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 Salt Active GENIUS™Nuclease is developed with ACROBiosystems' unique enzyme AI evolution platform based on wild-type Serratia marcescens endonuclease. It is capable of maintaining high specific activity to effectively degrade nucleic acids in any form across a broad salt concentration range (0-500 mM NaCl), especially high salt up to 500mM NaCl, which makes it suitable for nucleic acid removal in processes that of higher salt conditions. 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, suitable for samples with 0-500 mM salt in presence of 5-10 mM Mg++
• clinical viral vaccine production
• clinical viral vector production for cell and gene therapy (CGT)
• Other clinical development and production uses

Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

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 USP<71> and Ph. Eur. 2.6.1.

Mycoplasma

Negative.

Endotoxin

Less than 10 EU/mg by the LAL method / rFC method.

Formulation

Supplied as 0.2 μm filtered solution in 25 mM Tris, 500 mM NaCl, 5 mM MgCl2, pH7.5.

Contact us for customized product form or formulation.

Shipping

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

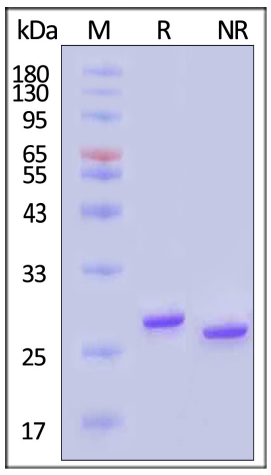
Storage

This product is stable after storage at:

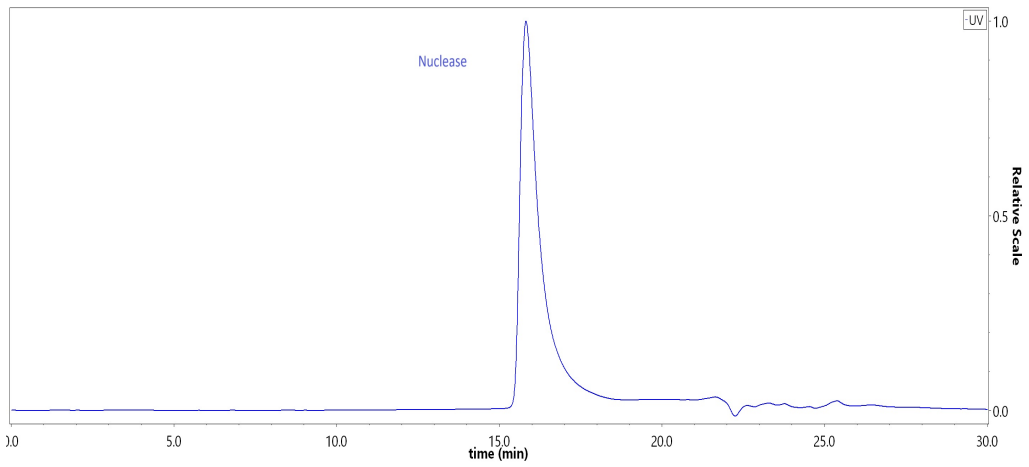
- The product MUST be stored at -20°C or lower upon receipt;
- -20°C for 5 years under sterile conditions.

SDS-PAGE

SEC-HPLC



The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

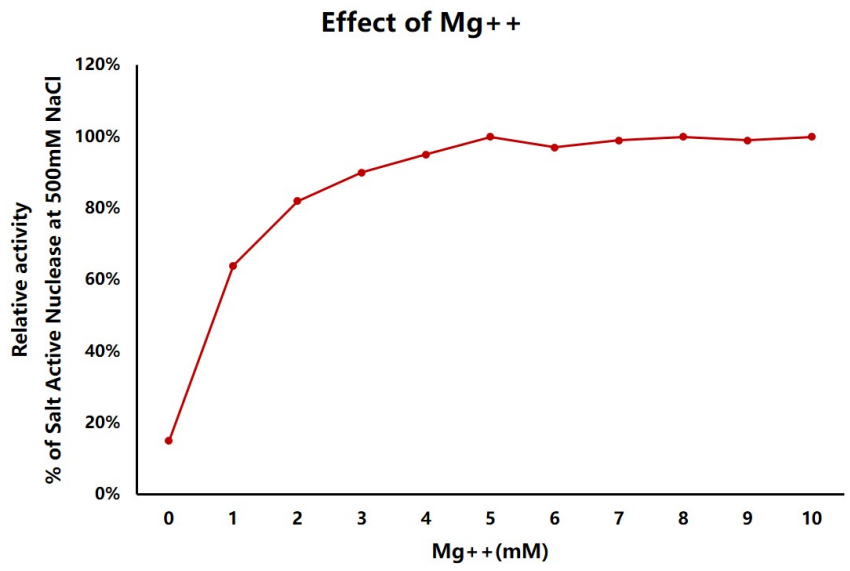


The purity of GMP Salt Active GENIUSNuclease (Cat. No. GMP-NUES13) was greater than 95% as determined by SEC-HPLC.

Bioactivity

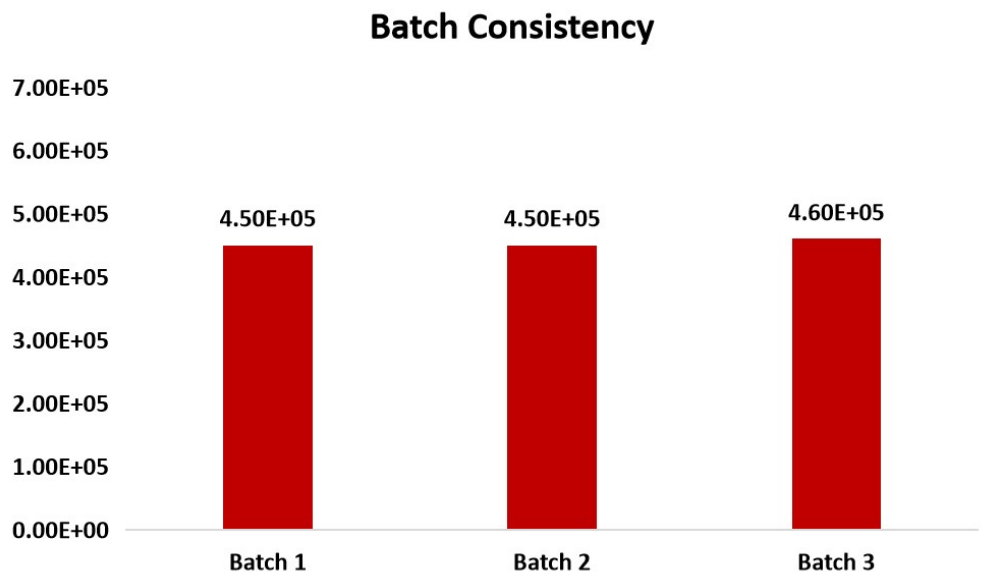
Specific activity for GMP Salt Active GENIUS™Nuclease is measured under standard assay conditions. The specific activity of GMP GENIUS Nuclease is >4.3E+05 unit/mg at 500 mM salt concentration (QC tested). One unit will digest sonicated salmon sperm DNA to acid-soluble oligonucleotides equivalent to 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.

GMP GENIUS Nuclease shows high specific activity.

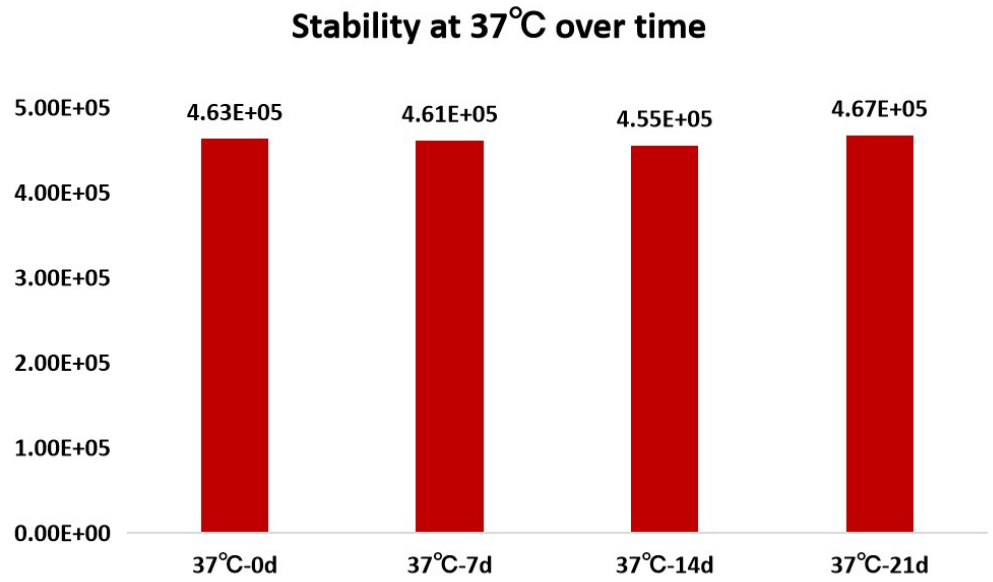


The effect of Mg++ concentrations on Salt Active GENIUS™Nuclease activity. The Nuclease requires 5 mM Mg++ cations for optimal activity.

Bioactivity-Stability



The specific activity shows that GMP Salt Active GENIUS™Nuclease (Cat. No. GMP-NUSE13) is stable in different batches.



The specific activity shows that GMP Salt Active GENIUS™Nuclease (Cat. No. GMP-NUSE13) is stable at 37℃ for 21 days.

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

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