

Recombinant NLS-SpCas9-NLS (Cas9) Nuclease Solution

Vials Cat. # PD1019

P 1

DISCLAIMER: This product is currently under development and is available as Catalog # PD1019 for research use only. Final cGMP product (Cat # AR1054) details are subject to change.

Product Description:

Akron's recombinant NLS-SpCas9-NLS (Cas9) Nuclease Solution is manufactured following all relevant cGMP guidelines for ancillary materials. The downstream purification process uses a multi-step orthogonal approach, without the use of affinity tags, to minimize exogenous impurities and ensure the delivery of highly purified and active substance for further manufacturing applications. Akron's Cas9 Nuclease is a single-chain, 162 kDa, non-glycosylated DNA endonuclease expressed in *E. coli*. The amino acid sequence comes from *Streptococcus pyogenes*, and the protein structure has been altered by the addition of a nuclear localization sequence (NLS) to both the N- and C- terminals of the protein. The addition of the NLS to the protein structure ensures that your RNP complex is effectively imported into the cell nucleus.

Product Features:

Active Substance

- NLS sequences added to both the N- and C- terminal
- Effective site-directed nuclease activity
- Carrier protein-free formulation

Manufacturing

- Multi-step downstream purification strategy excluding affinity tags
- Sterile microfiltration and aseptic filling
- Animal free expression system with *E. coli* host

Quality

- Relevant cGMP guidelines followed in manufacture, testing, and release
 - USP <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
 - EP 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products
 - ISO 13485:2016, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
 - ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present during the Production of Cellular Therapeutic Products

Recombinant NLS-SpCas9-NLS (Cas9) Nuclease Solution

Vials Cat. # PD1019

P 2

Release Testing:

- Appearance
- Protein Content (UV Spectrophotometry)
- Purity (RP-HPLC)
- Nuclease cutting efficiency
- Residual Host Cell Protein & DNA (final cGMP product)
- Bacterial Endotoxins (USP <85> / EP 2.6.14) (final cGMP product)
- Sterility (USP <71> / EP 2.6.1) (final cGMP product)

Stability:

- Under long-term stability program
- Store at -80 °C
- Keep out of light and avoid repeated freeze-thaw cycles
- Ships with Dry Ice

For Use Statement:

Final cGMP product: For research use or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

DISCLAIMER: Currently available as Catalog # PD1019, for research use only, not for further manufacturing. cGMP material (Catalog # AR1054) under development.

Related Products:

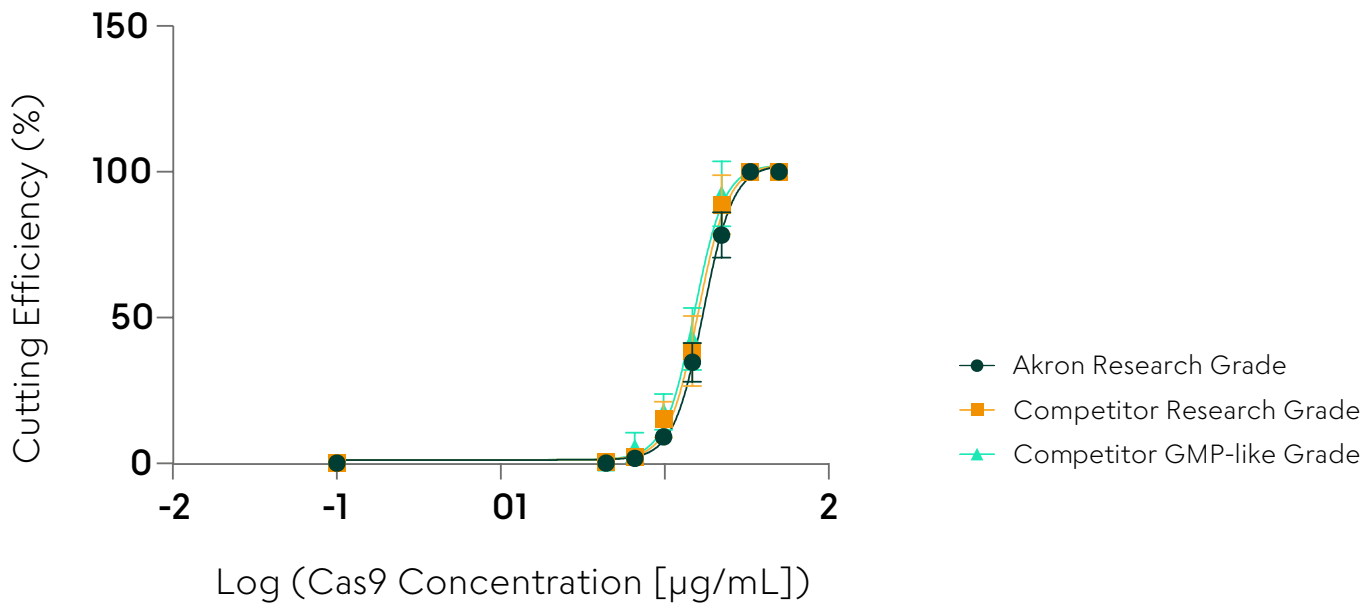
Catalog Number	Product Name	Size
AK8223-1000	Recombinant Human Interleukin-2 (rHu IL-2)	1 mg
AK9984-1000	Recombinant Human Interleukin-2 (rHu IL-2) Prefilled Syringe	1 mL
AK9842-0040	Recombinant Human Interleukin-7 (rHu IL-7)	40 µg
AK9823-0040	Recombinant Human Interleukin-15 (rHu IL-15)	40 µg
AK9833-0040	Recombinant Human Interleukin-21 (rHu IL-21)	40 µg
AK9995-0020	Recombinant Human Interleukin-12 (rHu IL-12)	20 µg
AK9999-0025	Recombinant Human Interleukin-18 (rHu IL-18)	25 µg
AK8228-0100	Human Serum Albumin (HSA) 25% Solution	100 mL
AR1010-0100	Human AB Serum, Converted from Octaplas®, Pooled Plasma (Human), Xeno-Free, Virus Inactivated	100 mL

Recombinant NLS-SpCas9-NLS (Cas9) Nuclease Solution

Vials Cat. # PD1019

P 3

Functionality Data:



For more information on our available products or for technical assistance, see contact info below.
For contract orders under master supply agreement, please inquire.