GMP Human FGF basic Protein

Catalog # GMP-FGCH17

Product Details

FGF-2 (Fibroblast Growth Factor-2) is a central member of the FGF family, with potent mitogenic and angiogenic activities. In MSC culture, FGF-2 is a key factor for maintaining MSC proliferation capacity, delaying senescence, and preserving multipotency, effectively enhancing MSC expansion efficiency and therapeutic potential. In iPSC culture, FGF-2 is a fundamental cytokine for maintaining self-renewal and pluripotency, inhibiting spontaneous differentiation through pathways such as MAPK/ERK activation, and also serves as an important signaling molecule for differentiation into various lineages, including neural and mesodermal lineages.

Product Features and Advantages

- **Specific Stem Cell Expansion Driver**: Efficiently supports hPSC and MSC expansion while maintaining stemness over multiple passages.
- **Reliable Large-Scale Supply**: Ensures batch production capacity, supporting robust and consistent manufacturing scale-up.
- **High Lot-to-Lot Consistency**: Ensures reliable and reproducible performance in every batch, supporting scalable applications.

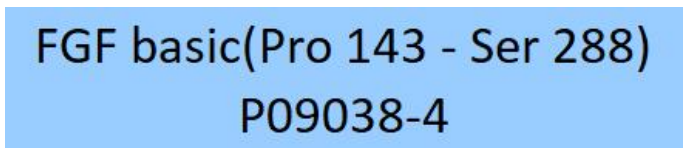
GMP Platform Advantages

- **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 FGF basic Protein (GMP-FGCH17) is expressed from *E. coli* cells. It contains AA Pro 143 - Ser 288 (Accession # P09038-4).

Molecular Characterization



This protein carries no "tag".

The protein has a calculated MW of 16.5 kDa. The protein migrates as 17 kDa±3 kDa under reducing (R) condition (SDS-PAGE).

N-terminal Sequence Analysis

chain1: Ala-Leu-Pro-Glu-Asp-Gly-Gly-Ser-Gly-Ala-Phe-Pro-Pro-Gly-His
chain2: Pro-Glu-Asp-Gly-Gly-Ser-Gly-Ala-Phe-Pro-Pro-Gly-His-Phe-Lys
(Routinely tested)

Endotoxin

Less than 10 EU/mg, tested by the LAL method in compliance with USP <85> and Ph. Eur. 2.6.14.

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

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 PBS, pH7.4 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.

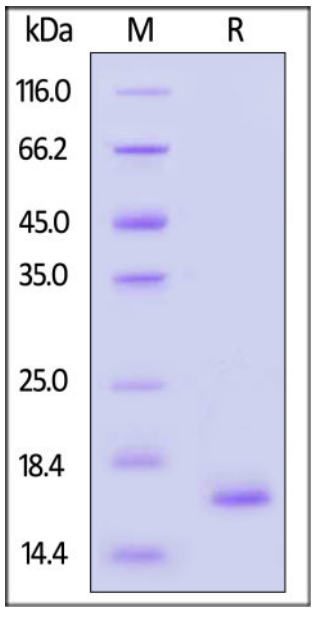
This product is stable after storage at:

- -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

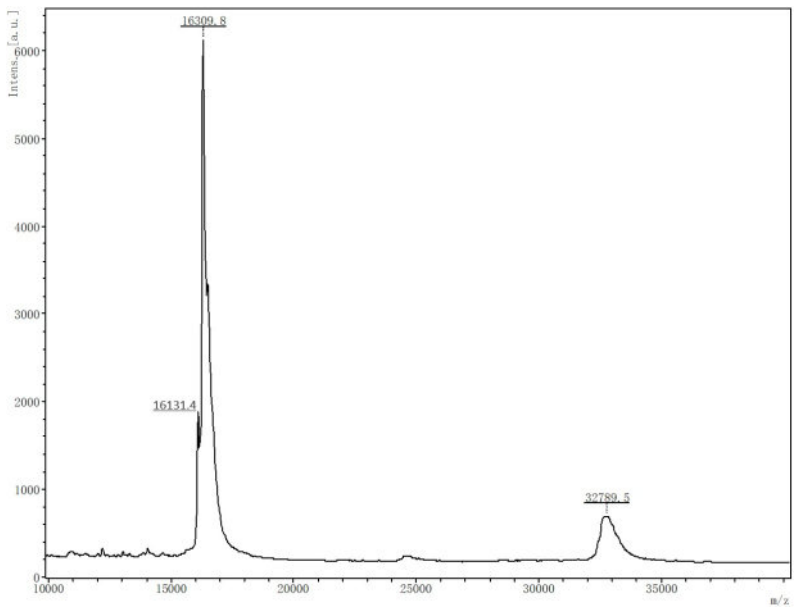
- QMS(ISO, GMP)
- Quality Advantages
- Quality Control Process

SDS-PAGE



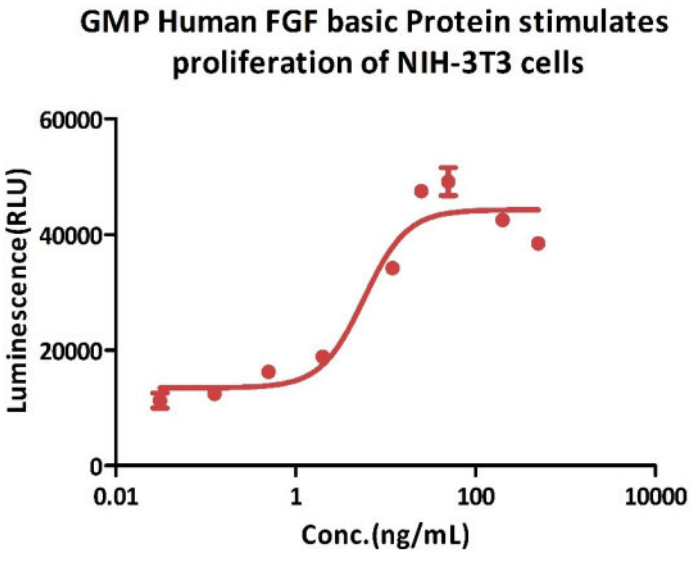
GMP Human FGF basic Protein on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

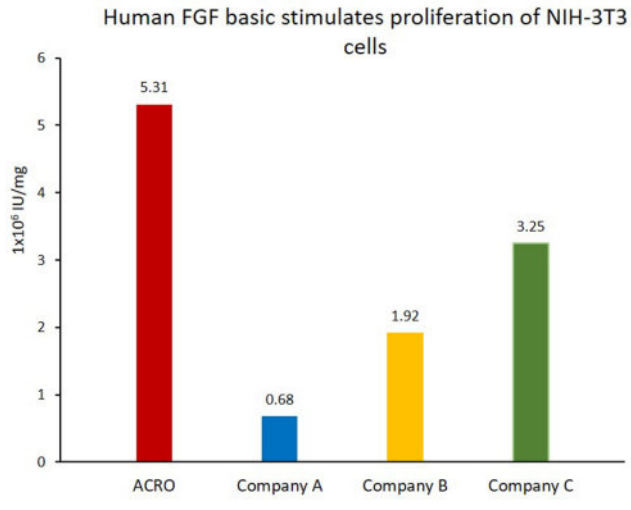
Mass Spectrometry



MALDI-TOF analysis of GMP Human FGF basic Protein (Cat. No. GMP-FGCH17). The labeled peaks at 16131.4 Da and 16309.8 Da correspond to the monomer FGF basic, both without the N-terminal Ala-Leu, and with the N-terminal Ala-Leu, respectively. The labeled peak at 32789.5 Da corresponds to the dimer FGF basic. The minor peak following the major peak is a matrix-associated artifact of the MALDI-TOF (Routinely tested).

Bioactivity-CELL BASE

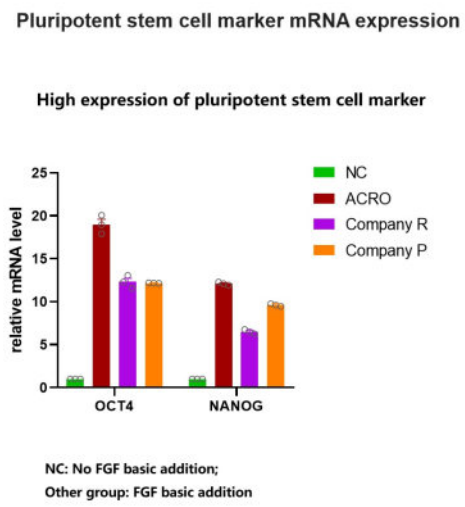


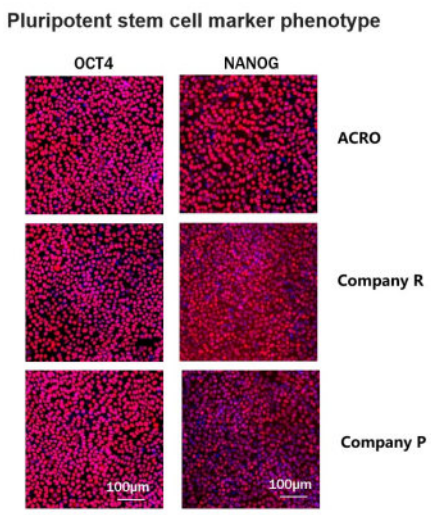


GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) stimulates proliferation of NIH/3T3 cells. The specific activity of GMP Human FGF basic Protein is >2.50 x 10^6 IU/mg, which is calibrated against Basic Fibroblast Growth Factor WHO International Standard (NIBSC code: 90/712) (QC tested).

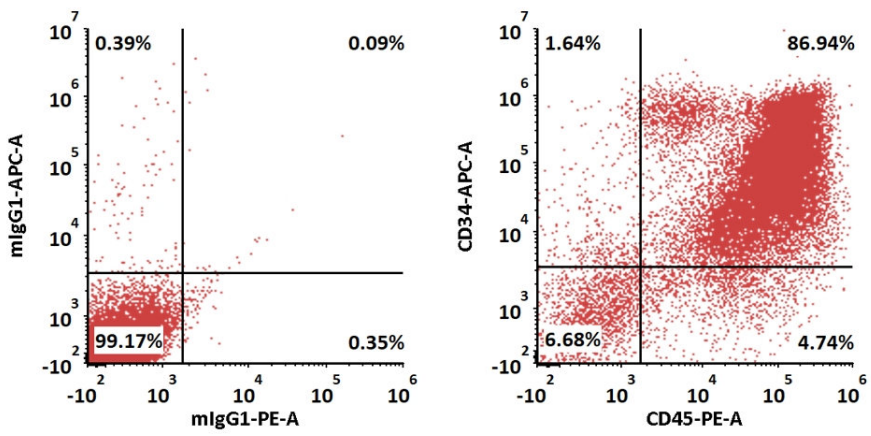
GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) exhibits superior activity compared to commercially available products.

Application Data

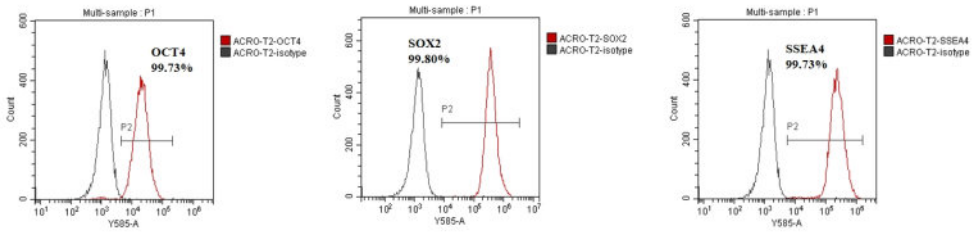




FGF basic (Cat. No. GMP-FGCH17) could highly support stemness maintenance in ESC/iPSC compared to other companies.
Left: The mRNA expression of pluripotent stem cell markers (Oct4, Nanog) was higher in Acro than in company R and company P.
Right: When FGF basic (35 μg/mL) is added into the culture media (StemSure hPSC medium) for iPSC, the cells remain high expression of pluripotent (Oct4+ or Nanog+; pink) markers.

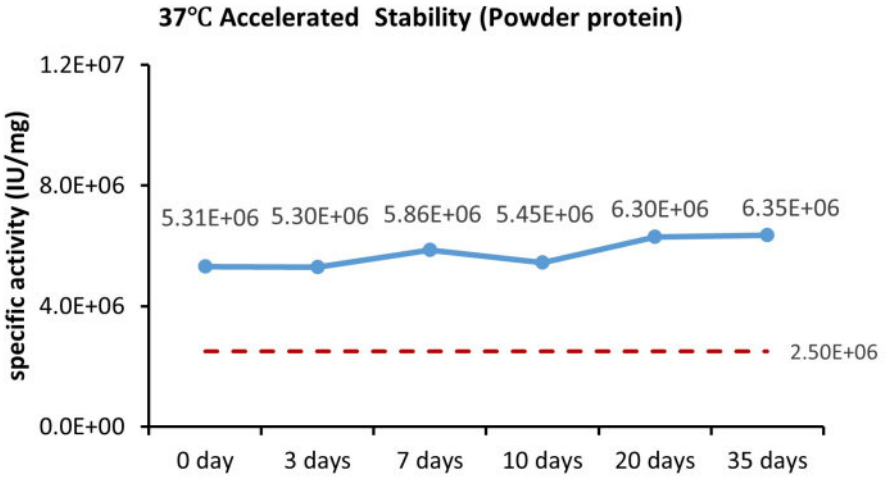


GMP Human SCF Protein (Cat. No. GMP-SCFH25), GMP Human Thrombopoietin Protein (Cat. No. GMP-THNH25), GMP Human Flt-3 Ligand Protein (Cat. No. GMP-FLLH28), GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) and GMP Human VEGF165 Protein (Cat. No. GMP-VE5H23) could significantly promote the iPSC differentiation to HSPCs after 14 days, highly expressed hematopoietic stem cell markers CD34 and CD45.

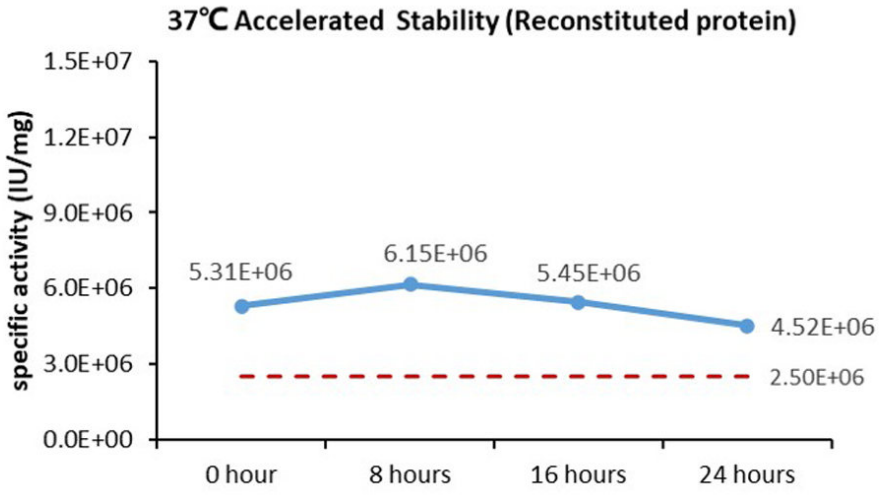


GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) and GMP Human TGF-Beta 1 Protein (Cat. No. GMP-TG1H25) could maintain the stemness of hiPSCs with high expression of stem cell genes OCT4, SOX2, and SSEA4 with GMP Human Laminin 521 Protein (Cat. No. GMP-LA5H24).

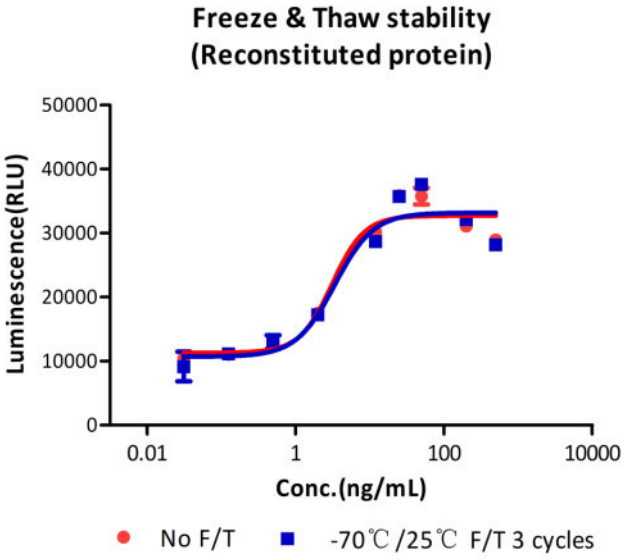
Bioactivity-Stability



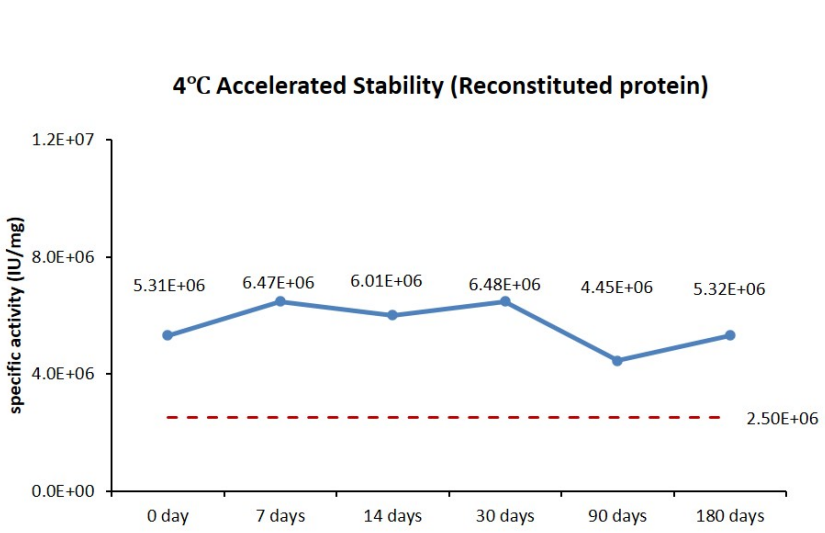
Cell-based assay demonstrates that the lyophilized GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable at 37°C for 35 days.



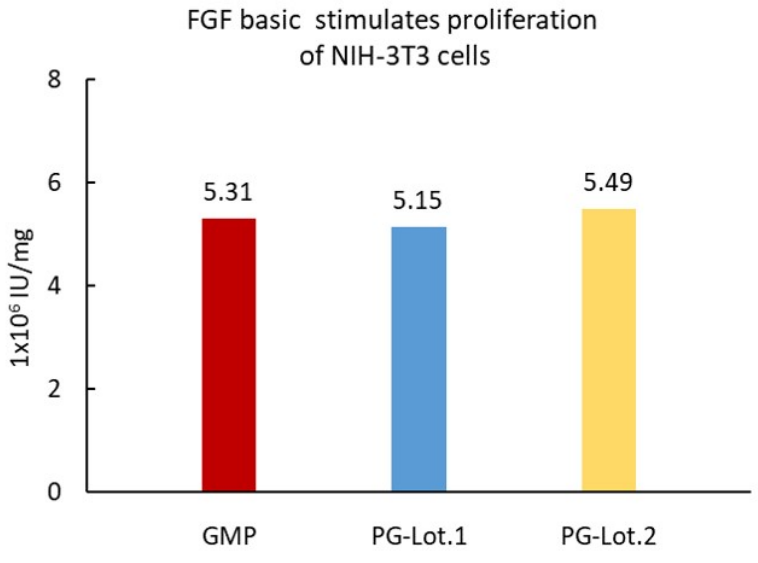
Cell-based assay demonstrates that the reconstituted GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable at 37°C for 24 hours.



Cell-based assay demonstrates that the reconstituted GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable after 3 freeze-thaw cycles.



Cell-based assay demonstrates that the reconstituted GMP Human FGF basic Protein (Cat. No. GMP-FGCH17) is stable at 4°C for 180 days.



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

Background

FGF basic (also known as FGF2 and HBGF-2) is an 18-34 kDa, heparin-binding member of the FGF superfamily of molecules (1-3). Superfamily members are characterized by the presence of a centrally placed beta -trefoil structure. FGF acidic (FGF-1) and FGF basic (FGF2) were the first two identified FGFs, and the designations acidic and basic refer to their relative isoelectric points. Human FGF basic is 288 amino acids (aa) in length. There are multiple start sites, four of which utilize atypical CUG codons, and one that initiates at an AUG start site (4 - 6). The four CUG start sites generate high molecular weight (HMW) FGF basic. There is a 34 kDa, 288 aa form, a 24 kDa, 210 aa form, a 22.5 kDa, 201 aa form, and a 22 kDa, 196 aa form. All are retained intracellularly, undergo extensive methylation, and possess one or more nuclear localization signals (NLS) (7-9). The AUG initiating form is 18 kDa and 155 aa in length. There is no signal sequence (ss). It is, however, secreted directly through the plasma membrane via a mechanism that appears to be dependent upon tertiary structure (10). In place of a ss, there is purportedly a 9 aa N-terminal prosegment that precedes a 146 aa mature segment (11). Early isolations of 18 kDa bovine FGF basic yielded 146 aa molecules, an effect attributed to the presence of acid proteases (12). The molecule contains a heparin-binding site (aa residues 128-144), and undergoes phosphorylation at Ser117 (13). There is also an ill-defined C-terminal NLS that may be more “functional” (or 3-dimensional) than structural (7). Human 146 aa FGF basic is 97% aa identical to mouse FGF basic (14).

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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1.1 ACROBiosystems ("ACRO") GMP grade products ("Products") are designed for research, manufacturing use or ex vivo use.

1.2 Products are NOT intended for diagnostic purposes or for direct or indirect administration into humans.

1.3 Purchaser shall not market, distribute, or resell Products obtained from ACRO without ACRO's prior written consent.

2. REVERSE ENGINEERING PROHIBITED & CONFIDENTIALITY

2.1 Purchaser shall not reverse-engineer, decompile, disassemble, sequence, analyze via bioinformatics, or otherwise attempt to discover the structure, sequence, composition, construction, manufacturing process, or any trade secret embodied in the Products. Purchaser shall not permit any third party to undertake such activities.

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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(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.
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(d) ANY PERSONAL INJURY, DEATH, OR DAMAGE TO TANGIBLE PROPERTY TO THE EXTENT PERMITTED BY LAW.

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5.2 End User explicitly acknowledges the Products are NOT FOR HUMAN ADMINISTRATION and agrees not to use them in any in vivo human application, directly or indirectly.

5.3 End Users unwilling to accept these terms must immediately: (a) cease all use; (b) notify ACRO or their supplier; and (c) return the unopened, unused Products.

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