

Recombinant Human IL-7 GMP

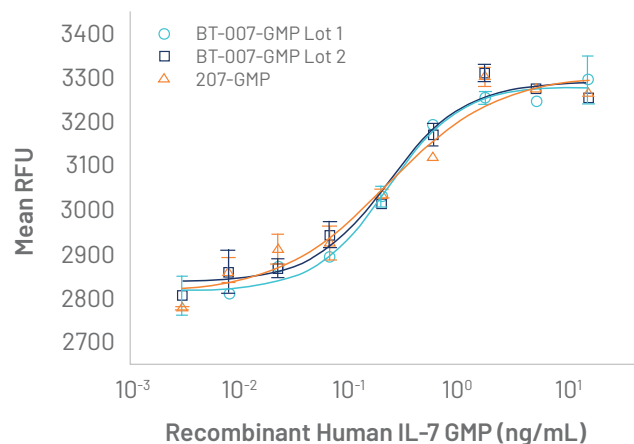
Catalog # BT-007-GMP

Recombinant IL-7 and IL-15 are used for *ex vivo* expansion of CAR T cell and TCR T cell therapies. Together, these cytokines promote rapid expansion of T cells, encourage naïve and memory t cell populations, and have potential to improve anti-tumor efficacy and T cell patient engraftment.

GMP-grade IL-7 and IL-15 can now be produced at a game-changing scale within Bio-Techne's new dedicated animal-free GMP facility, resulting in a steady supply of proteins for cell therapy manufacturing.

GMP Recombinant Human IL-7 is the first protein produced in the new facility. This next generation protein has the same quality control specifications as the legacy GMP IL-7 protein, allowing for a seamless transition and future scalability.

- Identical GMP IL-7 protein sequence and bioactivity specifications to the legacy GMP IL-7 product (Catalog # 207-GMP)
- Manufactured in a state-of-the-art facility dedicated solely to animal-free GMP proteins
- Scalable manufacturing process to meet future demand from the industry
- Research-grade IL-7 (Catalog # BT-007-AFL) is also produced in new animal-free facility using the same sequence and source as GMP-grade.



GMP-grade Recombinant Human IL-7 stimulates proliferation of PHA-activated human peripheral blood lymphocytes. Comparison to two lots of GMP IL-7 (Catalog # BT-007-GMP) manufactured in the new GMP facility to the legacy GMP IL-7 (Catalog # 207-GMP). Bioassay data for two lots of the new GMP IL-7 are nearly identical to the legacy GMP IL-7 with ED50 values within the margin of error.

Request a sample:

scaleready.com/gmp-cytokine-sample-request
or contact info@scaleready.com



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Recombinant Human IL-7 Specification Comparison

Specification		207-GMP (Legacy)	BT-007-GMP	BT-007-AFL
Manufacturing Site		Minneapolis, MN USA	St Paul, MN USA	St Paul, MN USA
Grade		GMP	GMP	Research
Sequence	Asp26-His177, with an N-terminal Met (Accession # P13232)	✓	✓	✓
Activity	Cell proliferation assay using PHA-activated human peripheral blood lymphocytes (PBL)	✓	✓	✓
Source	<i>E. coli</i>	✓	✓	✓
Purity	>97%	✓	✓	✓
N-terminal Sequencing	Met-Asp-(Cys)-Asp-Ile-Glu-Gly-Lys-Asp-Gly	✓	✓	✓
Sterility Test	Tested per USP71 guidelines	✓	✓	Tested per USP61
Mass Spectrometry	Dominant peak 17518	✓	✓	✓
Pack Sizes (µg)		25, 1000	25, 1000	25, 100, 1000
Formulation		Lyophilized from a 0.2 µm filtered solution in PBS	Lyophilized from a 0.2 µm filtered solution in PBS with trehalose	Lyophilized from a 0.2 µm filtered solution in PBS with trehalose
Host Cell Protein	ELISA <0.5 ng/µg	✓	✓	✓
Endotoxin	<0.01 LAL Method	✓	✓	✓
Mycoplasma	Ribosomal RNA hybridization assay: Negative	✓	✓	✓
Reconstitution	100 µg/mL in PBS	✓	✓	✓
Facility	Animal-free	Dedicated space	Dedicated facility	Dedicated facility

Features Of The New State-Of-The-Art GMP Facility

- Entire facility dedicated to manufacturing GMP proteins
- Animal-free facility – No animal components are allowed in the facility
- Capacity – 61,000 ft to meet your supply requirements now and in the future
- ISO 5/7/8 cleanrooms for entire production process

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Contact us: info@scaleready.com

ScaleReady is a Joint Venture formed by Bio-Techne, Fresenius Kabi, and Wilson Wolf. Combining selected offerings from the three partners, the ScaleReady manufacturing platform combines tools and technologies for cell culture, cell activation and expansion, gene editing, and cell processing.

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Certifications And Regulatory Guidelines Followed:

USP Chapter <104>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products

USP Chapter <92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing

Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products

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