

GMP PRODOTS™
PROTEINS, A USER GUIDE
REDUCING RISK FOR CELL THERAPY
MANUFACTURING

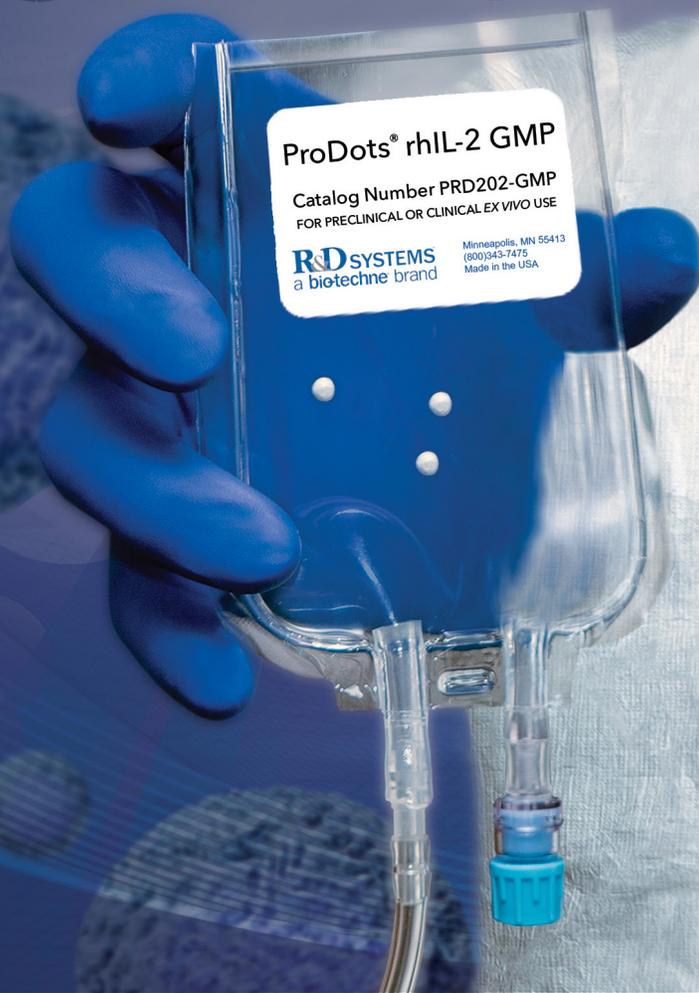
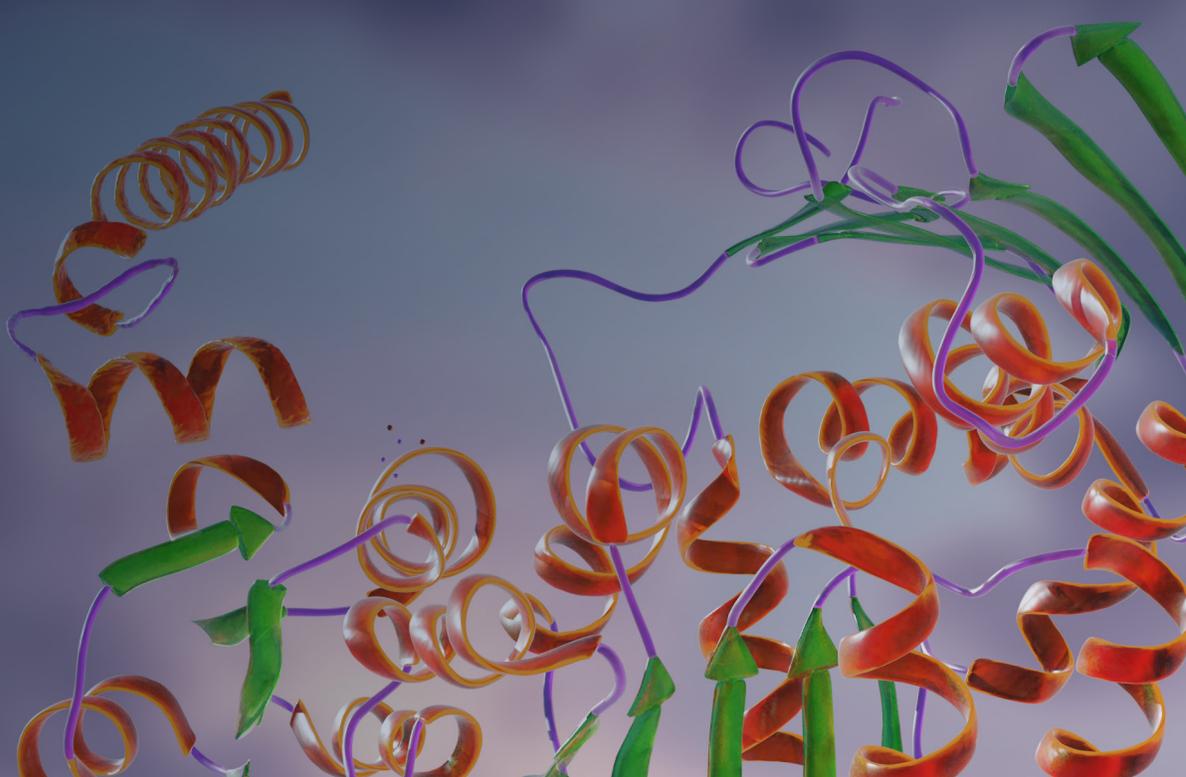




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INTRODUCTION

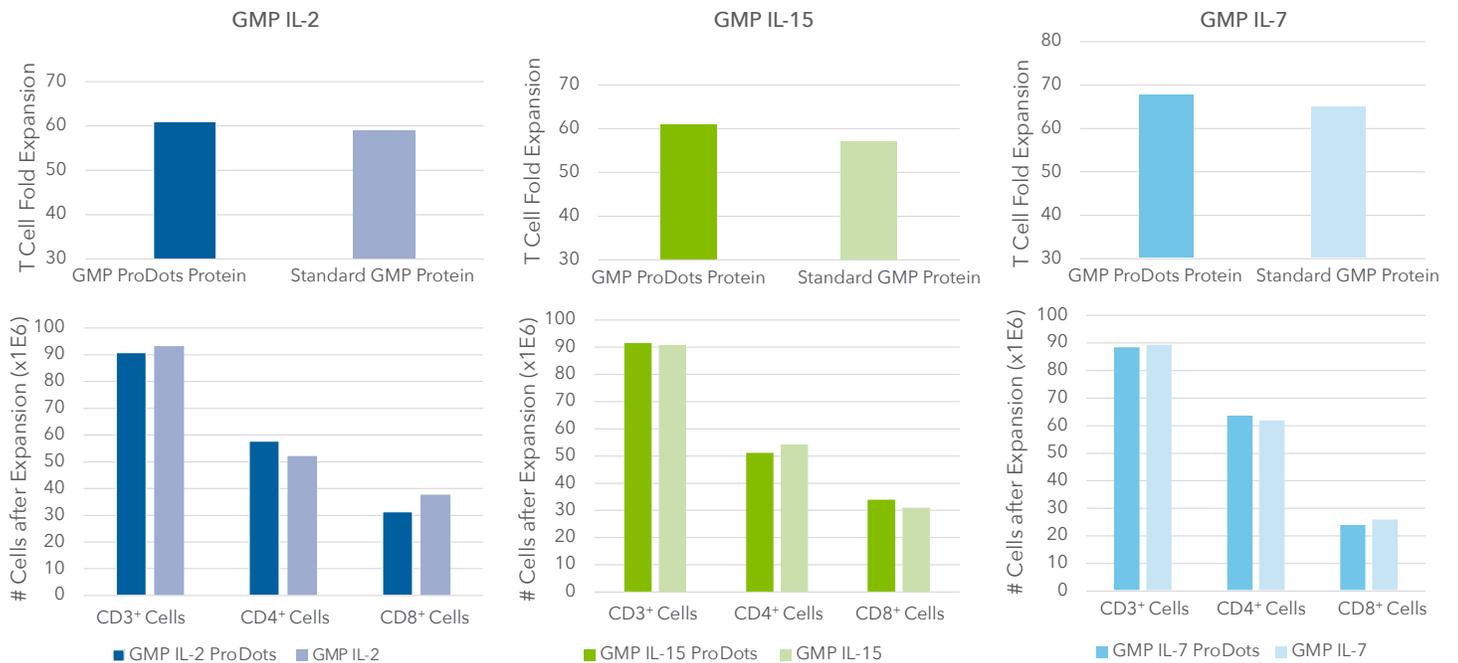
Minimize risk in Cell and Gene Therapy manufacturing and overcome the complexities of raw material handling by delivering cytokines directly into cell cultures with GMP ProDots™ Proteins. GMP ProDots Proteins are formulated as lyophilized protein spheres packaged in animal-free, sterile bags for integration into closed process cell culture systems.

GMP ProDots Proteins are manufactured under the same quality systems that we follow for Bio-Techne's standard GMP Proteins. Our proven GMP manufacturing expertise combined with an innovative formulation eliminates the need for protein aliquoting, allows for a closed process system, and de-risks the manufacturing process.

ADVANTAGES OF GMP PRODOTS PROTEINS

- Closed processing cytokine addition
- Eliminate protein aliquoting
- Limit handling errors to de-risk the process step
- Improve efficiency of GMP protein supplementation
- Customizable options
- Translatable from research grade to GMP-grade

Comparative bioactivity testing with relevant assay systems showing the functional equivalence of our protein formulations. GMP ProDots Proteins show equivalent performance with Bio-Techne's standard formulation GMP Proteins.



Human PBMCs were cultured for 9 days with ExCellerate™ Human T Cell Media, the Cloudz™ Human T Cell Activation Kit, and the indicated GMP proteins.

PROTOCOL FOR USING GMP PRODOTS™ PROTEINS

GMP ProDots Proteins can be added to your cell culture media with either a weldable tube or a needle-free port. Refer to the diagram below to identify features of GMP ProDots Protein bags mentioned in these protocols.

WELDABLE TUBING METHOD



Video available at <https://youtu.be/FgQLXU-NT2Q>

1. Hang the GMP ProDots Proteins bag directly below the media bag. Sterile weld the GMP ProDots Proteins bag directly to the media bag.
2. Unclamp the tubing and allow up to 25 mL of media to flow into the GMP ProDots Proteins bag by gravity. Clamp the tubing after media has been added to the bag. Dissolve the GMP ProDots Proteins by gently mixing the media around in the bag. Visually confirm that the GMP ProDots Proteins have completely dissolved.
3. Release the tubing clamp and allow the reconstituted protein to flow into the media bag. Raise the GMP ProDots Proteins bag above the media bag to ensure that all dissolved protein is transferred to the media bag. Repeat steps 2 and 3 to perform a second wash.
4. Clamp the tubing to prevent media from flowing back into the GMP ProDots Proteins bag.
5. Media supplemented with cytokines is now ready to be used for cell culture.
6. If using more than one GMP ProDots Proteins bag, repeat steps 1-5 with additional GMP ProDots Proteins bags.

NEEDLE-FREE PORT METHOD

1. Connect a needle-free syringe with up to 25 mL of media directly to the GMP ProDots Proteins bag.
2. Inject media into the GMP ProDots Proteins bag. Dissolve protein by gently mixing the media around in the bag. Visually confirm that the GMP ProDots Proteins have completely dissolved.
3. Draw the reconstituted protein out of the bag with the syringe. Repeat steps 2 and 3 to perform a second wash.
4. Inject reconstituted protein into the media bag.
5. Media supplemented with cytokines is now ready to be used for cell culture.
6. If using more than one GMP ProDots Proteins bag, repeat steps 1-4 with additional GMP ProDots Proteins bags.

GMP PRODOTS™ PROTEINS DETAILS

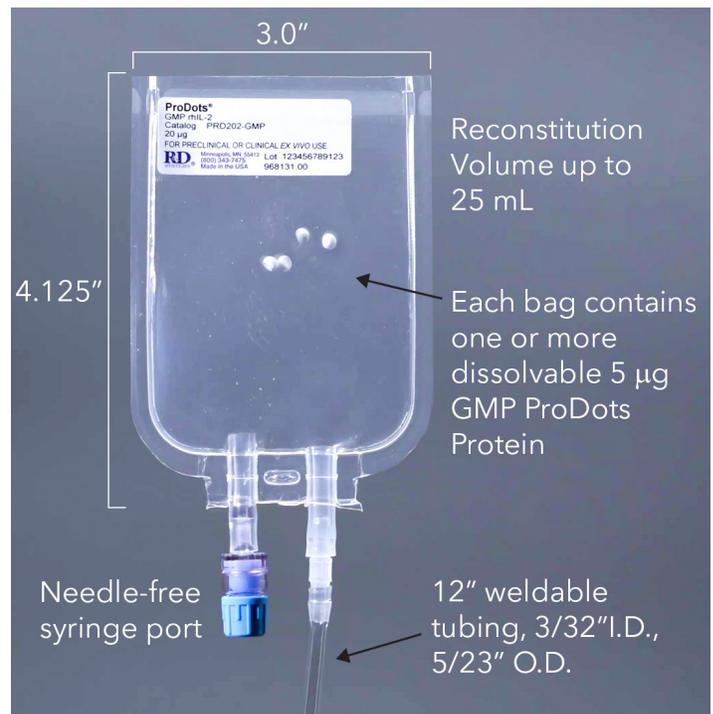
GMP PRODOTS PROTEINS CHARACTERISTICS

Manufactured under an animal-free and GMP controlled process

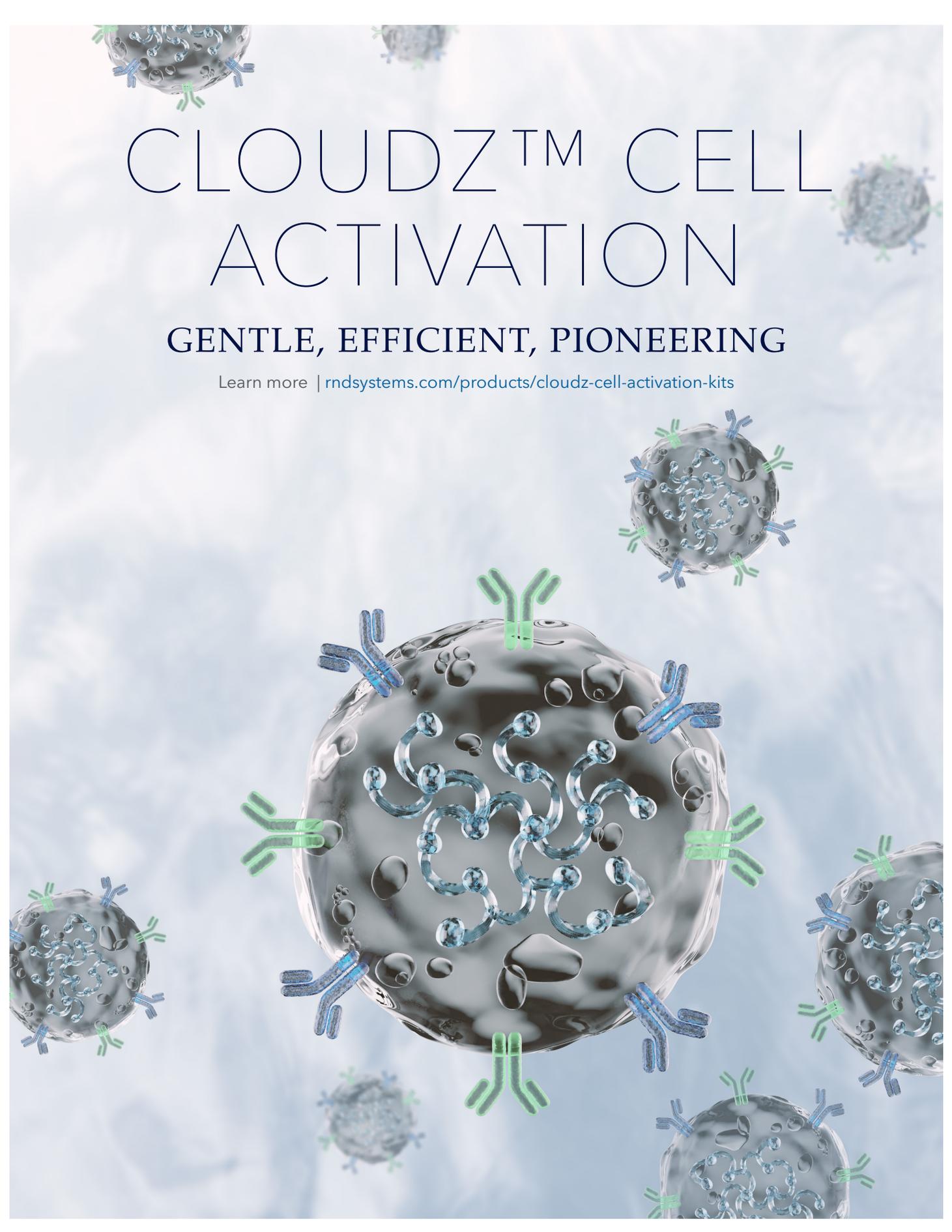
- Dissolve rapidly in cell culture media
- Equivalent bioactivity as standard lyophilized GMP proteins

GMP PRODOTS PROTEINS BAG SPECIFICATIONS

- Maximum media capacity = 25 mL
- Single-use, animal-free bags are tested to USP <85> guidelines
- Sterile docking by weldable PVC tubing or syringe port
- Contain a pre-aliquoted amount of GMP protein



PROTEIN	CATALOG #	RECOMMENDED CONCENTRATION	PROTEIN MASS PER BAG	NUMBER OF PRODOTS PER BAG	GMP PROTEIN CATALOG #
GMP ProDots Recombinant Human IL-2 Protein	PRD202-GMP	20 ng/mL	20 µg	4	202-GMP
GMP ProDots Recombinant Human IL-7 Protein	PRD207-GMP	10 ng/mL	10 µg	2	207-GMP
GMP ProDots Recombinant Human IL-15 Protein	PRD247-GMP	5 ng/mL	5 µg	1	247-GMP

A 3D scientific illustration of a cell, possibly a dendritic cell, with a porous, grey, spherical surface. The cell is covered with various receptors and antibodies. Blue Y-shaped structures are attached to the surface, and green Y-shaped structures are also visible. Inside the cell, there are blue, wavy, interconnected structures. The background is a light blue, textured surface with faint, larger-scale versions of the cell structure.

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