GMP GENPower™ NLS-Cas9 Nuclease

Catalog # GMP-CA9S18

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

Endotoxin

Less than 0.01 EU per μg by the LAL method.

Host Cell Protein

≤ 10 ng/mg tested by ELISA.

Host Cell DNA

≤ 1 ng/mg 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.

Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

Concentration

10 mg/ml

Formulation

Supplied as 0.2 μm filtered solution in 20 mM Tris, 300 mM NaCl, 0.1 mM EDTA, 1 mM TCEP, pH7.5 with protectants.

Contact us for customized product form or formulation.

Shipping

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

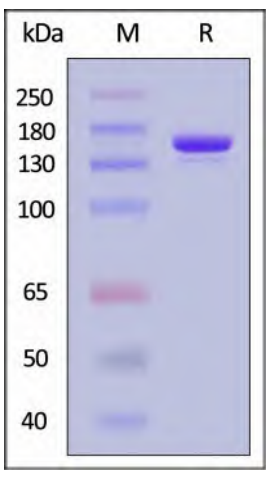
Storage

Please avoid repeated freeze-thaw cycles.

This product is stable after storage at:

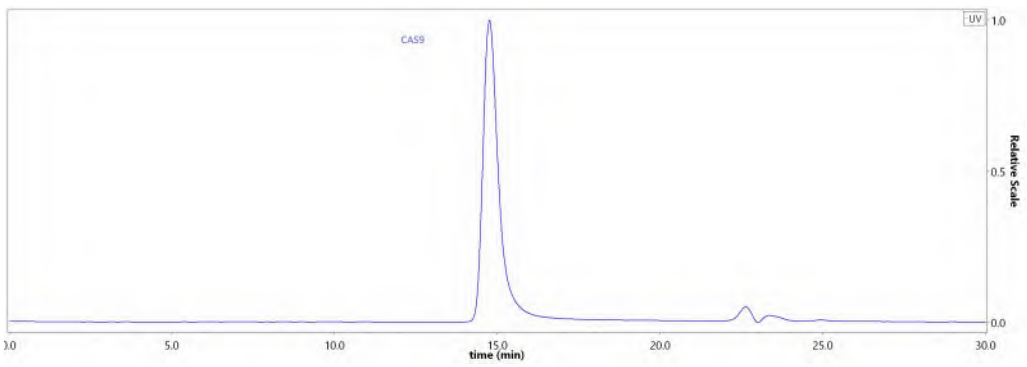
- The product MUST be stored at -20°C or lower upon receipt;
- -20°C for 5 years under sterile conditions.

SDS-PAGE



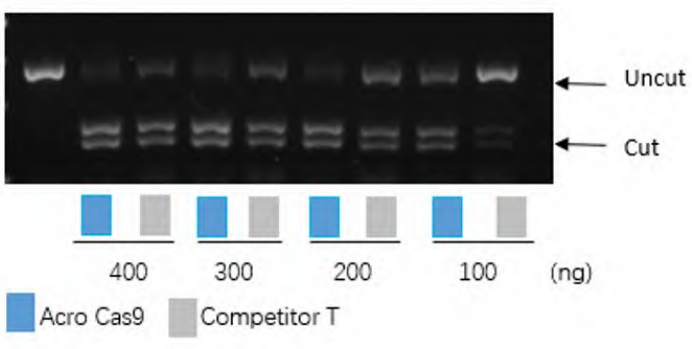
GMP GENPower™ NLS-Cas9 Nuclease on SDS-PAGE under reducing (R) condition. The gel was stained with Coomassie Blue. The protein has a calculated MW of 162.4 KDa. The protein migrates as 145±5 kDa when calibrated against Star Ribbon Pre-stained Protein Marker under reducing (R) condition (SDS-PAGE).The purity of the protein is greater than 95%.

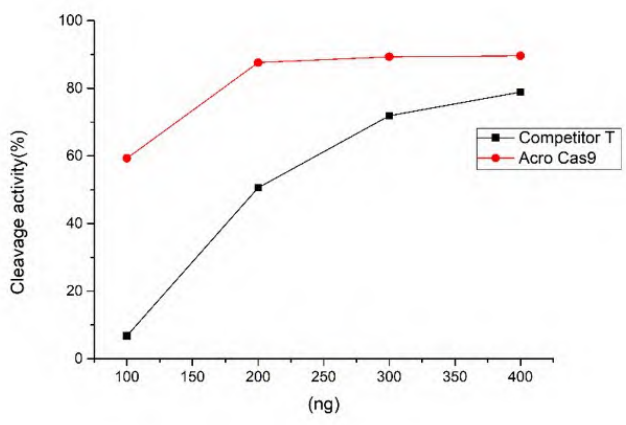
SEC-HPLC



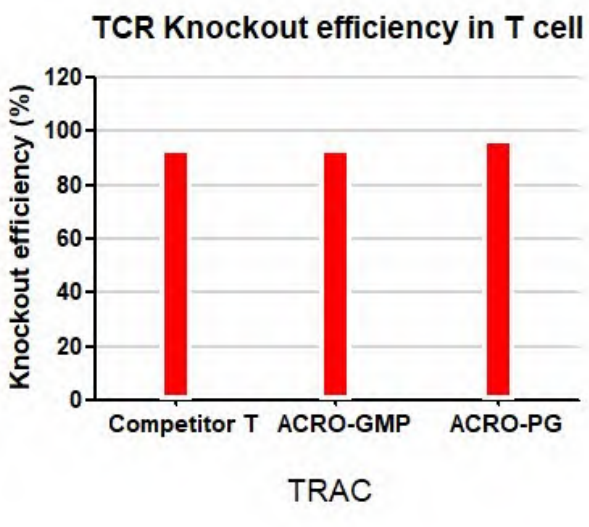
The purity of GMP GENPower™ NLS-Cas9 Nuclease (Cat. No. GMP-CA9S18) was greater than 95% as determined by SEC-HPLC.

Bioactivity





Different amounts of Cas9 were incubated with the same amount of excess gRNA and plasmid for 60 minutes at 37°C. When using 400-200 ng Acro Cas9, the cutting efficiency is greater than 90%. In comparison, when using a 200 ng Competitor T, the cutting efficiency is only about 50%.



The TCR knockout efficiency with GMP GENPower™ NLS-Cas9 Nuclease in human primary T cells, GMP GENPower™ NLS-Cas9 Nuclease achieved over 95% knockout efficiency.

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

Background

CRISPR (clustered regularly interspaced short palindromic repeat) is an adaptive immune system that provides protection against mobile genetic elements (viruses, transposable elements and conjugative plasmids)，CRISPR clusters contain spacers, sequences complementary to antecedent mobile elements, and target invading nucleic acids. CRISPR clusters are transcribed and processed into CRISPR RNA (crRNA). In type II CRISPR systems correct processing of pre-crRNA requires a trans-encoded small RNA (tracrRNA), endogenous ribonuclease 3 (rnc) and this protein. The tracrRNA serves as a guide for ribonuclease 3-aided processing of pre-crRNA; Cas9 only stabilizes the pre-crRNA:tracrRNA interaction and has no catalytic function in RNA processing. Subsequently Cas9/crRNA/tracrRNA endonucleolytically cleaves linear or circular dsDNA target complementary to the spacer; Cas9 is inactive in the absence of the 2 guide RNAs (gRNA). The target strand not complementary to crRNA is first cut endonucleolytically, then trimmed 3'-5' exonucleolytically. DNA-binding requires protein and both gRNAs, as does nuclease activity. Cas9 recognizes the protospacer adjacent motif (PAM) in the CRISPR repeat sequences to help distinguish self versus nonself, as targets within the bacterial CRISPR locus do not have PAMs. DNA strand separation and heteroduplex formation starts at PAM sites; PAM recognition is required for catalytic activity.

Clinical and Translational Updates

Please contact us via TechSupport@acrobiosystems.com if you have any question on this product.