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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 23527-2009

Replacing GB/T 23527-2009

**Quality requirements for enzyme preparations - Part 1: Protease
preparations**

(English Translation)

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Table of Contents

- Foreword
- Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and Definitions

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" to be drafted.

This document specifies the technical requirements related to food quality. For relevant food safety requirements, please refer to relevant laws, regulations, policies and food safety standards and other documents.

This document is part 1 of GB/T 23527 "Quality Requirements for Enzyme Preparations". GB/T 23527 has issued the following parts.

--- Part 1: Protease preparations.

This document replaces GB/T 23527-2009 "Protease Preparations". Compared with GB/T 23527-2009, except for structural adjustment and editorial Besides the changes, the main technical changes are as follows.

- Added the term "protease preparation" and "protease activity unit" (see 3.2, 3.3);
- Changed the definition of "protease activity" (see 3.4, 3.2 of the 2009 edition);
- Changed the "enzyme activity" requirement in the physical and chemical requirements (see Table 2, Table 1 of the 2009 edition);
- Deleted "hygienic requirements" (see 5.3 of the 2009 edition);
- Changed the test methods for loss on drying and fineness (see 6.3, 6.4, 6.3, 6.4 of the 2009 edition);
- Changed the factory inspection items (see 7.3, 7.3.1 of the 2009 edition);
- Changed the content of the sign (see 8.1, 8.1 of the 2009 edition);
- Deleted "shelf life" (see Chapter 9 of the 2009 edition);

---Deleted the list of "categories, codes and production bacteria of commonly used protease preparations in China" (see Appendix A of the 2009 edition);

--- Added other buffer solutions in "Determination of protease activity by Folin method" (see A.3.8.4);

--- Added other substrates in "Determination of protease activity by ultraviolet spectrophotometry" (see B.3);

---Changed the reagents in the "Automatic biochemical analysis method for the determination of alkaline protease activity" (see C.3, D.4 of the 2009 edition);

--- Added the test method of "determination of protease activity microcolorimetry" (see Appendix D).

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

With the rapid development of the enzyme preparation industry, the types of enzyme preparations are developing towards diversification, and the product quality has been raised to a new level.

There has been considerable progress and development in both techniques and varieties. The formulation of GB/T 23527 "Quality Requirements for Enzyme Preparations" is the product quality and quality requirements for enzyme preparations.

The standardization and standardization of detection methods is the basic work to standardize the order of the enzyme preparation and related products industry and promote the development of the industry.

GB/T 23527 "Quality Requirements for Enzyme Preparations" is proposed to consist of four parts.

--- Part 1: Protease preparations;

--- Part 2: Lipase preparations;

--- Part 3.alpha-amylase preparation;

--- Part 4: Immobilized glucose isomerase preparation.

With the product innovation and development of the protease preparation industry, according to the industry product research and collection of product categories, in addition to microbes covered by the original standard Protease products derived from biological fermentation, as well as plant tissue extraction products such as papain, bromelain, and ficin Pepsin, trypsin and other animal tissue extraction products. In addition, according to the product development needs of domestic and foreign detection method industries, in this

revision in, the determination conditions of GB/T 23527-2009 enzyme activity determination method were updated and improved, and the micro-colorimetric method was added.

Quality requirements for enzyme preparations Part 1: Protease preparations

1 Scope

This document specifies the product classification, requirements, inspection rules, marking, packaging, transportation and storage of protease preparations, and describes the test method.

This document is applicable to the production, inspection and sales of protease preparations derived from microbial fermentation or plant tissue.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references for documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 191 Packaging, storage and transportation icon marks Preparation of GB/T 601 Chemical Reagent Standard Titration Solution GB/T 602 Preparation of Standard Solution for Determination of Impurities in Chemical Reagents Preparation of preparations and products used in GB/T 603 test methods for chemical reagents GB/T 6682 Analytical laboratory water specifications and test methods QB/T 1803 General test method for industrial enzyme preparations

3 Terms and Definitions

The following terms and definitions apply to this document.

protease

Enzymes that can catalyze the hydrolysis of peptide bonds inside protein molecules to convert them into polypeptides or amino acids.

Protease preparations protease preparations it is a product prepared by preparation and other processes with extracted and purified protease as the main catalytic active component.

Note: In the preparation process, ingredients that are helpful for product storage, stability and use can be added.

Under certain temperature and pH conditions, the amount of protease needed to hydrolyze casein to produce 1 μg tyrosine in 1 min is 1 enzyme activity unit.

Note: Indicated by "U".

Protease activity protease activity the ability to catalyze the hydrolysis of protein into polypeptides and amino acids, expressed as 1g of solid protease preparation (or 1mL of liquid protease preparation) containing Some enzyme activity units.