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
- No animal derived peptone and lactose used in production process

Product Details

GMP GENIUS™Nuclease is a tag-free recombinant form of Serratia marcescens extracellular endonuclease produced in Escherichia coli using a proprietary process at ACROBiosystems. GMP GENIUS™Nuclease performs optimally at low and physiological salt concentrations (0-200 mM NaCl). The product is a homodimer with monomer molecular masses of about 30 kDa. The enzyme is a non-specific nuclease with high specific activity, degrading single- and double-stranded nucleic acids in any form (single stranded, double stranded, linear, circular, and supercoiled). It hydrolyzes internal phosphodiester bonds present between the nucleotides to 5'- phosphorylated oligonucleotides of 3-5 bases in length.

Application

Elimination of nucleic acids from biologics, optimal for samples with 0-200 mM salt in presence of 2-10 mM Mg++
• clinical viral vaccine production
• clinical viral vector production for cell and gene therapy (CGT)
• Other clinical development and production uses

Operating Conditions

GMP GENIUS™Nuclease is functional between pH 6 and 10 (optimal at pH8 - 8.5) , and from 0°C to 50 °C (optimal at 37 °C - 45 °C). $Mg2+$ (1-2 mM) is required for enzyme activity.1 mM EDTA reduced the activity by 30% in the presence of 1 mM $MgCl2$; 0.1 M EDTA eliminated all enzyme activity. In the presence of 1 mM $MgCl2$, enzyme levels were reduced 75% by 0.1 M $CaCl2$ or 1 M NaCl. Under standard assay conditions, 1 mM iodoacetate had no effect on the enzymatic rate, whereas 1 mM mercaptoethanol and maleic acid reduced the activity by only 5 to 10%. 10 mM p- Chloromercurybenzoate completely inactivates the enzyme, while 0.64 M beta-mercaptoethanol in the presence of 2 M urea causes only partial inactivation of the enzyme. 4 or 7 M Urea increases the enzyme activity.

Purity

>95% as determined by SDS-PAGE.

Enzyme Activity

≥250 U/μL

Host Cell Protein

<0.05 ng/μg of protein tested by ELISA.

Protease Activity

Negative.

Sterility

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

Mycoplasma

Negative.

Endotoxin

Less than 10 EU/mg by the LAL method.

Heavy Metals

≤10 ppm.

Formulation

Supplied as 0.2 μm filtered solution in 20 mM Tris, 20 mM NaCl, 2 mM $MgCl2$, pH8.0.

Contact us for customized product form or formulation.

Shipping

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

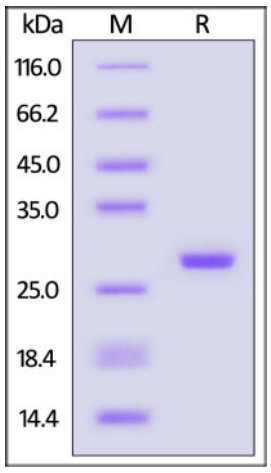
Storage

This product is stable after storage at:

- The product MUST be stored at -20°C or lower upon receipt;
- -20°C for 5 years under sterile conditions.

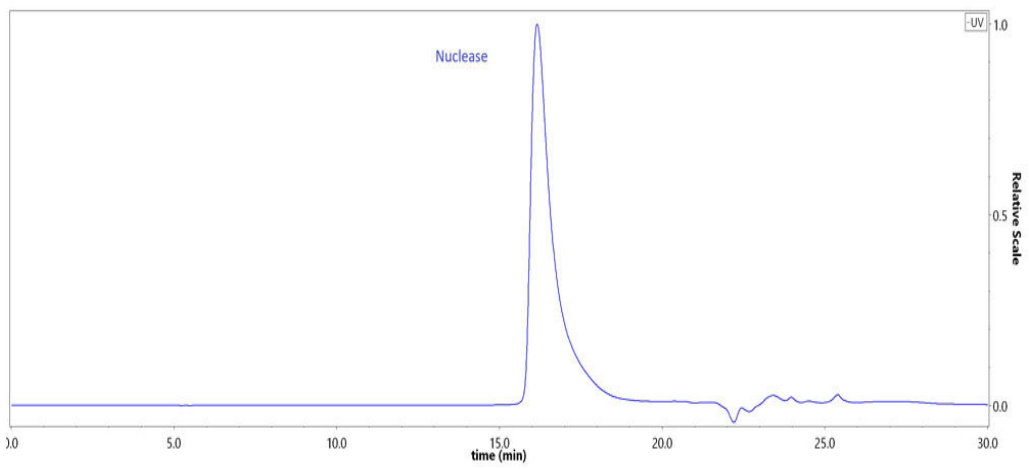
>99% as determined by SEC-HPLC.

SDS-PAGE



The gel was stained with Coomassie Blue. The purity of the protein is greater than 95%.

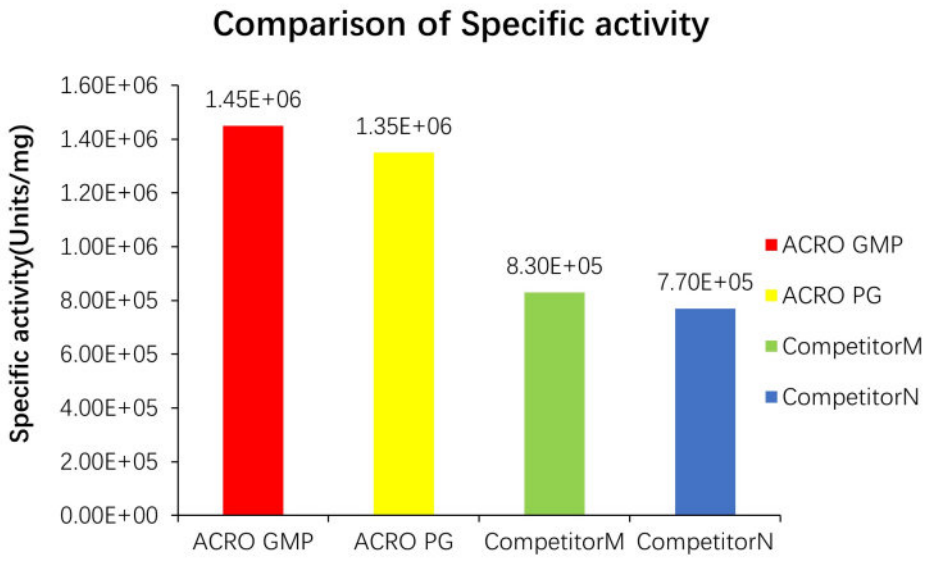
SEC-HPLC



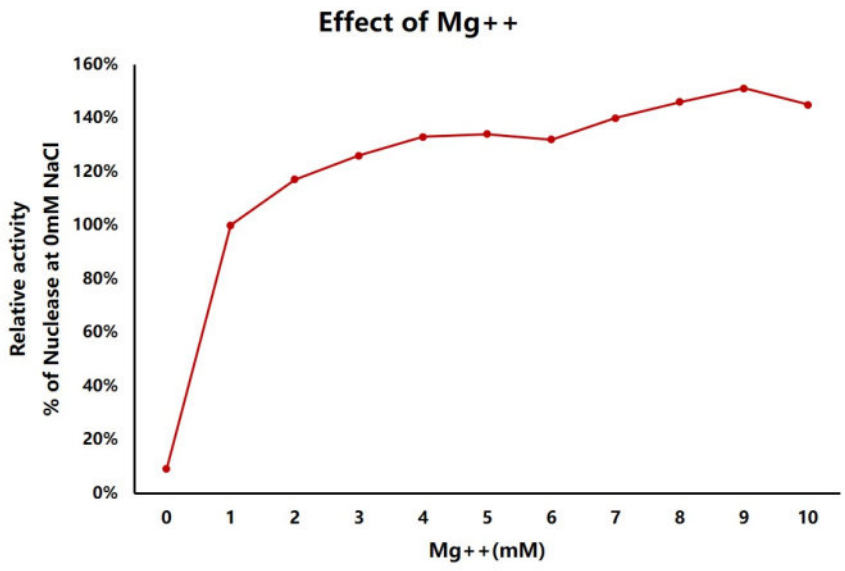
The purity of GMP GENIUS™Nuclease (Cat. No. GMP-NUES19) was greater than 99% as determined by SEC-HPLC.

Bioactivity

Specific activity for GMP GENIUS Nuclease is measured under standard assay conditions. The specific activity of GMP GENIUS Nuclease, is > 1.2 x 10^6 unit/mg protein (QC tested). One unit will digest sonicated salmon sperm DNA to acid-soluble oligonucleotides equivalent to a ΔA260 of 1.0 in 30 min at pH 8.0 at 37 °C, which corresponds approximately to complete digestion of 37 µg DNA,Note that 1 KU=1000 units.

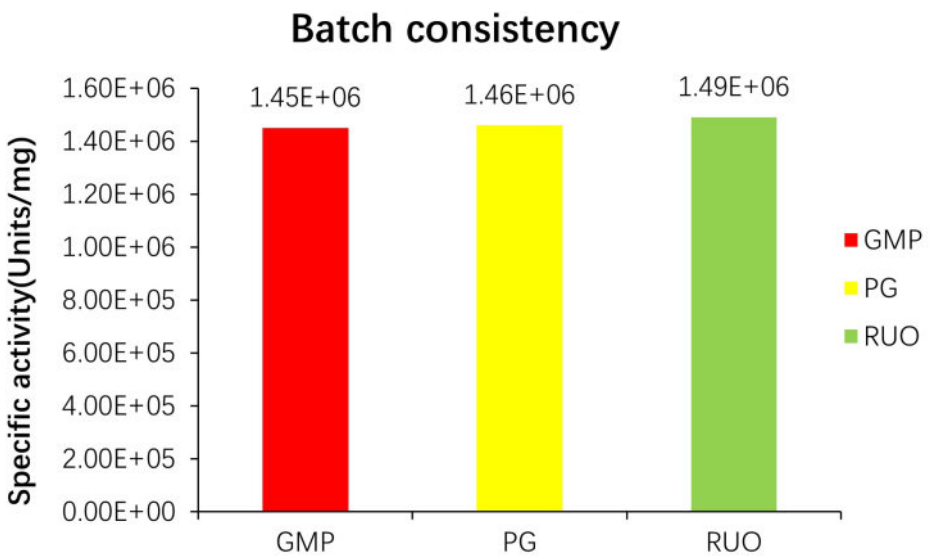


GMP GENIUS Nuclease shows high specific activity.

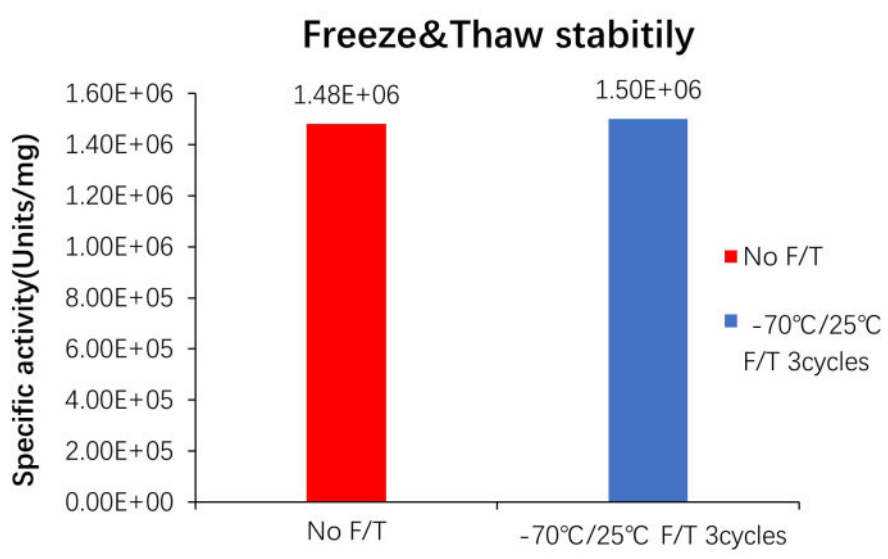


The effect of Mg++ concentrations on GENIUS™Nuclease activity. The Nuclease requires 1-2 mM Mg++ cations for optimal activity.

Bioactivity-Stability



The specific activity shows that GMP GENIUS™Nuclease (Cat. No. GMP-NUES19) is stable in different batches.



The specific activity shows that GMP GENIUS™Nuclease (Cat. No. GMP-NUES19) is stable after 3 freeze-thaws.

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

Batch-to-batch consistency

Clinical and Translational Updates