PEPROTECH®
OUR SUPPORT, YOUR DISCOVERY

PEPROGMP®
Cytokines

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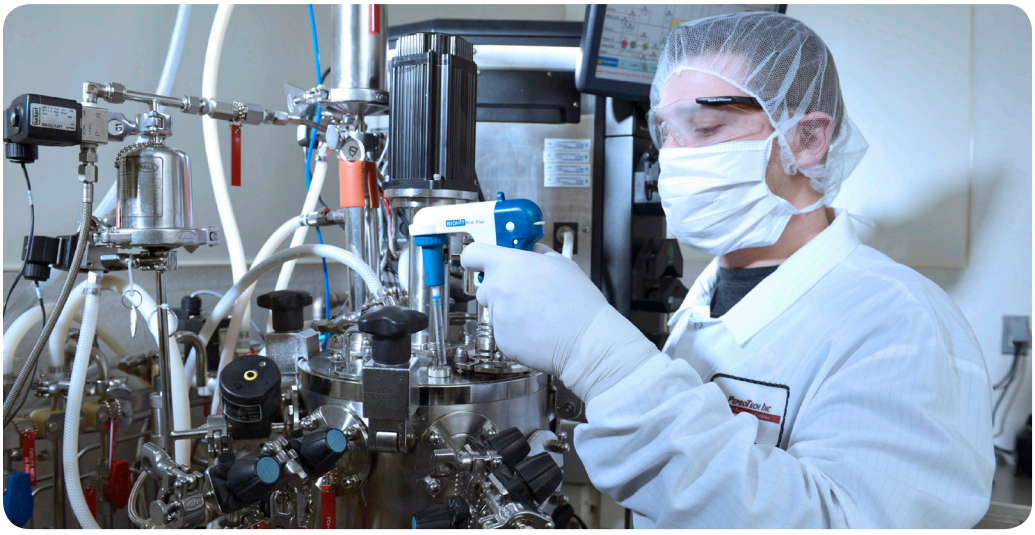
Helping unlock the promise of cellular therapies and regenerative medicines

PeproGMP® Cytokines

The rapidly evolving field of regenerative medicine offers exciting opportunities to develop new solutions for an unlimited array of diseases, injuries, and genetic disorders. Modern advances in immunology, developmental biology, genetics, and cell biology are driving research in this emerging area—and opening up a huge new potential market for related therapies.

As cell therapies transition from the lab to patients' bedsides, ensuring the highest levels of quality and safety is a significant and critical challenge. PeproTech's PeproGMP® Cytokines help researchers meet that challenge. Consistent with federal requirements and best practices for cell therapy, gene therapy, and tissue-engineered products for clinical applications, PeproGMP® Cytokines are manufactured and tested in compliance with US FDA GMP (Good Manufacturing Practices) regulations and the ISO 9001 quality management systems standard, without the use of animal-derived materials.



Controlled GMP *E. coli* fermentation production

The benefits of our rigorous process are clear: 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.

- **ISO7-certified cleanrooms and controlled laboratories**
- **Qualification and validation program**
- **Materials management**
- **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**

Quality Control/Quality Assurance

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

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

Identity and Purity

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

Protein Content

- UV spectroscopy
- SDS-PAGE with Western blotting

Safety

- Residual *E. coli* DNA testing
- Sterility: 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 WHO standards

Documentation

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

PeproGMP® Cytokines:

PeproGMP® Human EGF	GMP100-15-100µg	100µg
PeproGMP® Human EGF	GMP100-15-500µg	500µg
PeproGMP® Human FGF-basic	GMP100-18B-25µg	25µg
PeproGMP® Human FGF-basic	GMP100-18B-100µg	100µg
PeproGMP® Human Flt-3-Ligand	GMP300-19-50µg	50µg
PeproGMP® Human Flt-3-Ligand	GMP300-19-100µg	100µg
PeproGMP® Human IL-3	GMP200-03-10µg	50µg
PeproGMP® Human IL-3	GMP200-03-100µg	100µg
PeproGMP® Human IL-6	GMP200-06-10µg	10µg
PeproGMP® Human IL-6	GMP200-06-100µg	100µg
PeproGMP® Human SCF	GMP300-07-50µg	50µg
PeproGMP® Human SCF	GMP300-07-100µg	100µg
PeproGMP® Human TPO	GMP300-18-50µg	50µg
PeproGMP® Human TPO	GMP300-18-100µg	100µg

Q&A

Q Can I use PeproGMP® Cytokines for GMP manufacturing of investigational products, and for manufacturing commercial therapeutic products?

A 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 Technical Support.

Q What is the risk classification for PeproGMP® Cytokines?

A 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-characterized 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

Q Is the facility where PeproGMP® Cytokines are manufactured GMP-certified by FDA? Has FDA inspected PeproTech? How would my QA department qualify PeproTech and PeproGMP® Cytokines?

A 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 GMPs, under a rigorous ISO 9001-compliant quality system. All aspects of manufacturing, testing, labeling, and packaging are stringently controlled, validated, and monitored by PeproTech QA. PeproTech provides detailed Certificates of Analysis and Certificates of Origin for all PeproGMP® product lines. SDS documents are also available.

Q Are PeproGMP® Cytokines animal-origin free and human-origin free?

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

Q **Do PeproGMP® Cytokines have the same biological properties as the PeproTech research-grade/animal-free grade cytokines I have been using for R&D studies?**

A Yes. PeproGMP® Cytokines are functionally equivalent to their research-grade counterparts.

Q **How are PeproGMP® Cytokines shipped?**

A 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
- www.iso.org/iso/home/standards/management-standards/iso_9000.htm

PeproTech Quality Policy Statement

PeproTech is committed to supplying our customers with the highest-quality products and services to achieve customer satisfaction, as well as to ensure compliance with the requirements of the quality management system and its continuing improvement.

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