PEPROTECH®
Part of Thermo Fisher Scientific

PeproTech products are now part of the gibco by Thermo Fisher Scientific Recombinant Protein Portfolio

PEPROGMP®
cytokines

Helping unlock the promise of cellular therapies and regenerative medicines

PeproGMP cytokines

Advanced manufacturing capabilities

In response to our clients' needs and the requirements of the cell and gene therapy markets, Gibco™ PeproTech™ products are now manufactured in our state-of-the-art manufacturing facility in Cranbury, New Jersey.

The rapidly evolving field of regenerative medicine offers exciting opportunities to develop new solutions for an array of diseases, injuries, and genetic disorders. With the recent addition of our Cranbury PeproTech product manufacturing facility, Thermo Fisher Scientific is able to meet the demand of the advancing markets in cell, gene, and tissue therapies. This 65,000 square-foot facility has ample space for GMP cleanrooms and supports the manufacturing of our bacterially expressed GMP proteins and expansion into cell culture–derived GMP products.

PeproTech GMP recombinant proteins are manufactured for use as ancillary materials by applying applicable principles of GMP and quality control requirements from USP (United States Pharmacopeia) Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products.

Quality management

We affirm that all aspects of our quality management system—from management of raw materials and equipment to facilities maintenance (environmental monitoring), manufacturing processes, audits, and inspection processes—are in compliance with relevant US FDA GMPs and all applicable standards and regulatory requirements.

The benefits of our rigorous process are clear: Gibco™ PeproGMP™ cytokines offer safety, purity, and simplified use in *ex vivo* manufacturing processes, as described in USP (United States Pharmacopeia) Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products.

All PeproGMP products are manufactured using materials free of animal-derived components

- Controlled and certified ISO Class 7 and Class 8 cleanrooms
- Qualification and validation program
- Materials management, including supplier qualification, and controlled and qualified raw materials
- 100% traceability
- Personnel training program
- Environmental monitoring
- Equipment calibration and maintenance
- Rigorous quality control program
- Documentation control and records
- Stability program
- Controlled processes
- QA review and support
- Master quality and supply agreement
- Aseptic techniques and sterile filtration
- Management review
- Procedures for complaints and recalls

Quality control

We perform extensive quality control testing to verify that PeproGMP cytokines meet rigorous standards for purity, identity, safety, activity, and lot-to-lot consistency.

Identity and purity

- N-terminal amino acid sequence analysis
- Molecular weight determination by mass spectrometry
- Reversed-phase HPLC analysis
- SDS-PAGE
- Western blotting

Protein content

- UV spectroscopy
- SDS-PAGE

Safety testing

- Residual *E. coli* DNA testing
- Sterility testing (USP standards): beginning, middle, and end processes
- Low endotoxin
- Mycoplasma

Biological activity

- Specific activity determined by product-specific *in vitro* bioassay, against reference standard and, when applicable, against standards of the World Health Organization (WHO)

Documentation

- Certificate of Analysis (COA)
- Certificate of Origin (COO)
- Safety Data Sheet (SDS)

PeproGMP cytokine FAQs

1. Can I use PeproGMP cytokines for GMP manufacturing of investigational products, and for manufacturing commercial therapeutic products?

Yes, PeproGMP cytokines are intended for use in GMP manufacturing of investigational or marketed clinical products, such as cell therapy, gene therapy, tissue-engineered products, combination products, or other advanced therapy medicinal products.

PeproGMP cytokines are not, however, therapeutic products or excipients, and hence are not suitable for direct administration to humans. See USP Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products for more information, or contact PeproTech product technical support at PeproTech.QualityAssurance@thermofisher.com.

2. What is the risk classification for PeproGMP cytokines?

PeproGMP cytokines are classified as Tier 2 under USP Chapter <1043>:

Tier 1: Low-risk, highly qualified materials (therapeutic drug or biologic, medical device)

Tier 2: Low-risk, well-categorised materials, produced in compliance with GMPs, and intended to be used as ancillary materials

Tier 3: Moderate-risk, not for use as ancillary materials

Tier 4: High-risk materials

3. Is the facility where PeproGMP cytokines are manufactured GMP-certified by the FDA? Has the FDA inspected the PeproTech product manufacturing facility? How would my QA department qualify PeproTech products such as PeproGMP cytokines?

The US FDA does not perform inspections or GMP certification of manufacturing facilities for ancillary reagents. In some countries, the national regulatory authority does inspect and certify GMP manufacturing facilities for all types of products, but FDA GMP inspections are limited to manufacturing facilities for therapeutic products and medical devices.

PeproGMP cytokines are manufactured in accordance with relevant US GMPs. All aspects of manufacturing, testing, labeling, and packaging are stringently controlled, validated, and monitored by PeproTech product QA. Thermo Fisher provides detailed Certificates of Analysis and Certificates of Origin for all PeproGMP product lines. SDS documents are also available.

4. Are PeproGMP cytokines animal origin–free and human origin–free?

Yes. Cytokines in the PeproGMP product line are manufactured using defined media, enzymes, and chemicals, none of which are derived from animal or human origin.

5. Do PeproGMP cytokines have the same biological properties as the research-grade PeproTech cytokines I have been using for R&D studies?

Yes. PeproGMP cytokines are functionally equivalent to their research-grade counterparts.

6. How are PeproGMP cytokines shipped?

The products are lyophilized, making them stable at a wide range of temperatures. Shipping is at ambient temperature. Upon request and at an additional cost, these products can be shipped on ice packs or dry ice.

References

- USP Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- FDA Guidance: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs)
- FDA Guidance: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)
- EC Regulation 1394/2007 on Advanced Therapy Medicinal Products
- EC Directive 2009/120/EC - Medicinal Products for Human Use as Regards Advanced Therapy Medicinal Products

PeproGMP products

Product description	Cat. No.	Size
PeproGMP Human Activin A	GMP120-14E-50UG	50 µg
	GMP120-14E-100UG	100 µg
PeproGMP Human BMP-4	GMP120-05ET-50UG	50 µg
PeproGMP Human IL-2	GMP200-02-50UG	50 µg
	GMP200-02-100UG	100 µg
	GMP200-02-1MG	1 mg
PeproGMP Human IL-3	GMP200-03-50UG	50 µg
	GMP200-03-100UG	100 µg
	GMP200-03-1MG	1 mg
PeproGMP Human IL-6	GMP200-06-10UG	10 µg
	GMP200-06-100UG	100 µg
PeproGMP Human IL-7	GMP200-07-50UG	50 µg
	GMP200-07-100UG	100 µg
PeproGMP Human IL-15	GMP200-15-50UG	50 µg
	GMP200-15-100UG	100 µg
PeproGMP Human IL-21	GMP200-21-50UG	50 µg
	GMP200-21-100UG	100 µg
	GMP200-21-1MG	1 mg
PeproGMP Human EGF	GMP100-15-100UG	100 µg
	GMP100-15-500UG	500 µg
	GMP100-15-1MG	1mg
PeproGMP Human FGF-basic	GMP100-18B-25UG	25 µg
	GMP100-18B-100UG	100 µg
	GMP100-18B-1MG	1 mg
PeproGMP Human Flt3-Ligand	GMP300-19-50UG	50 µg
	GMP300-19-100UG	100 µg
	GMP300-19-1MG	1 mg
PeproGMP Human Heregulinb-1	GMP100-03-50UG	50 µg
	GMP100-03-100UG	100 µg
	GMP100-03-1MG	1 mg
PeproGMP Human KGF	GMP100-19-50UG	50 µg
	GMP100-19-100UG	100 µg
	GMP100-19-1MG	1 mg
PeproGMP Human LIF	GMP300-05-50UG	50 µg
	GMP300-05-100UG	100 µg
PeproGMP Human PDGF-AA	GMP100-13A-50UG	50 µg
	GMP100-13A-100UG	100 µg
PeproGMP Human SCF	GMP300-07-50UG	50 µg
	GMP300-07-100UG	100 µg
	GMP300-07-1MG	1 mg
PeproGMP Human TPO	GMP300-18-50UG	50 µg
	GMP300-18-100UG	100 µg
PeproGMP Human $VEGF_{165}$	GMP100-20-50UG	50 µg
	GMP100-20-100UG	100 µg
	GMP100-20-1MG	1 mg

We are continually adding new GMP products.
Please contact PeproTech.GMP@thermofisher.com for our most up-to-date product list.

Note: these products are not available to order on thermofisher.com. Please visit peprotech.com to purchase them.

Product quality policy statement

We are committed to supplying our customers with high-quality products and services to achieve customer satisfaction, as well as to help ensure compliance with the requirements of the quality management system and its continued improvement.

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