ZINZYME

Tinzyme Co., Limited

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BsaI, GMP Grade

Product Number: M062012 animal-free, ampicillin-free

Shipping and Storage

-20±5°C.

Description

Restriction endonucleases are a class of endonuclease that recognize specific deoxynucleotide sequences and cleave the phosphodiester bond between two deoxyribonucleotides at specific sites in each chain. BsaI derived from Bacillus Thermophilus, is a commonly used restriction endonuclease. BsaI recognizes the following sequence:

5'...GGTCTC(N)1↓...3';

3'...CCAGAG(N)5↑...5'.

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.

Quality Criterion

Test	Standard
Appearance	Clear and transparent solution
Visible Particles	Meet the specification
pН	7.0-8.0
Activity	10KU/ml-10.5KU/ml
Endonuclease Residues	The degradation of substrate was $\leq 10\%$
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RNase Residues	The degradation of substrate was $\leq 10\%$
Bacterial Endotoxins	≤1EU/ml
Heavy Metal Residues	≤10ppm
Microbial Limit	Total aerobic microbial count $\leq 1 \text{cfu}/10 \text{ml}$, total yeasts and molds count $\leq 1 \text{cfu}/10 \text{ml}$

Production according to the following specifications

- 1. ISO 9001:2015, certified facility.
- 2. GMP appendix cell therapy products, State Drug Administration.
- 3. General introduction to human gene therapy Chinese Pharmacopoeia 2020, 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.

Unit Definition

At 37°C, pH 7.5, within 1 h, the amount of enzyme required for totally digestion $1\mu g$ λDNA (HindIII digestion, none Dcm methylation) is defined as one unit of enzyme activity.

Storage buffer



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10mM Tris-HCl; 300mM NaCl; 1mM DTT; 0.1mM EDTA; 0.5mg/ml HAS; 50% Glycerol; pH 7.4 at 25°C.

Package

Item	Quantity
BsaI, GMP Grade (10U/μl)	100μl

Reaction System (50µl)

Components	Quantity
10×BsaI Reaction Buffer, GMP Grade	5μ1
Substrate DNA	1μg
BsaI, GMP Grade	1µl
RNase Free Water	Up to 50µl

Related Product

Product No.	Product Name	Product No.	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-T701	T7 RNA Polymerase, GMP Grade
GMP-M012	E. coli Poly(A) Polymerase, GMP Grade	GMP-M036	Pyrophosphatase, Inorganic (yeast), GMP Grade
M062012B	10×BsaI Reaction Buffer, GMP Grade	GMP-DI05	DNase I, GMP Grade