

#### **Features**

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- Animal-Free materials
- Batch-to-batch consistency
- Stringent quality control tests
- No animal derived peptone and lactose used in production process.

#### **Product Details**

GMP Salt Active GENIUS<sup>TM</sup>Nuclease is screened by ACRObiosystems' unique enzyme evolution platform. It has specific activity at high salt concentrations (500mM), which degrades both single- and double-stranded nucleic acids in any form (single stranded, double stranded, linear, circular, and supercoiled).

#### **Application**

- AAV virus purification;
- Recombinant protein purification;
- Viscosity reduction in protein extracts.

# **Enzyme Activity**

 $> 250 \text{ U/}\mu\text{L}$ 

#### Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

#### **Host Cell Protein**

<0.05 ng/ug of protein tested by ELISA.

#### **Endotoxin**

Less than 0.01 EU per µg by the LAL method.

#### **Protease activity**

Negative.

### **Sterility**

Negative.

## Mycoplasma

Negative.

#### **Formulation**

Supplied as  $0.2~\mu m$  filtered solution in 25 mM Tris, 500 mM NaCl, 5 mM MgCl2, pH7.5 with glycerol as protectant.

Contact us for customized product form or formulation.

#### **Shipping**

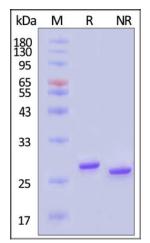
This product is supplied and shipped with dry ice, please inquire the shipping cost.

#### Storage

This product is stable after storage at:

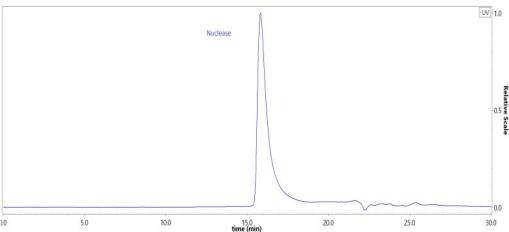
- The product MUST be stored at -20°C or lower upon receipt;
- -20°C for 5 years under sterile conditions.

#### **SDS-PAGE**



GMP Salt Active GENIUSNuclease 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 <u>Star Ribbon Pre-stained Protein Marker</u>).

# SEC-HPLC



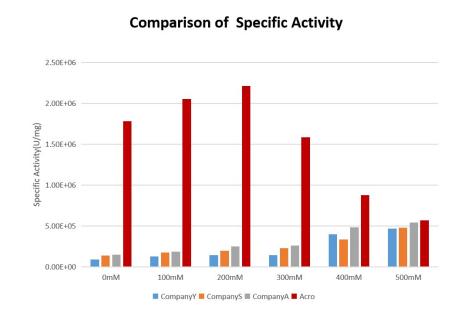
The purity of GMP Salt Active GENIUSNuclease (Cat. No. GMP-NUES13) was greater than 95% as determined by SEC-HPLC.

# Bioactivity



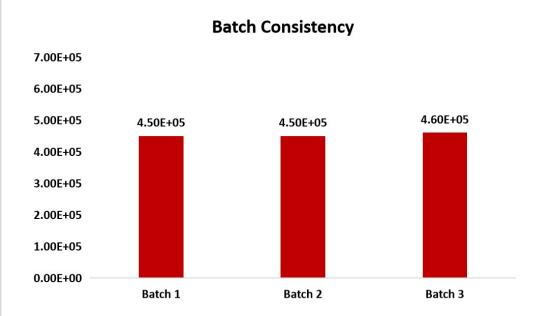


Specific activity for GMP Salt Active GENIUS<sup>TM</sup>Nuclease is measured under standard assay conditions. The specific activity of GMP GENIUS Nuclease, is >4.3E+05 unit/mg protein. One unit will digest sonicated salmon sperm DNA to acid-soluble oligonucleotides equivalent to a  $\Delta A260$  of 1.0 in 30 min at pH 8.0 at 37 °C, which corresponds approximately to complete digestion of 37  $\mu$ g DNA.



.GMP GENIUS Nuclease shows high specific activity.

#### **Bioactivity-Stability**



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

# Stability at 37°C over time 5.00E+05 4.63E+05 4.61E+05 4.65E+05 4.67E+05 3.00E+05 2.00E+05 1.00E+05 37°C-0d 37°C-7d 37°C-14d 37°C-21d

The specific activity shows that GMP Salt Active GENIUS<sup>TM</sup>Nuclease (Cat. No. GMP-NUSE13) is stable at 37°C 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



# **GMP Salt Active GENIUS™Nuclease**





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**

