Stock Name : Novoprotein Stock Code: 688137



# **GMP Grade Products**

Novoprotein Scientific Inc.

# INDEX

1	Novoprotein's GMP Quality Management System
2	Regulatory Basis 2
3	Quality Control <sup>2</sup>
4	FDA DMF
5	Files Support for IND 3
6	GMP Grade Products
	(1) Recombinant anti-Human CD3 mAb/CD28 mAb4
	(2) NovoNectin®5
	(3) Vitronectin 6
	(4) Cell/Organoid Culture Cytokines and Antibodies7
	(5) Recombinant Cas9 Nuclease 9
	(6) (High Salt Active) BenzoNuclease <sup>®</sup> ····································
	(7) mRNA Raw Materials and Reagents14
7	GMP Grade Products Summary

# **Dedicated & Professional**

Novoprotein Scientific Inc. (Novoprotein) is a high-tech enterprise with more than 10 years of extensive experience in the recombinant protein industry, focusing on protein technology, and advanced in R&D, production, sales, and application solutions to raw materials and techniques for biopharmaceuticals, in vitro diagnosis, mRNA vaccines, and basic life science research. Our principal products include target proteins and cytokines, recombinant antibodies, molecular enzymes and reagents, as well as providing related technical services. Novoprotein possesses R&D and manufacturing bases in Shanghai, Suzhou, and Heze.

# novoprotein E # E a



BenzoNuclease®

# GMP Grade Factory 8000m<sup>2</sup>

FDA DMF 15

Raw Materials for mRNA Drugs: 10

Raw Materials for Biologic Drugs: 5

Gene and Cell Therapy Customers 200+

Help Customers Succeed in CDE/FDA IND or EUA 16

Gene and Cell Therapy Customers:8

mRNA Vaccine Customers:8

Recombinant Protein Vaccine Customer: 1

# Novoprotein's GMP Quality Management System

The GMP products provided by Novoprotein have been certified by ISO 9001:2015 and are produced in accordance with GMP quality management system. The GMP quality management system is implemented to ensure the controllability and traceability of materials and processes.

- Adequate number of personnel and a well-established personnel training process
- The factory facilities and equipment comply with GMP and are regularly maintained and verified
- A comprehensive document management system, including process procedures, quality standards and inspection methods, complete batch production and inspection records, etc
- A comprehensive supplier management process, raw material and product management process
- Strict production process management, effective pollution prevention and cross contamination measures
- A comprehensive quality assurance and control system, with each product audited by QC and released by QA
- Fully validated equipment, processes, and inspection methods

# 2 Regulatory Basis

- (1) (Good Manufacturing Practice of Medical Products (2010 version, NMPA))
- (2) 《GMP Appendix Cellular therapeutic product》 National Medical Products Administration
- (3) 《Pharmacopoeia of the People' s Republic of China》 2020 version, National Pharmacopoeia Commission
- (4) USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- (5) USP Chapter <92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing

(6) Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products

# 3 Quality Control

- Animal-free materials and pharmaceutical-grade excipients are used for the production
- The production process has virus inactivation and removal steps, and some products can provide virus removal process validation reports
- Conduct comprehensive testing of production cell lines in accordance with the requirements of the pharmacopoeia, ensuring no virus or external factor contamination, and provide inspection reports
- Sterile, ampicillin-free, mycoplasma-free
- Medicinal penicillin bottle packaging



πονορ





Drug Master Files (DMFS) are archive files submitted by the holder to the FDA, which contain detailed information on the production facilities, process flow, quality control, raw materials, packaging materials, and other processes used in the production, processing, packaging, and storage of drug products for human use. DMF can be used for one or more clinical applications (IND), innovative drug applications (NAD), simplified new drug applications (ANDA), bioproduct license applications (BLA), as well as amendments and supplements to various applications mentioned above. The raw material supplier submits the required technical content directly to the FDA for filing and obtains a filing number in the form of a DMF document. Drug applicants can use the DMF filing number directly instead of providing specific information about raw materials and excipients during the filing process.

# Novoprotein has obtained FDA DMF registration for 15 GMP Grade products, including 10 mRNA vaccine drug raw materials and 5 biopharmaceutical raw materials.

Cat. No.	Product Name	DMF No.
GMP-C013	Recombinant Human IL-2	037809
GMP-CD47	Recombinant Human IL-7	037735
GMP-C016	Recombinant Human IL-15	037736
GMP-1701	Recombinant Cas9 Nuclease, GMP Grade	039085
GMP-1707	BenzoNuclease®, GMP Grade	035864
GMP-RE026	BsaI, GMP Grade	037810
GMP-RE057	BspQI, GMP Grade	038671
GMP-RE015	XbaI, GMP Grade	038881
GMP-E121	T7 RNA Polymerase, GMP Grade	038343
GMP-E125	RNase Inhibitor, GMP Grade	038410
GMP-M036	Pyrophosphatase, Inorganic (yeast), GMP Grade	038438
GMP-E127	DNase I, GMP Grade	038364
GMP-M062	Vaccinia Capping Enzyme, GMP Grade	038330
GMP-M072	mRNA Cap 2´-O-Methyltransferase, GMP Grade	038439
GMP-E224	RNase R, GMP Grade	039011

# 5 Files Support for IND

No.	File Name	No.	File Name
1	Business License	9	Certificate of Analysis (COA)
2	IS09001 Certification	10	Manufacture Process
3	Declaration of GMP Quality Management System	11	Testing Methods (including mycoplasma, sterility, endotoxin, activity testing, etc.)
4	Declaration of TSE/BSE	12	Stability Report
5	Material Safety Data Sheet (MSDS)	13	Key Materials List
6	Certificate of Origin (COO)	14	Verification Report of Cell Bank
7	Equipments List of Production and Inspection	15	Verification Report on Virus Removal Process
8	Quality Standards	16	Other Required Documents (negotiable)

**Distributed by:** 

# 6 GMP Grade Products

#### (1) Recombinant anti-Human CD3 mAb/CD28 mAb, GMP Grade

The first signal for T cell activation *in vivo* comes from the T cell receptor (TCR) specifically recognizing the MHC molecule-antigen polypeptide complex on the surface of the antigen presenting cell (APC); the interaction between the co-stimulatory molecule CD28 on the surface of the T cell and its ligand B7 (CD80/86) (second signal) can enhance the activation and proliferation of T cells. The activation of T cells *in vitro* can be achieved by binding anti-CD3 mAb to CD3 molecules, and anti-CD28 mAb can bind CD28 as a costimulatory molecule for T cell activation.

Novoprotein provides GMP grade humanized Anti-CD3 mAb and Anti-CD28 mAb. Anti-CD3 mAb is derived from the OKT3 through humanized modification, targeting CD3e; Anti-CD28 mAb can bind CD28 as a costimulatory molecule for T cell activation.



Figure 2. Schematic diagram of the mechanism of CD3/CD28 antibodies in T cell activation

## Product Information

Cat. No.	Product Name
GMP-A018	Recombinant anti-Human CD3 mAb
GMP-A063	Recombinant anti-Human CD28 mAb



#### (2) NovoNectin<sup>®</sup>, GMP Grade

NovoNectin<sup>®</sup> (recombinant human Fibronectin, FN-CH296) can be used for cell attachment, spreading, differentiation, and proliferation. It can greatly improve the infection efficiency of retroviruses on mammalian cells. VLA-4 and VLA-5 on the cell surface bind to the CS-1 site and the cell-binding domain on NovoNectin<sup>®</sup>, respectively, and the retroviral vector binds to the heparin-binding domain, thus promoting the transfection efficiency of retroviruses and lentiviruses on cells. NovoNectin<sup>®</sup> can be mixed with humanized monoclonal antibody CD3 for the coating to enhance T cell amplification.

Recombinant Human NovoNectin<sup>®</sup> is expressed by *E. coli* and is manufactured using animal-origin-free raw materials. Corresponding drug products are manufactured with pharmaceutical-grade excipients. The manufacturing follows the "Good Manufacturing Practice for Drugs (2010 Revision)" with strict control of residual bacterial endotoxin, residual host cell protein, and residual exogenous DNA to ensure product quality, safety, and efficacy.

#### Recommendations for Use:

#### NovoNectin<sup>®</sup> for plate coating:

- Calculate the amount of NovoNectin<sup>®</sup> required on the basis of 5 μg/cm<sup>2</sup> coating area and dilute the protein mother liquor to 20–100 μg/mL with normal saline;
- 2. Add the protein mother liquor to the coated vessel to cover the vessel surface and allow it to stand at room temperature for 2 h or at 4 ° C overnight;
- \* Add 0.5 mL/well to the 24-well plate; add 2 mL/well to the 6-well plate or 35 mm dish;

#### Viral transfection:

- 1. Add the virus supernatant onto the NovoNectin<sup>®</sup>-coated plate at 125–250 μL/cm<sup>2</sup>;
- \* MOI = 1, virus titer >  $1 \times 10^8$ .
- 2. Allow standing at 37 ° C for 4–6 h for complete virus adsorption;
- \* In the case of a lower virus titer, Concentrate the virus supernatant before use.
- 3. Prepare the target cells to a suspension of  $0.2-1 \times 10^5$  cells;
- \* The target cells may be activated 24 h in advance.
- 4. Add the target cells to the previously processed dish at  $0.5-2.5 \times 10^4$  cells/cm<sup>2</sup>;
- 5. Incubate at 37 ° C for 2–3 days;

\* In the case of a higher virus titer, the virus may be directly mixed with the cells and the mixture shall be added to the NovoNectin<sup>®</sup>-coated dish for culture at an appropriate density.

6. The infected cells can be cultured in a conventional way.



Measured by its ability to support Jurkat cell attachment and spreading when used as a substratum for cell culture.

#### Product Information

Cat. No.	Product Name
GMP-CH38	NovoNectin®, GMP Grade <b>Distributed by:</b>

#### (3) Vitronectin, GMP Grade

Vitronectin is a large glycoprotein found in blood and the extracellular matrix (ECM). Vitronectin is involved in a number of biological activities including cell adhesion, cell spreading and migration, cell proliferation, extracellular anchoring, fibrinolysis, hemostasis, and complement mediated immune defense. It is worth noting that in the culture of pluripotent stem cells, due to the clear chemical composition of the protein, Recombinant Human Vitronectin helps to reduce the instability, compared with human plasma-derived Vitronectin and basement membrane extracts (BMEs).

Recombinant Human Vitronectin is expressed by mammalian cells, and is produced with raw materials of pharmaceutical applicable level. The host protein residue, nucleic acid residue and common pathogens are strictly controlled, and the production and quality management procedures of the product comply with GMP regulations to ensure the traceability of the production process and all raw materials.

#### High Activity





Measured by its ability to support iPS cell attachment and spreading when used as a substratum for cell culture. The ED50 for this effect is  $0.12 \mu g/mL$ .

The activity of Recombinant Human Vitronectin (Cat. No.:GMP-C395) was compared to another commercially available product.

## Suggested Product Dosage (Recommended Working Concentration: 0.5µg/ml)

Culture vessel	Approximate surface area	VTN
6-well plate	10 cm²/well	0.5µg/well
12-well plate	4 cm <sup>2</sup> /well	0.2µg/well
24-well plate	2 cm <sup>2</sup> /well	0.1µg/well
35-mm dish	10 cm <sup>2</sup>	0.5µg
60-mm dish	20 cm <sup>2</sup>	lμg
100-mm dish	60 cm <sup>2</sup>	Зμg
T-25 flask	25 cm <sup>2</sup>	1.25µg
T-75 flask	75 cm <sup>2</sup>	3.75µg

## Product Information

Cat. No.	Product Name
GMP-C395	Recombinant Human Vitronectin

## (4) Cell/Organoid Culture Cytokines and Antibodies, GMP Grade

#### Product Features

200+ cell therapy clients are using

Successfully assisted clients in applying for IND

High purity, high activity, and low endotoxin

High lot-to-lot consistency

Stable long-term supply

## High Activity



Measured in a cell proliferation assay using CTLL-2 mouse cytotoxic T cells. The specific activity of Recombinant human IL-15(Cat.No.:GMP-C016) is  $\geq 1.0 \times 10^7$  IU/mg, which is calibrated against human IL-15 WHO International Standard (NIBSC code: 95/554).

High Lot-to-Lot Consistency



Three independent lots were tested for activity and plotted on the same graph to show lot-to-lot consistency of IL-7.



The activity of Recombinant human IL-15 (Cat. No.:GMP-C016) was compared to another commercially available product.



Three independent lots were tested for activity and plotted on the same graph to show lot-to-lot consistency of IL-4.

## Cell/Organoid Culture Cytokines and Antibodies

Cell Type	Cytokines & Functional Antibodies	
T Cell	CD3 mAb、CD28 mAb、IL-2、IL-7、IL-15、Tscm Expender®	
NK Cell	CD16 mAb、NKG2D mAb、IL-12、IL-15、IL-18、IL-21	
DC Cell	IL-1 alpha、IL-1 beta、IL-4、GM-CSF、TNF alpha	
MSC Cell	bFGF、BMP-4、EGF、IGF-1、IL-6、TGF-β1、PDGF-BB	
iPSC-derived T Cell	bFGF、BMP-4、FLT3L、IL-3、IL-7、SCF、VEGF165	
iPSC-derived NK Cell	BMP-4、FLT3L、IL-2、IL-3、IL-7、IL-15、SCF、VEGF165	
iPSC-derived Macrophage Cell	bFGF、BMP-4、FLT3L、GM-CSF、IL-3、IL-7、IGF-1、M-CSF、SCF、VEGF165	
iPSC-derived Dopaminergic Neurons/Neural Precursor Cell	BDNF、FGF8b、GDNF、SHH 、TGF beta3	
	Motoneuron: BFGF、BDNF、CNTF、GDNF、IGF-1、SHH	
iPSC-derived other Nerual Cell	Astrocyte: Activin A、BMP-4、bFGF、CNTF、EGF、IGFI、NRG1Beta	
	NPC/NSC: BFGF、NT-3	
iPSC-derived Cardiomyocyte	Activin A、BMP-4、BFGF、DKK1、SCF、TGF-beta 1、transferrin、VEGF165、 Wnt 3a	
iPSC-derived Islet Cell	Activin A、KGF	
Organoids	Activin A、BDNF、bFGF、EGF、FGF8b、FGF-9、GDNF、HGF、IGF-1、KGF、 Noggin、OSM、PDGF-BB、R-Spondin 1、TGF-β1、VEGF165、Vitronectin	

#### (5) Recombinant Cas9 Nuclease, GMP Grade

#### Product Features



#### Product Data





The analytical results of the cell samples edited by different brands of Cas9 proteins showed that Novoprotein Cas9 protein is superior to its competitors in both editing efficiency and knockout score.

#### (2) T7EI Cleavage Efficiency



Different Cas9/sgRNA RNP complexes were delivered to the 293T cells by electroporation. After 48 h, the cells were collected and the genomic DNA was extracted for the T7EI testing. The test results showed that under the same conditions, the cleavage efficiency of Novoprotein Cas9 nuclease is superior to that of its competitors. Lane 1: marker; Lane 2: Novoprotein; Lane 3: brand A; Lane 4: brand B; Lane 5: negative control (target gene+ T7EI);Lane 6: negative control (target gene).

#### Product Information

Cat. No.

Product Name

GMP-1701

Recombinant Cas9 Nuclease, GMP Grade

#### (6) (High Salt Active) BenzoNuclease<sup>®</sup>, GMP Grade

BenzoNuclease<sup>®</sup> is a genetically engineered recombinant endonuclease derived from *Serratia marcescensa*. BenzoNuclease<sup>®</sup> has been shown to exert a broad spectrum of substrate specificity to degrade both DNA and RNA into 5'-monophosphate-terminated oligonucleotides, which are three to five bases in length—whether single-stranded, double-stranded, linear, circular or supercoiled. It is also known as "omnipotent nuclease" because of its high efficiency in degrading any form of DNA and RNA.

BenzoNuclease<sup>®</sup> is an effective tool enzyme for the removal of all forms of DNA and RNA from biologicals, both in laboratory studies and in industrial-scale production. Through efficient nucleic acid removal, the effect and yield of follow-up experiments and production can be significantly improved, and the performance is better than other nucleic acid removal methods.

# Novoprotein provides BenzoNuclease<sup>®</sup> and High Salt Active BenzoNuclease<sup>®</sup> (HSAB) produced under GMP conditions.

Reliable quality and stable supply to assist your product development and production.

#### **Product Applications**

- Used to remove exogenous nucleic acid from vaccine products, reduce the risk of residual toxicity of nucleic acid and improve product safety
- Used to reduce the viscosity of feed liquid caused by nucleic acid, shorten the processing time and increase the protein yield
- Used to remove nucleic acid winding on the surface of particles (viruses, inclusion bodies, etc.), which is conducive to the release and purification of particles
- Used to prepare samples for ELISA, column chromatography, 2D electrophoresis and western blot analysis. The resolution and recovery can be improved after BenzoNuclease<sup>®</sup> treatment
- Used to prevent cell clumping









Viral Vector Vaccine

Recombinant Protein and Antibody Drugs

Gene Therapy

Cell Therapy

# BenzoNuclease®, GMP Grade

#### Strict Quality Control and Production Standards Create Reliable BenzoNuclease<sup>®</sup>:

- No animal-derived and human-derived ingredients, no ampicillin antibiotic
- Protein purity  $\geq$  99%
- Without protease activity
- Bacterial Endotoxin level < 0.01EU/KU

Element Standard	Criteria
Appearance	clear, transparent solution
Visible Particles	meet the specification
pH	7.5-8.5
Activity	250-400U/µl
Specific Activity	$\geq 1.1 \times 10^6  \text{U/mg}$
Purity	≥ 99%
Protease Activity	no protease activity detectable
Bacterial Endotoxins	< 0.01 EU/KU
Host-cell Protein Residues	$\leqslant 0.005\%$
Sterility	meet the specification
Heavy Metal	≤ 10 ppm

## Product Information

Cat. No.	GMP-1707 DMF Filed	GMP-1709	
Product Name	BenzoNuclease®, GMP Grade	BenzoNuclease® (Tag-free), GMP Grade	
Package size	100KU/200KU/5000KU	100KU/500KU/5000KU	
Molecular Weight	32kDa	30±3.0kDa	
pI	6.99	6.2	
Tag	6×His	Tag-free	
Purity	$\geq$ 99% (SDS-PAGE, SEC-HPLC)		
Optimal pH	8		
Optimal Temperature	Optimal Temperature 37°C		
Cofactor	1-10 mM Mg <sup>2+</sup>		
Formulation	20 mM Tris-HCl pH8.0, 2 mM MgCl <sub>2</sub> , 20 mM NaCl, 50% (v/v) glycerol		
Storage	Store at -20°C $\pm$ 5°C. Avoid repeated freeze-thaw cycles. Properly stored BenzoNuclease <sup>®</sup> is stable for at least 24 months.		
Unit Definition	In a 2.625 mL reaction system at 37°C and pH 8.0, one unit of BenzoNuclease® is defined as the amount of enzyme that causes a change in absorbance at 260 nm of 1.0 absorption units within 30 minutes.		

## BenzoNuclease® ELISA Kit

BenzoNuclease<sup>®</sup> ELISA Kit can detect and quantitatively analyze the residue of BenzoNuclease<sup>®</sup> in viral vectors and vaccine production with high sensitivity and specificity. The sensitivity is 0.014ng/mL, and the detection range is 0.014ng/mL-10ng/mL.



Step 1: Test sample added to the well Step 2: Detection Antibody added to the well Step 3: Colorimetric detection with TMB substrate

## Product Information

Cat. No.	Product Name	Size
PA018	BenzoNuclease® ELISA Kit	96T

## High Salt Active BenzoNuclease®, GMP Grade

High Salt Active BenzoNuclease<sup>®</sup> is a GMP Grade nuclease developed as the most efficient solution for removal of both single and double stranded DNA and RNA at high salt conditions. This nonspecific endonuclease has peak activity at 500mM salt concentrations.

For Adenoviruses and Adeno-Associated Viruses (AAVs), which are often harvested from crude cell lysate, salt is typically added to such lysates to reduce viral aggregation, facilitating more effective nuclease action to digest residual DNA. The high salt tolerance of HSAB is particularly beneficial.

#### Optimal Temperature

The best temperature for HSAB to degrade nucleic acid is 37°C, and it is active in the range of 0~42°C.





The optimum reaction pH for HSAB to degrade nucleic acid is 8, and it is active in the range of  $6\sim10$ .



#### Effect of Monovalent Cations

HSAB has the best enzyme activity in the high salt system of 500mM, and is highly suitable for the purification needs of AAVs, Ads and other viruses.



#### Product Information

Cat. No.	Product Name	Size
GMP-1711	High Salt Active BenzoNuclease® (HSAB), GMP Grade	100KU/500KU/5000KU

#### (7) mRNA Raw Materials and Reagents, GMP Grade

With the continuous progress of life science, mRNA is used as a drug in the fields of disease treatment and vaccine. The mRNA synthesized in vitro in 1990 was expressed in cells for the first time, and the mRNA vaccine in 2020 played an important role in the fight against the COVID-19. mRNA-based therapeutic modalities have caused a revolution in medicine.

mRNA vaccines have the advantages of fast development speed, flexibility, simple production process, platform-based, easy to expand production capacity, can be used for precise and personalized treatment, and can present multiple antigens at one time. The structure of mRNA vaccine is simple and can be synthesized in batches, and can be screened in high throughput during the research and development stage, which significantly saves research and development time. Effective mRNA vaccines have the characteristics of high yield, strong stability, low autoimmunity, high expression, strong antigen specificity of expression, and good stimulation effect.

Novoprotein provides total solution for RNA vaccines/drugs to solve difficulties in development and production. All products are produced with pharmaceutical grade raw materials, strictly control host protein residues, nucleic acid residues, etc., in line with GMP standards of production and quality management procedures, to ensure that the production process and all raw materials can be traced.

#### Advantages



Data as of April 30, 2024

#### Applications (Novoprotein's IVT and capping system)

	Yield(µg)	Capping efficiency	Integrity	dsRNA content(ng/μg)
eGFP	220	98.56%	94.1%	0.015
Luciferase	183	99.97%	92.1%	0.060



Capillary electrophoresis showed good integrity and high purity of the transcript.



eGFP and luciferase mRNA were expressed successfully after transfection.



Mass spectrometry detection shows high capping efficiency.



ON Luciferase mRNA **Distributed by:** 

CliniSciences Group

# GMP Grade mRNA Raw Materials and Reagents List

## mRNA Preparation

Application	Cat. No.	Product Name	
	GMP-RE057	BspQI, GMP Grade	
	GMP-EB057	10×BspQI Reaction Buffer, GMP Grade	
	GMP-RE026	BsaI, GMP Grade	
Plasmid Linearization	GMP-RE036	BsaI ( <i>E. coli</i> ), GMP Grade	
	GMP-EB026	10×BsaI Reaction Buffer , GMP Grade	
	GMP-RE015	XbaI, GMP Grade (OMF Filed)	
	GMP-EB015	10×XbaI Reaction Reaction Buffer, GMP Grade	
	GMP-E121-H200	T7 RNA Polymerase, GMP Grade	
	GMP-EB231	10  imesTranscription Buffer, GMP Grade	
	GMP-E122-H200	T7 RNA Polymerase 2.0, GMP Grade	
In Vtro Transcription	GMP-E125	RNase Inhibitor, GMP Grade OMF Filed	
	GMP-M036	Pyrophosphatase, Inorganic (yeast), GMP Grade	
	GMP-E131	T7 RNA Transcription Enzyme Mix, GMP Grade	
	GMP-S033D-S036D	NTP (200mM Tris Solution), GMP Grade	
dsDNA Template Digestion	GMP-E127	DNase I, GMP Grade (MIFFIRE)	
	GMP-M062	Vaccinia Capping Enzyme, GMP Grade	
	GMP-M072	mRNA Cap 2′-O-Methyltransferase, GMP Grade	
mRNA Capping	GMP-EB62	10×Capping Reaction Buffer, GMP Grade	
	GMP-S062	SAM (32mM), GMP Grade	
	GMP-S024N	GTP, GMP Grade (10mM)	
	GMP-M012	<i>E. coli</i> Poly(A) Polymerase, GMP Grade	
mRNA Tailing	GMP-EB12	10×Poly(A) Polymerase Buffer, GMP Grade	
	GMP-S023N	ATP, GMP Grade (10mM)	

## circRNA Preparation

Application	Cat. No.	Product Name
	GMP-M050	T4 RNA Ligase 2, GMP Grade
circRNA Preparation and Purification	GMP-E224	RNase R, GMP Grade
	GMP-EB224	10×RNase R Buffer, GMP Grade

## Purification

Application	Cat. No.	Product Name	
mDNA Durification	N243	RNA Clean Beads	
	S125	Lithium Chloride Precipitation Solution	

# mRNA Substance Quality Control

Application	Cat. No.	Product Name	
	CD001	mRNA Capping Detection Sample Preparation Kit(Beads)	
	CD002	mRNA Capping Detection FlashPrep Kit	
mRNA Capping Detection	E124	RNase H	
	E134	Thermostable RNase H	
	E151	RNase T1	
mRNA failing Detection	E242	NovoNGS® mRNA Magnetic Isolation Kit	
	PA101	Pyrophosphatase, Inorganic ELISA Kit	
mRNA Raw Material Enzyme Residue Detection	PA102	T7 RNA Polymerase ELISA Kit	
	PA105	RNase Inhibitor ELISA Kit	
dsRNA Dontent Detection	RD017	NovoFast dsRNA ELISA Kit	
RNase Residue Detection	DT007	RNase Detection Kit	
DNase Residue Detection	DT009	DNase Detection Kit	
DNA Template Residue Detection	E106	NovoStart® Probe qPCR SuperMix (UDG)	
	E406	NovoStart® High-Specificity Probe qPCR SuperMix (UDG)	
E. coli HCD Detection	DR001	NovoStart® <i>E. coli</i> DNA Residue Detection Kit	
mRNA Enzymes Identification	PA007	mRNA Enzymes DIBA Kit	

## Catalog mRNA

Application	Cat. No.	Product Name
Reportor Gene/ Functional Gene mRNA	MR008 / MR010	eGFP mRNA / eGFP mRNA (N1-Me-Pseudo UTP)
	MR009 / MR011	Luciferase mRNA / Firefly Luciferase mRNA (N1-Me-Pseudo UTP)
	MR201	eGFP circRNA
	MR202	Luciferase circRNA
	MR105	mCherry mRNA (N1-Me-Pseudo UTP)
	MR015	OVA mRNA(N1-Me-Pseudo UTP)
	MR016	hEPO mRNA(N1-Me-Pseudo UTP)
	MR107 / MR019	Cas9 mRNA / Cas9 mRNA( N1-Me-Pseudo UTP)
	GMP-MR005	piggyBac mRNA, GMP Grade

# **7** GMP Grade Products Summary

## **CGT GMP Grade Relative Products**

Cat. No.	Product Name
GMP-B038	anti-Human CD3/CD28 Beads
GMP-A037	Recombinant anti-Human 4-1BB mAb
GMP-A091	Recombinant anti-Human CD16 mAb
GMP-A063	Recombinant anti-Human CD28 mAb
GMP-A018	Recombinant anti-Human CD3 mAb
GMP-A052	Recombinant anti-Human CD52 mAb
GMP-A065	Recombinant anti-Human CD56 mAb
GMP-A075	Recombinant anti-Human NKG2D mAb
GMP-C687	Recombinant Human Activin A
GMP-C076	Recombinant Human BDNF
GMP-C029	Recombinant Human EGF
GMP-C046	Recombinant Human FGF basic
GMP-C798	Recombinant Human FGF-8b
GMP-C198	Recombinant Human FGF-9
GMP-CA82	Recombinant Human Flt-3 Ligand
GMP-C226	Recombinant Human GDNF
GMP-CC79	Recombinant Human GM-CSF
GMP-C414	Recombinant Human GPC3
GMP-CJ72	Recombinant Human HGF
GMP-CI57	Recombinant Human IFN-gamma
GMP-C070	Recombinant Human IL-1 alpha
GMP-CG93	Recombinant Human IL-1 beta
GMP-C013	Recombinant Human IL-2 <sup>[DME File]</sup>
GMP-CD66	Recombinant Human IL-2
GMP-CF63	Recombinant Human IL-3
GMP-CD03	Recombinant Human IL-4
GMP-C009	Recombinant Human IL-6
GMP-CD47	Recombinant Human IL-7
GMP-CI58	Recombinant Human IL-12
GMP-C016	Recombinant Human IL-15 <sup>(DIFFRE)</sup>
GMP-CD72	Recombinant Human IL-18
GMP-CC45	Recombinant Human IL-21
GMP-CH73	Recombinant Human KGF
GMP-C023	Recombinant Human LR3 IGF-1

Distributed by:



Cat. No.	Product Name
GMP-CG11	Recombinant Human MICA
GMP-CB89	Recombinant Human Noggin
GMP-C099	Recombinant Human OSM
GMP-C199	Recombinant Human PDGF-BB
GMP-CX83	Recombinant Human R-Spondin 1
GMP-CI56	Recombinant Human sCD40 Ligand
GMP-CD53	Recombinant Human SCF
GMP-CA59	Recombinant Human TGF-beta 1
GMP-C008	Recombinant Human TNF-alpha
GMP-CJ95	Recombinant Human TPO
GMP-CR96	Recombinant Human VEGF165
GMP-C395	Recombinant Human Vitronectin
GMP-1701	Recombinant Cas9 Nuclease, GMP Grade
GMP-1707	BenzoNuclease <sup>®</sup> , GMP Grade <sup>CMFFIND</sup>
GMP-1709	BenzoNuclease® (Tag-free), GMP Grade
GMP-1711	High Salt Active BenzoNuclease® (HSAB), GMP Grade
GMP-CH38	NovoNectin® GMP Grade
GMP-1647	Tscm Expander®

## mRNA Vaccine GMP Grade Relative Products

Turn to P15-P16 for the details.

# **CliniSciences** Group

#### Austria

Company: CliniSciences GmbH Address: Sternwartestrasse 76, A-1180 Wien - Austria Telephone: +43 720 115 580 Fax: +43 720 115 577 Email: oesterreich@clinisciences.com Web: https://www.clinisciences.com

#### Finland

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064 Email: suomi@clinisciences.com Web: https://www.clinisciences.com

#### Iceland

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1. Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064 Email: island@clinisciences.com Web: https://www.clinisciences.com

#### Netherlands

Company: CliniSciences B.V. Address: Kraijenhoffstraat 137A, 1018RG Amsterdam, - Netherlands Telephone: +31 85 2082 351 Fax: +31 85 2082 353 Email: nederland@clinisciences.com Web: https://www.clinisciences.com

#### Portugal

Company: Quimigen Unipessoal LDA Address: Rua Almada Negreiros, Lote 5, Loja 14, 2615-275 Alverca Do Ribatejo - Portugal Telephone: +351 30 8808 050 Fax: +351 30 8808 052 Email: info@guimigen.com Web: https://www.quimigen.pt

#### Switzerland

Company: CliniSciences AG Address: Fracht Ost Flughafen Kloten CH-8058 Zürich - Switzerland Telephone: +41 (044) 805 76 81 Fax: +41 (044) 805 76 75 Email: switzerland@clinisciences.com Web: https://www.clinisciences.com

#### Belaium

Company: CliniSciences S.R.L Address: Avenue Stalingrad 52, 1000 Brussels - Belgium Telephone: +32 2 31 50 800 Fax: +32 2 31 50 801 Email: belgium@clinisciences.com Web: https://www.clinisciences.com

#### France

Company: CliniSciences S.A.S Address: 74 Rue des Suisses, 92000 Nanterre- France Telephone: +33 9 77 40 09 09 Fax: +33 9 77 40 10 11 Email: info@clinisciences.com Web: https://www.clinisciences.com

#### Ireland

Company: CliniSciences Limited Address: Ground Floor, 71 lower Baggot street Dublin D02 P593 - Ireland Telephone: +353 1 6971 146 Fax: +353 1 6971 147 Email: ireland@clinisciences.com Web: https://www.clinisciences.com



Company: CliniSciences AS Address: c/o MerVerdi Munkerudtunet 10 1164 Oslo - Norway Telephone: +47 21 988 882 Email: norge@clinisciences.com Web: https://www.clinisciences.com

Spain

Company: CliniSciences Lab Solutions Address: C/ Hermanos del Moral 13 (Bajo E), 28019, Madrid - Spain Telephone: +34 916 750 700 Fax: +34 91 269 40 74 Email: espana@clinisciences.com Web: https://www.clinisciences.com

#### uк

Company: CliniSciences Limited Address: 11 Progress Business center, Whittle Parkway, SL1 6DQ Slough- United Kingdom Telephone: +44 (0)1753 866 511 or +44 (0) 330 684 0982 Fax: +44 (0)1753 208 899 Email: uk@clinisciences.com IWeb: https://www.clinisciences.com

Version 07-01-2025



#### Denmark

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064 Email: danmark@clinisciences.com Web: https://www.clinisciences.com



#### Germany

Company: Biotrend Chemikalien GmbH Address: Wilhelm-Mauser-Str. 41-43, 50827 Köln - Germany Telephone: +49 221 9498 320 Fax: +49 221 9498 325 Email: info@biotrend.com

Web: https://www.biotrend.com

#### Italv

Company: CliniSciences S.r.I Address: Via Maremmana inferiore 378

Roma 00012 Guidonia Montecelio - Italy Telephone: +39 06 94 80 56 71 Fax: +39 06 94 80 00 21 Email: italia@clinisciences.com Web: https://www.clinisciences.com

#### Poland

Company: CliniSciences sp.Z.o.o. Address: ul. Rotmistrza Witolda Pileckiego 67 lok. 200 - 02-781 Warszawa -Poland Telephone: +48 22 307 0535 Eax: +48 22 307 0532 Email: polska@clinisciences.com Web: https://www.clinisciences.com

#### Sweden

Company: CliniSciences ApS Address: Oesterbrogade 226, st. 1, Copenhagen, 2100 - Denmark Telephone: +45 89 888 349 Fax: +45 89 884 064 Email: sverige@clinisciences.com Web: https://www.clinisciences.com



#### USA

Company: Biotrend Chemicals LLC Address: c/o Carr Riggs Ingram, 500 Grand Boulevard, Suite 210 Miramar Beach, FL 32550- USA Telephone: +1 850 650 7790 Fax: +1 850 650 4383 Email: info@biotrend-usa.com Web: https://www.biotrend-usa.com



