Enterokinase, GMP Grade

Cat No.: GMP-PE001 animal-free

01/ Product Description

Enterokinase (light chain), highly specifically recognizes the Asp-Asp-Asp-Asp-Lys sequence and hydrolyzes the polypeptides at the C-terminus of Lys. It can convert trypsinogen to trypsin in vivo, and fusion proteins with this recognition sequence can also be cleaved. This product, enterokinase, produced by recombinant yeast secretion and expression system, is of a high purity, high bio-activity, and an excellent stability, which allows a wide range of working condition (4-45℃, pH 4.5-9.5) even keeps a part of bio-activity in the presence of various detergent and denatured agents.

This product is from a large scale GMP leveled recombinant enterokinase production via *Pichia pastoris* expression. Applying pharmaceutical leveled adjuvant and material for production, strictly controlling host protein residues, nucleic acid residues and other impurities, we guarantee manufacture and quality control practice complying to GMP regulation, as well as all the materials traceable.

02/ Quality Criterion

Element	Standard
Appearance	clear, transparent solution
Visible Particles	meet the specification
pH	7.0-8.0
Activity	≥ 1U/μl
Bacterial Endotoxin Residues	< 10EU/ml
Colony Count	aerobic bacteria: < 10^3cfu/ml, yeasts and moulds: < 10^2cfu/ml
Purity	≥ 95%
Non-specific Protease Residues	meet the specification
Host-cell Protein Residues	≤ 50ppm
Exogenous DNA Residues	≤ 100pg/mg
Mycoplasma	Negative
Heavy Metal Residues	≤ 10ppm

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

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/ Unit Definition

At 37℃, within 16 hours, the amount of enzyme required that will degrade 95% of 0.5 mg Thioredoxin-NP-27, the substrate, turning to NP-27 is defined as one unit of enzyme activity.

05/ Buffer for Storage

20mM Tris-HCl, 200mM NaCl, 2mM $CaCl_2$, 50% Glycerol, pH 7.40.

06/ Storage Condition

-20±5℃.

07/ Product Packaging (A Package)

Item	Quantity
Enterokinase, GMP Grade (1U/μl)	50μl

08/ Reaction Condition

1. A typical buffer for reaction: at 20℃-25℃, 20mM Tris-HCl, 50mM NaCl，2mM $CaCl_2$.
   Just for example, user needs to determinate the appropriate reaction condition setting for each case.

09/ Note

1. Under the conditions of >2M Urea, >250mM NaCl, >20mM β-ME, >0.1% SDS, >50mM imidazole, the digestion effect will be affected. If the sample solution contains one or more of the above components, in order to obtain ideal digestion results, it is recommended to dialyze the sample into 1× reaction buffer before digestion.
2. Pre-experiments for different proteins are recommended in advance to determine optimal reaction conditions.

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