

Recombinant Human IL-7 GMP

Catalog # BT-007-GMP

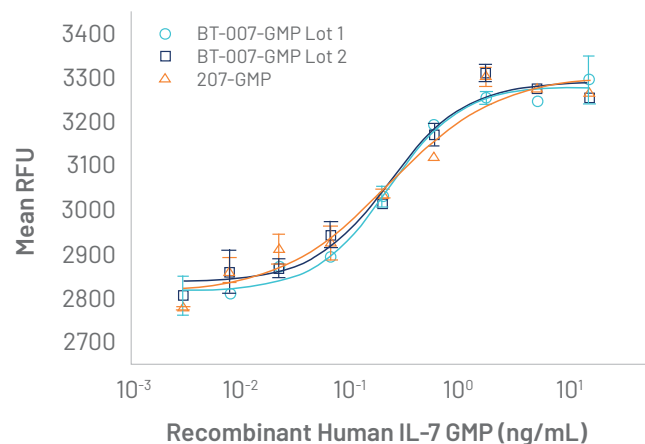
Recombinant IL-7 and IL-15 are used for *ex vivo* expansion of CAR T cell and TCR T cell therapies. Together, these cytokines promote rapid expansion of T cells, encourage naive and memory t cell populations, and have potential to improve anti-tumor efficacy and T cell patient engraftment.

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.

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



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.

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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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Certifications And Regulatory Guidelines Followed:

USP Chapter <1043>, 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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