GMP Monoclonal Anti-Human CD28 Antibody

Catalog # GMP-MC2824

GMP Platform Advantages

- **Quality Assurance**: Global QMS with comprehensive and stringent QC release criteria.
- **End-to-End GMP Compliance**: Full manufacturing and QC under a cGMP system.
- **Comprehensive Control of Adventitious Agents**: Stringent biosafety from cell banks to final release.
- **Comprehensive Regulatory Support**: Includes RSF and DMF to meet global requirements.
- **Resilient Supply Chain**: Intelligent modular facilities ensure a stable global supply.
- **Professional Support**: Extensive manufacturing and application expertise to accelerate development.

Source

HEK293 cells-expressed human GMP Monoclonal Anti-Human CD28 Antibody.

Isotype

Mouse IgG1 | Mouse Kappa

Conjugate

Unconjugated

Specificity

This product is a specific antibody specifically reacts with CD28.

N-terminal Sequence Analysis

HC: Asp-Ile-Val-Lys-Leu-Gln-Gln-Ser-Gly-Ala-Glu-Leu-Val-Lys-Pro
LC: Asp-Ile-Gln-Met-Thr-Gln-Ser-Pro-Ala-Ser-Leu-Ser-Val-Ser-Val
(Routinely tested)

Endotoxin

Less than 2 EU/mg, tested by the LAL method in compliance with USP <85> and Ph. Eur. 2.6.14.

Protein A

<5 ppm of protein tested by ELISA.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

Sterility

Sterility testing was performed using the membrane filtration method in compliance with USP <71> and Ph. Eur. 2.6.1.

Mycoplasma

Negative

Formulation

Supplied as 0.2 μm filtered solution in PBS, polysorbate 80, pH7.4 with protectants.

Contact us for customized product form or formulation.

Vial Specification

2R (13 mm neck finish)

Shipping

This product is supplied and shipped with dry ice, please inquire the shipping cost.

Storage

For long term storage, the product should be stored at liquid state at -70°C.

Please avoid repeated freeze-thaw cycles.

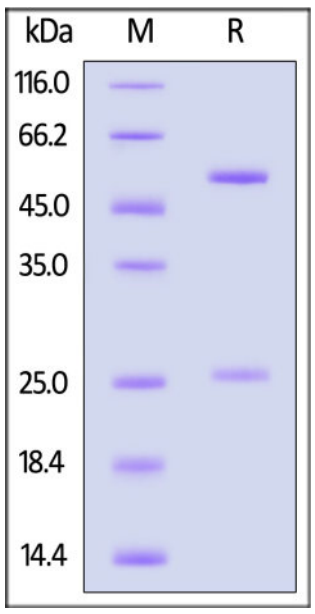
This product is stable after storage at:

- 2-8°C for 12 months under sterile conditions;
- -70°C for 5 years.

ACRO Quality Management System

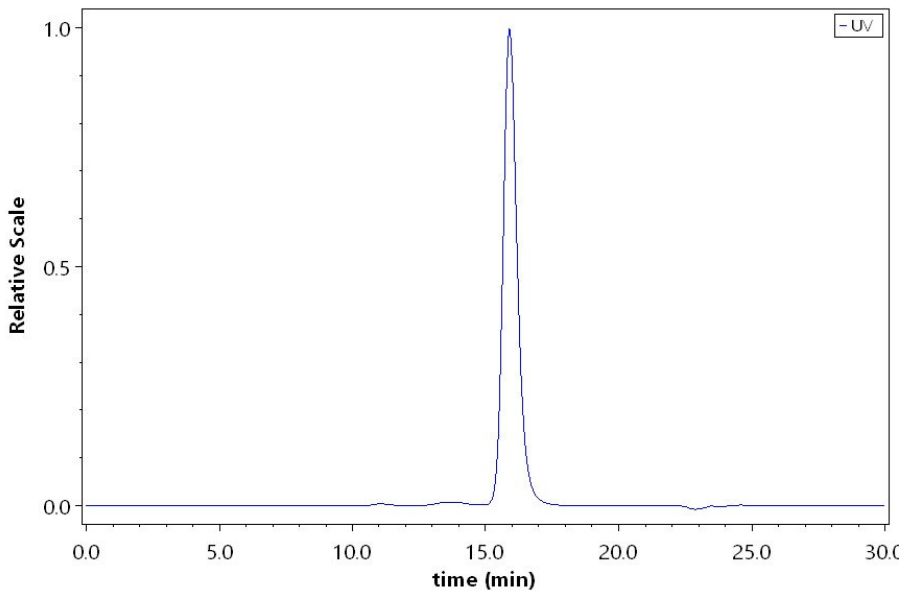
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



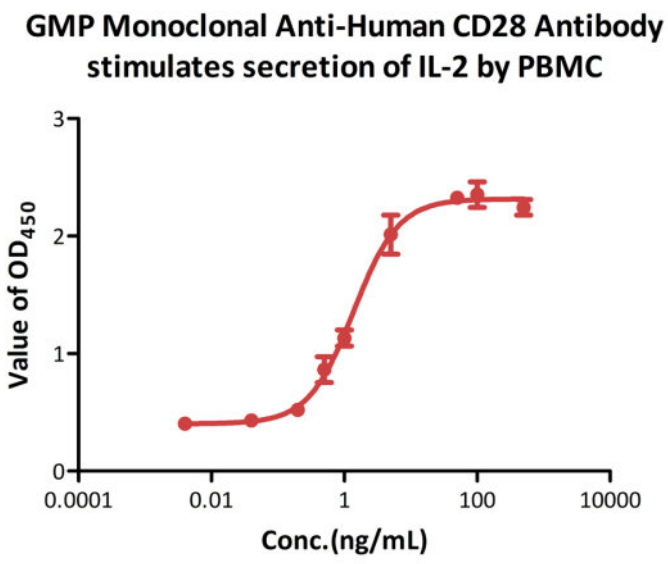
GMP Monoclonal Anti-Human CD28 Antibody on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

SEC-HPLC

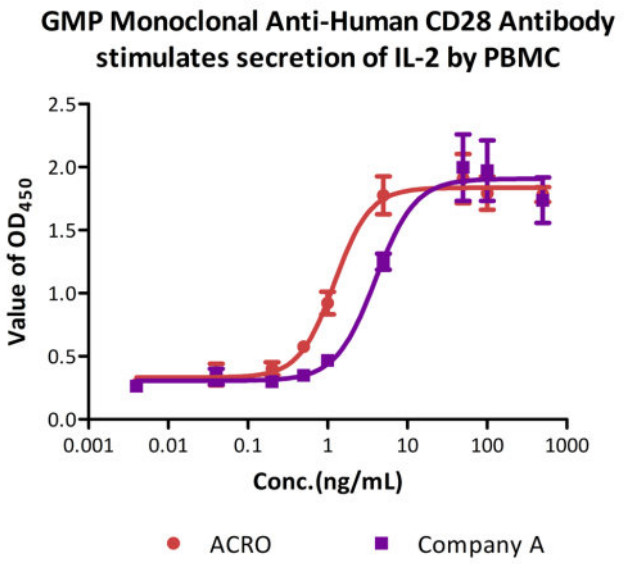


The purity of GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) was greater than 95% as determined by SEC-HPLC.

Bioactivity-CELL BASE

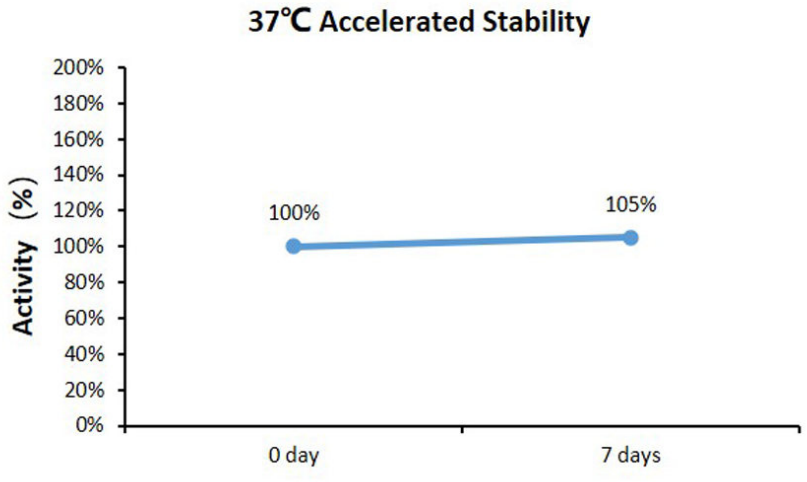


GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) stimulates secretion of IL-2 by PBMC stimulated with 4ng/mL GMP Monoclonal Anti-Human CD3 Antibody (OKT3). The typical EC50 for this effect is 1.382 ng/mL (QC tested).

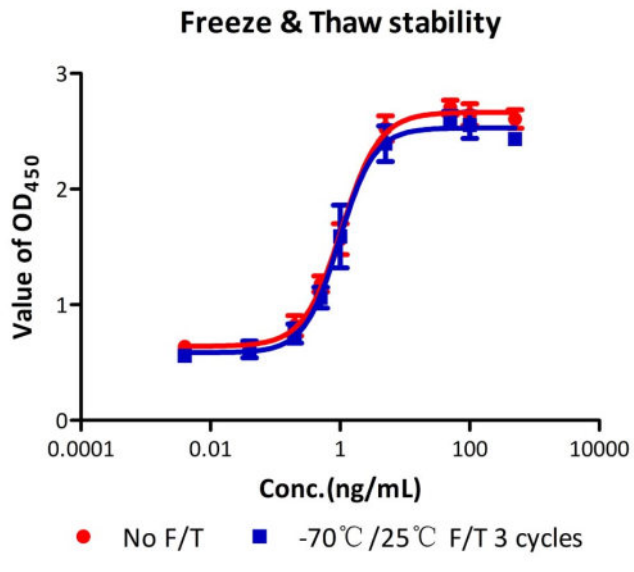


GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) exhibits superior activity compared to commercially available product.

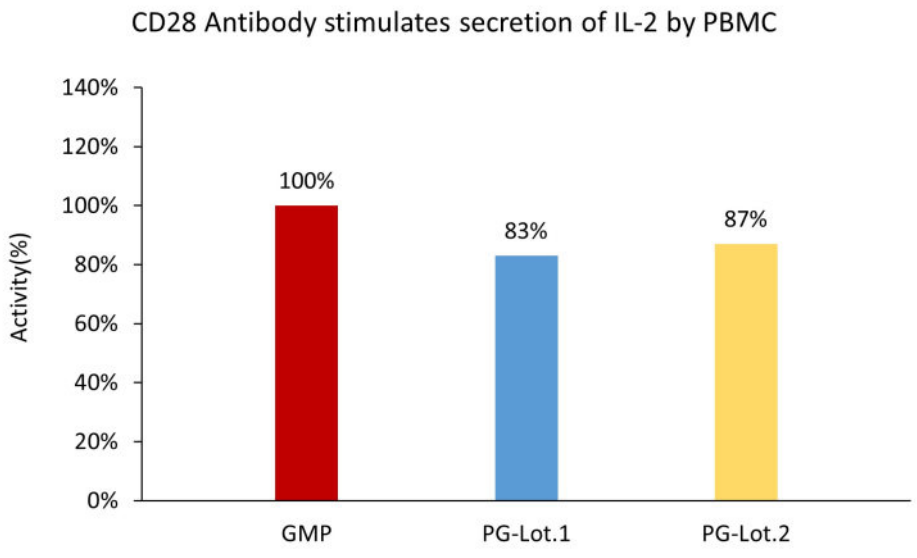
Bioactivity-Stability



Cell-based assay demonstrates that GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) is stable at 37°C for 7 days.



Cell-based assay demonstrates that GMP Monoclonal Anti-Human CD28 Antibody (Cat. No. GMP-MC2824) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates batch-to-batch consistency between Acro's GMP and PG CD28 Antibody.

Background

T-cell-specific surface glycoprotein CD28 is also known as TP44, is a single-pass type I membrane protein which contains one Ig-like V-type (immunoglobulin-like) domain. is one of the molecules expressed on T cells that provide co-stimulatory signals, which are required for T cell activation. CD28 is the receptor for CD80 (B7.1) and CD86 (B7.2). When activated by Toll-like receptor ligands, the CD80 expression is upregulated in antigen presenting cells (APCs). The CD86 expression on antigen presenting cells is constitutive. CD28 is the only B7 receptor constitutively expressed on naive T cells.

MANUFACTURING SPECIFICATIONS

ACROBiosystems GMP grade products are produced under a quality management system and in compliance with relevant guidelines: Ph. Eur General Chapter 5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products; USP<92>Growth Factors and Cytokines Used in Cell Therapy Manufacturing; USP<1043>Ancillary Materials for Cell, Gene, and Tissue-Engineered Products; ISO/TS 20399-1:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products.

ACROBiosystems Quality Management System Contents：

- GMP-certified facility (compliance with FDA cGMP, EMA GMP, ICH, ISO9001/13485/MDSAP, and certified by third-party SGS, UL, and RX360)
- Animal origin-free materials, equipments, and facilities
- Materials sourced only from approved suppliers
- ISO 5 cleanrooms and automatic filling equipment
- Professional quality personnel and training programs
- Validated analytical testing methods in accordance with the ICH guidelines
- Safety Testing (Sterility, Mycoplasma, etc): compliant with USP, EP, etc
- In-depth stability studies

- Fully batch production and control records
- Equipment maintenance and calibration

ACROBiosystems provide rigorous quality control tests (fully validated equipment, processes and test methods) on our GMP grade products to ensure that they meet stringent standards in terms of purity, safety, activity and inter-batch stability, and each bulk QC lot mainly contains the following specific information:

- SDS-PAGE
- Protein content
- Endotoxin level
- Residual Host Cell DNA content
- Residual Host Cell Protein content
- Biological activity analysis
- Microbial testing
- Mycoplasma testing
- In vitro virus assay
- Batch-to-batch consistency

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