

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

GMP Human Apolipoprotein E / APOE3 Protein (GMP-APEH35) is expressed from CHO cells. It contains AA Lys 19 - His 317 (Accession # [P02649-1](#)).

Predicted N-terminus: Lys 19

Molecular Characterization

APOE(Lys 19 - His 317)
P02649-1

This protein carries no "tag".

The protein has a calculated MW of 34.2 kDa. The protein migrates as 37 kDa±3 kDa when calibrated against [Star Ribbon Pre-stained Protein Marker](#) under reducing (R) condition (SDS-PAGE) due to glycosylation.

Endotoxin

Less than 10 EU/mg, tested by the rFC method in compliance with USP <86> and Ph. Eur. 2.6.32.

Host Cell Protein

<0.5 ng/µg of protein tested by ELISA.

Host Cell DNA

<0.001 ng/µg of protein tested by qPCR.

Sterility

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

Mycoplasma

Negative

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 µm filtered solution in 20 mM MOPS, 150 mM NaCl, 5 mM CHAPS, 2 mM TCEP, pH7.3 with protectants.

Contact us for customized product form or formulation.

Vial Specification

2R (13 mm neck finish)

Shipping and Storage

This product is supplied and shipped on blue ice.

Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

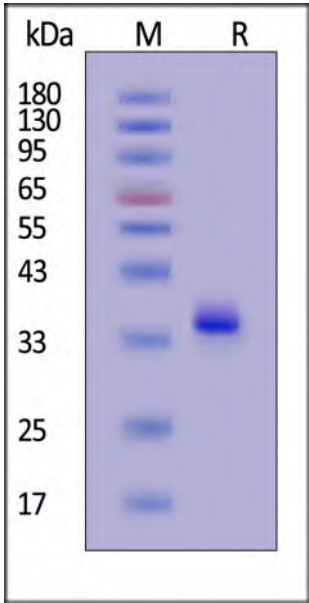
This product is stable after storage at:

- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

ACRO Quality Management System

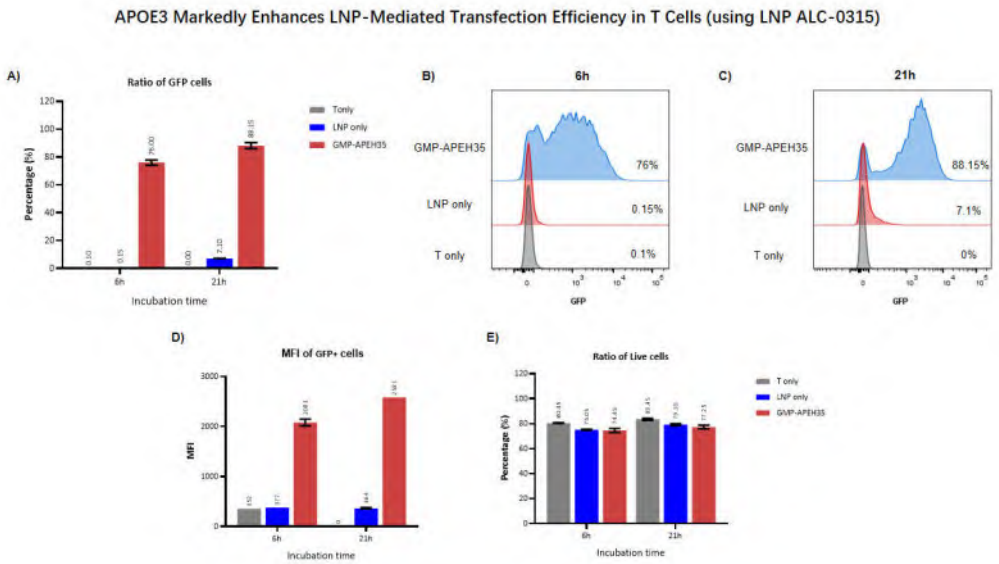
- [QMS\(ISO, GMP\)](#)
- [Quality Advantages](#)
- [Quality Control Process](#)

SDS-PAGE

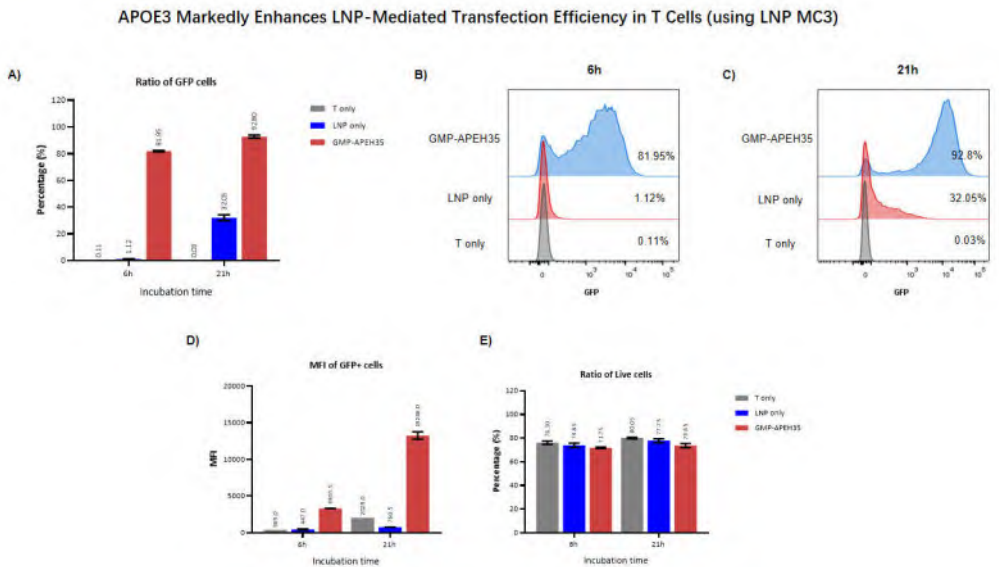


GMP Human Apolipoprotein E / APOE3 Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With [Star Ribbon Pre-stained Protein Marker](#)).

Application Data



T cells purified by CD4 (ACRO, Cat. No. MBS-S004) and CD8 (ACRO, Cat. No. MBS-S005) NanoSort Microbeads sorting were activated with T cell Activation/Expansion CD3/CD28 Beads (ACRO, Cat. No. GMP-MBS001) for 24 h, then seeded at 1×10^5 cells/well and treated with 1 $\mu\text{g/mL}$ LNP and 0.1 $\mu\text{g/mL}$ GMP Human Apolipoprotein E / APOE3 Protein (ACRO, Cat. No. GMP-APEH35). After incubation at 37 $^{\circ}\text{C}$ with 5% CO_2 for 6 h or 21 h, cells were harvested and analyzed by flow cytometry for GFP fluorescence intensity, with cell viability assessed via 7-AAD staining. The results showed that, compared with LNP alone, the combination with APOE3 significantly increased the percentage of GFP-positive cells (Figure A,B,C) and the mean fluorescence intensity (MFI) (Figure D), whereas cell viability did not differ significantly among groups (Figure E). Data are presented as the mean $\pm$ SD (n=3).



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Background

APOE is an apolipoprotein, a protein associating with lipid particles, that mainly functions in lipoprotein-mediated lipid transport between organs via the plasma and interstitial fluids. APOE is a core component of plasma lipoproteins and is involved in their production, conversion and clearance. Apolipoproteins are amphipathic molecules that interact both with lipids of the lipoprotein particle core and the aqueous environment of the plasma. As such, APOE associates with chylomicrons, chylomicron remnants, very low density lipoproteins (VLDL) and intermediate density lipoproteins (IDL) but shows a preferential binding to high-density lipoproteins (HDL). It also binds a wide range of cellular receptors including the LDL receptor/LDLR, the LDL receptor-related proteins LRP1, LRP2 and LRP8 and the very low-density lipoprotein receptor/VLDLR that mediate the cellular uptake of the APOE-containing lipoprotein particles.

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
- Residual moisture
- Batch-to-batch consistency

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- 2.2 All specifications, data, and know-how related to the Products provided by ACRO are ACRO's confidential information and shall be protected accordingly.

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- (b) Obtaining any necessary regulatory approvals or intellectual property licenses for Purchaser's use.
- (c) Compliance with all applicable laws, regulations (including but not limited to cGMP/GLP where claimed), and industry standards.
- (d) Conducting all necessary quality control, safety, efficacy, and validation testing of Products within Purchaser's process or final product.
- (e) Proper storage, handling, and use of Products according to ACRO's instructions.

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- (b) ANY DIRECT DAMAGES, COSTS, OR EXPENSES EXCEEDING THE AMOUNT PAID BY PURCHASER FOR THE SPECIFIC PRODUCT(S) GIVING RISE TO THE CLAIM.
- (c) DAMAGES ARISING FROM: (i) MISUSE, ABUSE, OR UNAUTHORIZED MODIFICATION OF PRODUCTS; (ii) USE BEYOND THE EXPIRATION DATE; (iii) IMPROPER STORAGE OR HANDLING; (iv) ACCIDENTAL DAMAGE; (v) FAILURE TO CONDUCT ADEQUATE VALIDATION OR TESTING BY PURCHASER; (vi) INFRINGEMENT CLAIMS RELATED TO PURCHASER'S USE; OR (vii) THE COST OF PROCURING SUBSTITUTE GOODS OR SERVICES.
- (d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

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- 5.1 By accepting, opening, or using the Products, the End User (Purchaser or its downstream recipient) agrees to be irrevocably bound by all terms herein.
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