Features

- Designed under ISO 9001:2015 and ISO 13485:2016
- Manufactured and QC tested under a GMP compliance factory
- 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 GENPower™ NLS-Cas9 Nuclease is a recombinant Streptococcus pyogenes Cas9 protein purified from Escherichia coli for CRISPR-based genome editing. The introduction of nuclear localization signals (NLS) can help Cas9 enter the nucleus, increasing the chance of genomic DNA cleavage.

Application

• Genetic modification of cells and gene therapy drugs (T cell, hematopoietic stem cell)
• High specificity detection of pathogens

Concentration

10 mg/mL

Purity

>95% as determined by SDS-PAGE.

>95% as determined by SEC-HPLC.

Host Cell Protein

≤10 ng/mg of protein tested by ELISA.

Host Cell DNA

≤1 ng/mg of protein 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.

Endotoxin

Less than 10 EU/mg by the LAL method.

Formulation

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

Contact us for customized product form or formulation.

Shipping

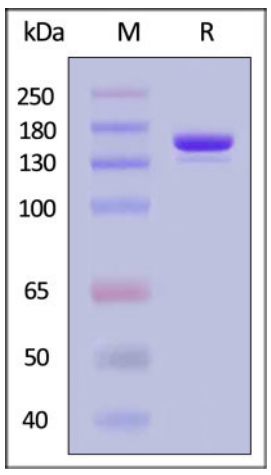
This product is supplied and shipped with dry ice, please inquire the shipping cost.

Storage

This product is stable after storage at:

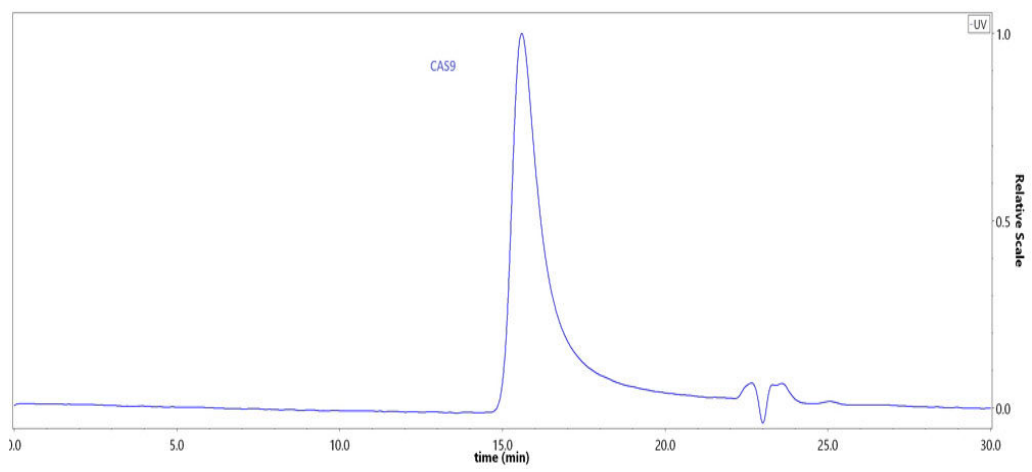
- The product MUST be stored at -20°C or lower upon receipt;
- -20°C for 5 years under sterile conditions.

SDS-PAGE



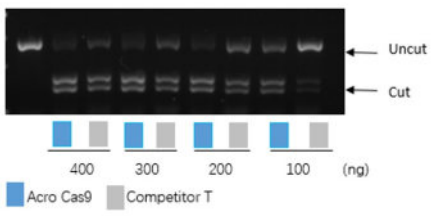
The gel was stained with Coomassie Blue. The purity of the protein is greater than 95% (With Star Ribbon Pre-stained Protein Marker).

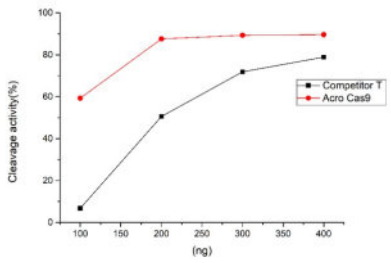
SEC-HPLC



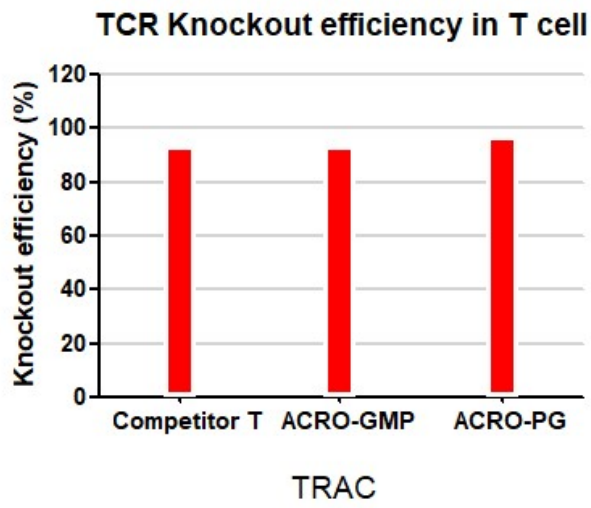
The purity of GMP GENPower™ NLS-Cas9 Nuclease (Cat. No. GMP-CA9S18) was greater than 95% as determined by SEC-HPLC.

Bioactivity



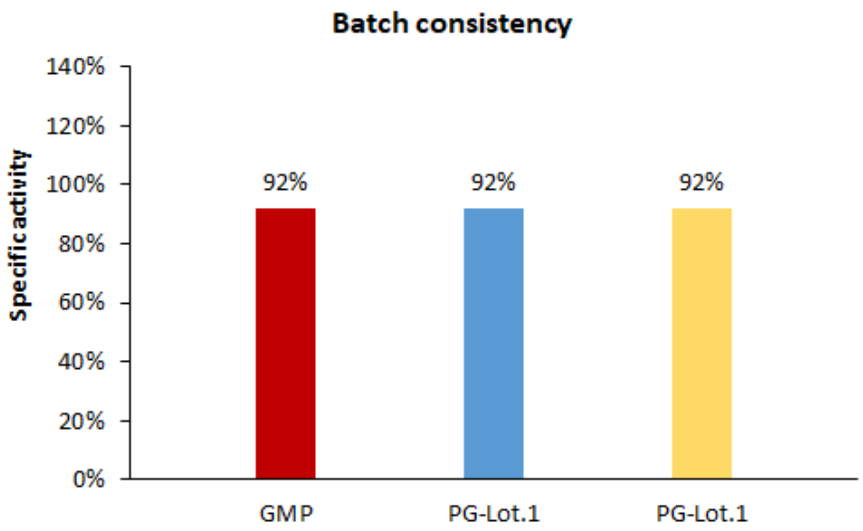


Different amounts of Cas9 were incubated with the same amount of excess gRNA and plasmid for 60 minutes at 37°C. When using 400-200 ng Acro Cas9, the cutting efficiency is greater than 90% (QC tested). In comparison, when using a 200 ng Competitor T, the cutting efficiency is only about 50%.



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.

Bioactivity-Stability



The bioactivity based assay shows batch-to-batch consistency between Acro's GMP and PG Cas9.

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