DNase I, GMP Grade

Cat. No.: GMP-E127 animal-free, ampicillin-free

01/ Product Description

DNase I (Deoxyribonuclease I) was initially isolated from bovine pancreas. It can randomly degrade single stranded or double stranded DNA with equal efficiency, generating oligonucleotides with 5'-P. The bioactivity of DNase I is highly dependent on Ca^{2+}, Mg^{2+} or Mn^{2+}. In the presence of Mg^{2+}, DNase randomly cuts dsDNA; in the presence of Mg^{2+}, DNase cleaves both strands of dsDNA at approximately the same site, resulting in a blunt end or a sticky end with 1 or 2 protruding nucleotides.

DNase I is GMP Grade produced in *Pichia pastoris*. 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 value	7.0-8.0
Activity	1.8KU/ml-2.2KU/ml
Purity	≥95%
Protein Content	Meet the specification
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/ Application

1. Synthesis of RNA without any DNA.
2. Remove DNA contamination, gDNA for example, in RNA sample for RT-PCR reaction.
3. Remove DNA template after IVT reaction catalyzed by RNA polymerase.
4. With the presence of Mn^{2+}, fragmentize DNA, generating random DNA fragment library.
5. In Apoptosis TUNEL detection, cleavage of gDNA for positive control.

05/ Definition of the Enzyme Activity

One unit is defined as the amount of enzyme required to completely degrading 1μg DNA of BR322 plasmid in 10minute at 37°C in a 50μl reaction volume.

06/ Buffer for Storage

10mM Tris-HCl (pH7.6); 2mM $CaCl_2$; 50% (v/v) Glycerol.

07/ Storage Conditions

At -20±5℃.

08/ Inactivation

Adding EDTA by the concentration of 2.5mM, with the temperature higher than 65℃ for 10 mins.

09/ Product Packaging

SKU	Components	Volume
GMP-E127-01A	DNase I, GMP Grade (2U/μl)	200μl
GMP-E127-M001	DNase I, GMP Grade (2U/μl)	1ml
GMP-E127-M010	DNase I, GMP Grade (2U/μl)	10ml
GMP-E127-M050	DNase I, GMP Grade (2U/μl)	50ml

10/ Directions:

Remove DNA template after IVT reaction:

1. Add 2-4U DNase I or an optimized amount in the reaction containing 1 μg DNA template.
2. Incubate at 37℃ for 15 mins.
3. Add EDTA to reach the final the concentration of 2.5 mM andincubate at 65℃ for 10 mins. To prevent RNA degradation during heating, phenol-chloroform extraction is recommended to remove DNase I, and purify RNA by ethanol precipitation .

11/ Precautions

1. Optimized pH value: 7.0-8.0
2. Activation ingredients: Mg^{2+} or Mn^{2+} is required for reaching maximum bioactivity
3. Inhibition ingredients: EDTA, EGTA, SDS.
4. Specificity: degradation of dsDNA endonuclease.
5. Keep the vial on ice when being out of storage condition (at -20±5℃).

12/ 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-E121	T7 RNA Polymerase, GMP Grade
GMP-M012	*E. coli* Poly(A) Polymerase, GMP Grade	GMP-M036	Pyrophosphatase, Inorganic (yeast), GMP Grade
GMP-E131	T7 RNA Transcription Enzyme Mix, GMP Grade	GMP-S023-0	NTPs, GMP Grade