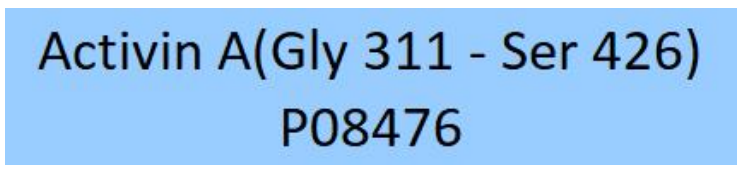
Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- FDA DMF filed
- Animal-Free materials
- Beta-lactam materials free
- Batch-to-batch consistency
- Stringent quality control tests

Source

GMP Human Activin A Protein(GMP-ACAH37) is expressed from CHO cells.
It contains AA Gly 311 - Ser 426 (Accession # P08476).
Predicted N-terminus: Gly 311

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 13.0 kDa. The protein migrates as 13 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 by the LAL method.

Host Cell Protein

<0.5 ng/μg of protein tested by ELISA.

Host Cell DNA

<0.02 ng/μg of protein tested by qPCR.

Sterility

The sterility testing was performed by membrane filtration method described in CP<1101>, USP<71> and Eur. Ph. 2.6.1.

Mycoplasma

Negative.

Purity

>95% as determined by SDS-PAGE.

Formulation

Lyophilized from 0.22 μm filtered solution in PBS, pH7.4 with protectants.

Contact us for customized product form or formulation.

Shipping

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

Storage

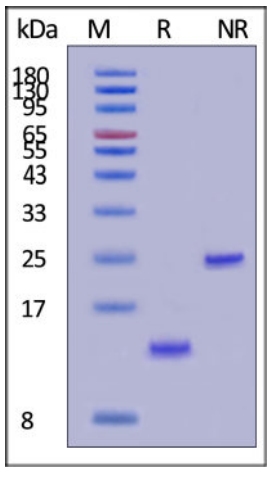
Upon receipt, store it immediately at -20°C or lower for long term storage.

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

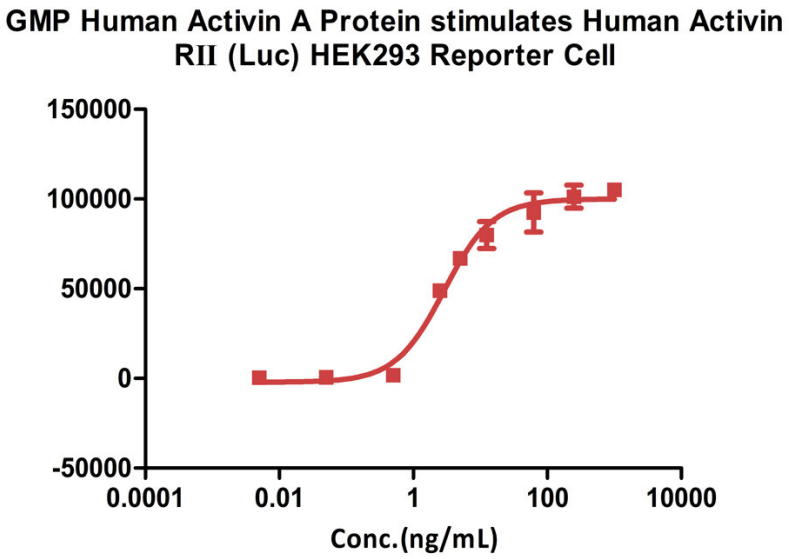
- -20°C to -70°C for 5 years in lyophilized state;
- -70°C for 12 months under sterile conditions after reconstitution.

SDS-PAGE

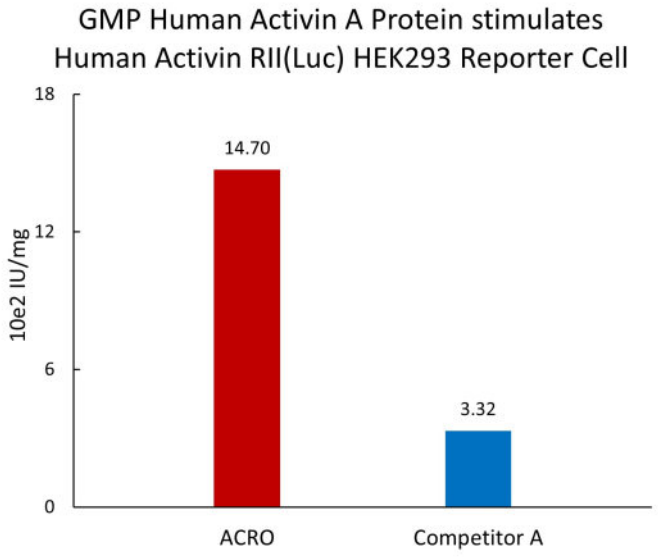


GMP Human Activin A Protein on SDS-PAGE under reducing (R) and non-reducing (NR) conditions. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

Bioactivity-CELL BASE

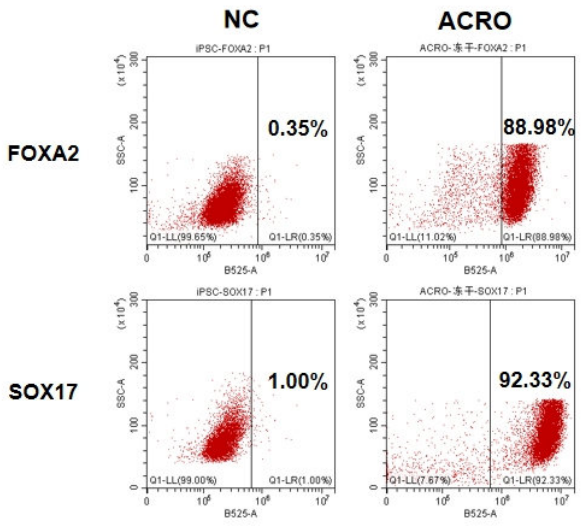


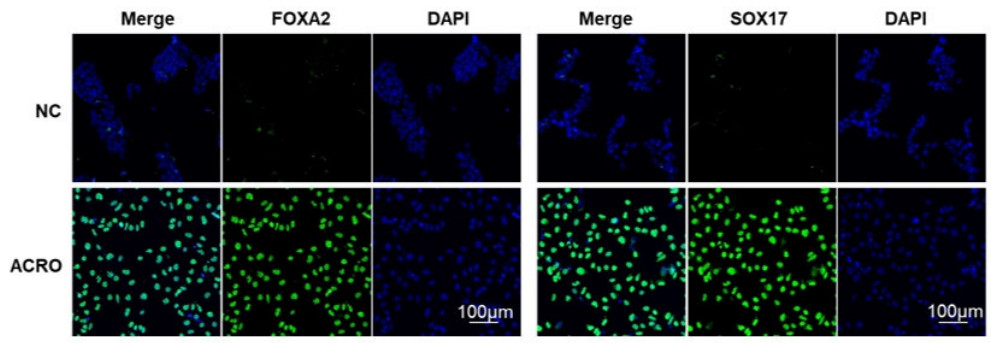
GMP Human Activin A Protein (Cat. No. GMP-ACAH37) stimulates Human Activin RII (Luc) HEK293 Reporter Cell. The specific activity of GMP Human Activin A Protein is > 5.00x10^2 IU/mg, which is calibrated against WHO Reference Reagent Activin A (Human, Recombinant) (NIBSC code: 91/626) (QC tested).



The activity of GMP Human Activin A Protein (Cat. No. GMP-ACAH37) was higher than other competing products.

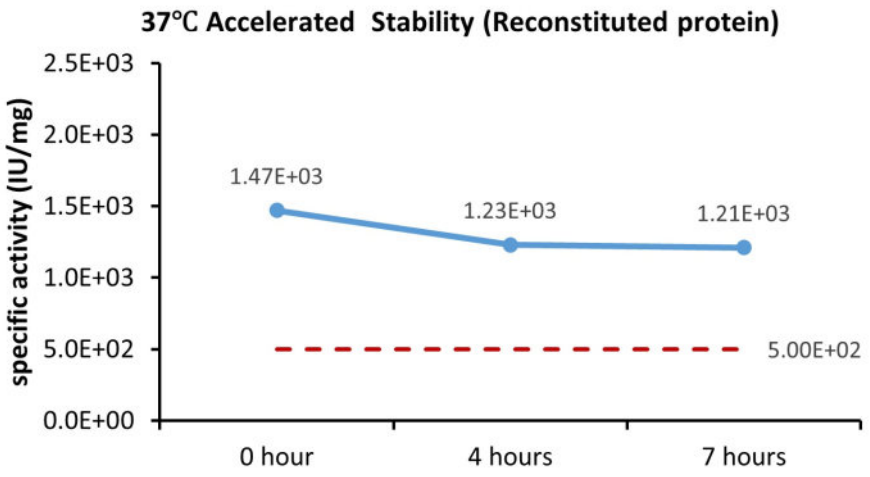
Application Data



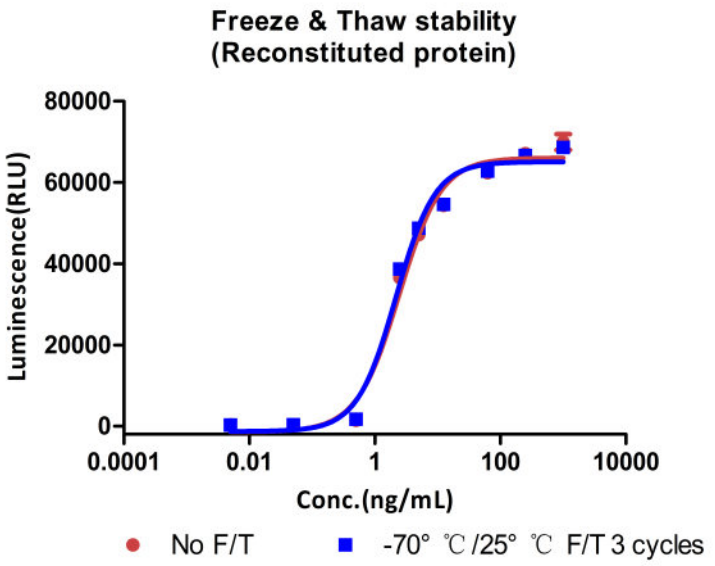


GMP Human Activin A Protein (Cat. No. GMP-ACAH37) could effectively induce the endoderm differentiation by FOXA2 and SOX17 expression in immunofluorescence and FACS.

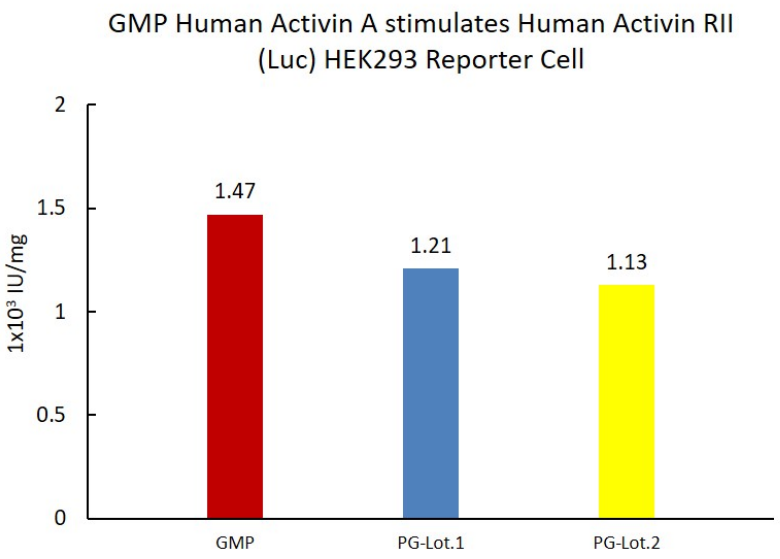
Bioactivity-Stability



The Cell based assay shows that GMP Human Activin A Protein (Cat. No. GMP-ACAH37) is stable at 37℃ for 7 hours.



The Cell based assay shows that GMP Human Activin A Protein (Cat. No. GMP-ACAH37) is stable after freezing and thawing 3 times.



The Cell based assay shows batch-to-batch consistency between Acro's GMP and PG Activin A.

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：

Designed under ISO 9001:2015 and ISO 13485:2016, Manufactured and QC tested under a GMP compliance factory.

Animal-Free materials

Materials purchased from the approved suppliers by QA

ISO 5 clean rooms and automatic filling equipment

Qualified personnel

Quality-related documents review and approve by QA

Fully batch production and control records

Equipment maintenance and calibration

Validation of analytical procedures

Stability studies conducted

Comprehensive regulatory support files

Request For Regulatory Support Files（RSF）

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

Background

Activin and inhibin are two closely related protein complexes that have almost directly opposite biological effects. Activin enhances FSH biosynthesis and secretion, and participates in the regulation of the menstrual cycle. Many other functions have been found to be exerted by activin, including roles in cell proliferation, differentiation, apoptosis, metabolism, homeostasis, immune response, wound repair, and endocrine function. Conversely inhibin down regulates FSH synthesis and inhibits FSH secretion.Activins are nonglycosylated homodimers or heterodimers of various β subunits (βA, βB, βC, and βE in mammals), while Inhibins are heterodimers of a unique α subunit and one of the β subunits. Activin A is a widely expressed homodimer of two βA chains. The βA subunit can also heterodimerize with a βB or βC subunit to form Activin AB and Activin AC, respectively. The 14 kDa mature human βA chain shares 100% amino acid sequence identity with bovine, feline, mouse, porcine, and rat βA.

Clinical and Translational Updates