T7 RNA Polymerase, GMP Grade

Cat. No.: GMP-E121 animal-free, ampicillin-free

01/ Product 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. Using double stranded DNA as the template, it transcribes RNA complementary to the single stranded DNA located at the downstream of T7 promoter. 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.

02/ Quality Elements

Element	Standard
Appearance	Clear and transparent solution
Identification	Positive
Visible Particles	Meet the specification
pH	7.5-8.5
Activity	49KU/ml-51KU/ml
Purity	≥95%
Protein Content	Meet the specification
Endonuclease Residues	The degradation of substrate was ⩽10%
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RNase Residues	The degradation of substrate was ⩽10%
Bacterial Endotoxins	<5EU/ml
Exogenous DNA Residues	≤100pg/mg
Host-cell Protein Residues	≤50ppm
Mycoplasma	Negative
Heavy Metals	≤10ppm
Microbial Limit	Total aerobic microbial count⩽1cfu/10ml, total yeasts and molds count⩽1cfu/10ml

03/ 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.

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04/ Product Feature

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

05/ Application

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

06/ Definition of the Enzyme Activity

At 37℃, pH 8.0, within 1 hour, the amount of enzyme required to incorporate 1 nmol tritium (^{3}H)) labeled GMP into acid-insoluble material is defined as one unit of enzyme activity.

07/ Buffer for Storage

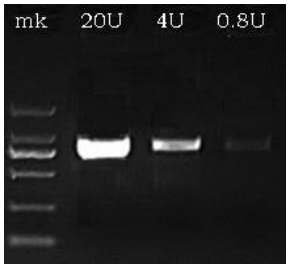
100 mM NaCl; 50 mM Tris-HCl (pH 7.9); 1 mM EDTA; 20 mM 2-mercaptoethanol; 0.1% Triton X-100; 50% (v/v) Glycerol.

08/ Storage Conditions

At -20±5℃.

09/ Application Examples

Fig: RNA transcription in vitro.



1) From left to right, the amount of T7 RNA Polymerases were 20 U, 4 U, 0.8 U.
2) The transcription fragment was 2Kb.

10/ Product Packaging

SKU	Components	Volume
GMP-E121-01A	T7 RNA Polymerase, GMP Grade (50U/μl)	100μl
GMP-E121-M001	T7 RNA Polymerase, GMP Grade (50U/μl)	1ml
GMP-E121-M010	T7 RNA Polymerase, GMP Grade (50U/μl)	10ml
GMP-E121-M050	T7 RNA Polymerase, GMP Grade (50U/μl)	50ml

11/ 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.

Directions:

1. To prevent RNase contanmination, add RNase Inhibitor up to 1U/μl in the reaction system before reaction.
2. It is essential that the template DNA is RNase-free and highly pure. OD260/280 value at 1.8~2.0 is recommended.

12/ Precautions

1. To obtain RNA of a certain length, the plasmid must be fully linearized, and the linearized plasmid must ensure that the duplex is blunt-ended or 5' -terminal protruding.
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.

13/ Related Products

Cat. No.	Product	Cat. No.	Product
GMP-M062	Vaccinia Capping System, GMP Grade	GMP-E125	RNase Inhibitor, GMP Grade
GMP-M072	mRNA Cap 2´-O-Methyltransferase, GMP Grade	GMP-E127	DNase I, GMP Grade
GMP-M012	*E. coli* Poly(A) Polymerase, GMP Grade	GMP-M036	Pyrophosphatase, Inorganic (yeast), GMP Grade
GMP-EB231	10×Transcription buffer, GMP Grade	GMP-E131	T7 RNA Transcription Enzyme Mix, GMP Grade
GMP-S023-026	NTPs, GMP Grade		