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

GB/T 23527.1-2023

Replacing GB/T 23527-2009

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

酶制剂质量要求 第1部分：蛋白酶制剂

Issued on: March 17, 2023

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Standardization Administration of China**

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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.

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,

1 Scope

China's national quality requirements for protease preparations. It is Part 1 of GB/T 23527 and specifies the terms and definitions, the product classification, the requirements, the test methods, the inspection rules and the labelling, packaging, transport and storage of protease enzyme preparations. An enzyme preparation is sold on activity rather than on composition, and that single fact governs the whole document. The active protein is a small fraction of what is in the container - the rest is the carrier, the stabiliser and the fermentation residues - so a percentage composition would say almost nothing. What the buyer needs is how much work the material does, and that is expressed in activity units defined by a specified assay under specified conditions. The difficulty is that a protease's activity depends entirely on those conditions. A protease is a catalyst that cleaves peptide bonds, and each family works in a different pH range: the acid proteases of the stomach and of fungal origin, the neutral proteases, and the alkaline proteases used in detergents, which is where most of the world's protease goes. An activity measured at the wrong pH, temperature or substrate is not comparable, and a unit defined by one assay cannot be converted to a unit defined by another. So the standard classifies the preparations by source and by pH range, and for each fixes the assay - substrate, buffer, temperature, time and the method of measuring the product - along with the declared activity and its tolerance, the residual moisture, the particle size for solid preparations, the microbiological limits, the absence of the producing organism and its toxins, and the storage conditions and shelf life, since activity declines from the day it is packed. Issued on 17 March 2023 and in force since 1 April 2024, it replaces GB/T 23527-2009.

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.

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

3.2 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.

3.3 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".

3.4 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.