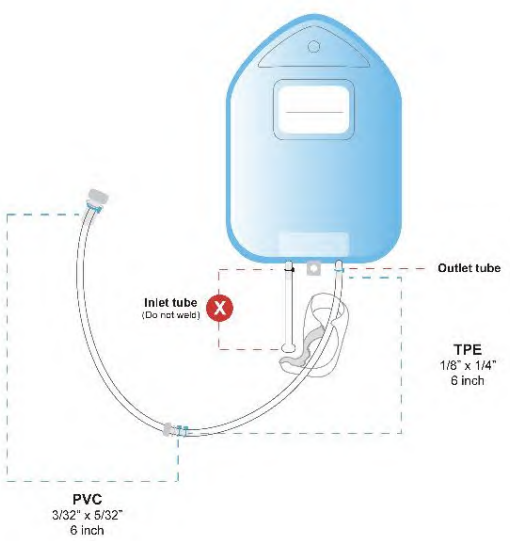


CytoPak GMP Human IL-7 Protein *(E. coli)* (Cat. No. GMP-L07H15GB01) stimulates proliferation of PHA-P-activated human peripheral blood mononuclear cell (PBMC). The specific activity of CytoPak GMP Human IL-7 Protein *(E. coli)* is > 1.00×10^8 IU/mg, which is calibrated against human IL-7 WHO International Standard (NIBSC code: 90/530) (QC tested).

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.

- **Connection Method**

Prepare

6. Take out CytoPak from -70 ℃ storage and thaw at room temperature 1 hour or 4℃ 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：

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies
- Fully batch production and control records
- Equipment maintenance and calibration

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

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

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(b) Obtaining any necessary regulatory approvals or intellectual property licenses for Purchaser's use.

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(d) Conducting all necessary quality control, safety, efficacy, and validation testing of Products within Purchaser's process or final product.

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(b) ANY DIRECT DAMAGES, COSTS, OR EXPENSES EXCEEDING THE AMOUNT PAID BY PURCHASER FOR THE SPECIFIC PRODUCT(S) GIVING RISE TO THE CLAIM.

(c) DAMAGES ARISING FROM: (i) MISUSE, ABUSE, OR UNAUTHORIZED MODIFICATION OF PRODUCTS; (ii) USE BEYOND THE EXPIRATION DATE; (iii) IMPROPER STORAGE OR HANDLING; (iv) ACCIDENTAL DAMAGE; (v) FAILURE TO CONDUCT ADEQUATE VALIDATION OR TESTING BY PURCHASER; (vi) INFRINGEMENT CLAIMS RELATED TO PURCHASER'S USE; OR (vii) THE COST OF PROCURING SUBSTITUTE GOODS OR SERVICES.

(d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

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