Tinzyme Co., Limited

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T7 RNA Polymerase, GMP Grade

Product Number: GMP-T701 Animal-free Ampicillin-free

Shipping and Storage

At -20±5℃.

Description

As a biological macromolecule, mRNA can be synthesized on a large scale by in vitro transcription (IVT). T7 promoter is one of the most efficient promoters at present. Therefore, T7 RNA polymerase can be used for in vitro transcription to obtain more synthetic products. T7 RNA polymerase is a T7 promoter-specific, DNA-dependent, 5'→3' RNA polymerase from T7 bacteriophage. Usingdouble stranded DNA as the template, it transcribes RNA complementary to the single stranded DNA located at the downstream of T7promoter. T7 RNA polymerase has been commonly used for in vitro mRNA synthesis.

The polymerase is GMP Grade produced in E. coli. Our manufacturing processes are strictly controlled to ensure the end products free from host protein or nucleic acid contaminations and other impurities following the Pharmaceutical Manufacturing Guidelines. We guarantee the manufacturing and quality control comply with GMP regulation for tracking each and every step of the manufacturing process, including raw material sourcing.

This product has completed the DMF record of FDA and passed the HALAL certification.

Quality Elements

Element	Standard
Appearance	transparent liquid
Visible impurities	complying to regulation
pH value	7.5-8.5
Active	49kU/ml-51kU/ml
purity	≥95%
Endonuclease residues	The degradation of substrate was ≤10%
Exonuclease residues	The degradation of substrate was ≤10%
RNase residues	The degradation of substrate was ≤10%
Endotoxin residues	<5EU/mg
Exogenous DNA residues	≤100 pg/mg
Host protein residues	≤50 ppm
Mycoplasma	Negative
Heavy metal residues	≤10 ppm

Annotation: ChP refers to the Pharmacopoeia of the People's Republic of China.

Complying to following regulations

1. ISO 9001:2015, certified facility.
2. 《GMP Appendix – Cellular therapeutic product》 National Medical Products Administration.
3. 《The Pandect of Genetic Therapeutic Product for Human》 Chinese 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.

Feature

Highly specific for T7 promoter, suitable for RNA in vitro synthesis.

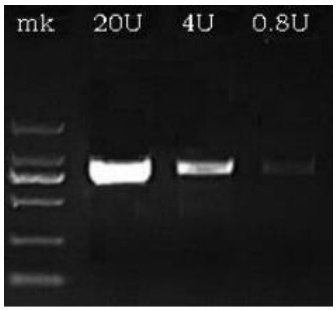
Application

1. Single stranded RNA synthesis
2. RNA probe synthesis.
3. siRNA precursor synthesis
4. Precursor for RNA splicing preparation
5. Capped RNA synthesis.

Examples

Fig: RNA transcription in vitro.

1. From left to right, the quantity of T7 RNA Polymerase copies were 20U, 4U, 0.8U.
2. DNA templates were segments of 2Kb.



Unit definition

At 37℃, pH8.0, within 1 hour, the amount of enzyme required that will incorporate 1nmol tritium labeled GMP into acid-insoluble material is defined as one unit of enzyme activity.

Storage buffer

100mM NaCl; 50mM Tris-HCl (pH 7.9); 1mM EDTA; 20mM 2-mercaptoethanol; 0.1% Triton X-100; 50% (v/v) Glycerol。

Package A

Components	Volume
T7 RNA Polymerase, GMP Grade (50U/μl)	100μl
T7 RNA Polymerase, GMP Grade (50U/μl)	1ml
T7 RNA Polymerase, GMP Grade (50U/μl)	10ml
T7 RNA Polymerase, GMP Grade (50U/μl)	50ml

Reaction system (20μl)

Components	Quantity
10×Transcription buffer, GMP Grade	2μl
ATP/GTP/CTP/UTP Mix	7.5-10mM for each
Template DNA	20ng-1μg
T7 RNA Polymerase, GMP Grade	50-200U
RNase Free Water	Up to 20μl

Reaction condition: at 37℃, for 2-3 hours.

Note:1)To prevent RNase pollution, it's feasible to Add RNase Inhibitor up to 1U/μl in the reaction system.

2)The template DNA should be RNase-free, pure, together with OD260/280 value which is recommended to be 1.8~2.0.

Note

1. For the efficiency of transcription for specified section, it's recommended to shape downstream section of template DNA into the ones with flush end or 5'protruding end before the reaction。
2. Since the 10×Transcription Buffer contains spermidine, which may bind nucleic acid and, generate insoluble complex at low temperature, it is recommended not adding template DNA and enzyme until the last step.

Related Products

Product Number	Product Name
GMP-M062	Vaccinia Capping Enzyme, GMP Grade
GMP-RI01	RNase Inhibitor, GMP Grade
GMP-M072	mRNA Cap 2′ O Methyltransferase, GMP Grade
GMP-DI05	DNase I Recombinant GMP grade
GMP-M012	Poly(A) Polymerase, GMP Grade
GMP-DI05	DNase I Recombinant GMP grade
GMP-M036	Pyrophosphatase, Inorganic (yeast), GMP Grade (ppase)
GMP-T701B	10×Transcription Buffer, GMP Grade
GMP-E131	T7 High Yield RNA Transcription kit
D1331	dATP 100mM solution
D2331	dGTP 100mM solution
D3331	dCTP 100mM solution
D4331	dTTP 100mM solution