

ICS 67.220.20

CCS X 60



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

**GB/T 23527.2-2025**

Replacing GB/T 23535-2009

---

**Quality requirements for enzyme preparations - Part 2: Lipase  
preparations**

酶制剂质量要求 第2部分：脂肪酶制剂

**Issued on: May 30, 2025**

**Implemented on: June 1, 2026**

---

**Issued by: State Administration for Market Regulation;  
Standardization Administration of the PRC**

## Table of Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

3.1 Lipase

3.2 Lipase preparations

3.3 Lipase activity

### 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" Drafting is required.

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

This document is Part 2 of GB/T 23527 "Quality requirements for enzyme preparations". GB/T 23527 has been published in the following parts.

- Part 1: Protease preparations;
- Part 2: Lipase preparations;
- Part 3: Amylase preparations;
- Part 4: Immobilized glucose isomerase preparations.

This document replaces GB/T 23535-2009 "Lipase Preparations". Compared with GB/T 23535-2009, except for structural adjustments and editorial changes, In addition to the modifications, the main technical changes are as follows.

- a) Added the definition of the term "lipase preparation" (see 3.2), and changed the definition of "lipase activity" (see 3.3, 3.2 of the 2009 edition);
- b) The content of "Product Classification" has been changed (see Chapter 4, Chapter 4 of the 2009 edition);
- c) The "enzyme activity" requirement in the physical and chemical requirements has been

changed (see Table 2, Table 1 of the 2009 edition), and the "fineness" index in the physical and chemical requirements has been added.

(See Table 2); Deleted "Health requirements" (see 5.3 of the 2009 edition);

d) The test methods for enzyme activity and loss on drying have been changed (see 6.3, 6.4, 6.2, 6.3 of the 2009 edition), and the test method for fineness has been added. Methods (see 6.5);

e) The contents of factory inspection, type inspection and judgment rules have been changed (see 7.3~7.5, 7.3 and 7.4 of the 2009 edition);

f) The contents of labeling, packaging, transportation and storage have been changed (see Chapter 8, Chapter 8 of the 2009 edition);

g) "Shelf life" has been deleted (see Chapter 9 of the 2009 edition).

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document was proposed and coordinated by the National Food Industry Standardization Technical Committee (SAC/TC64).

This document was drafted by: Qingdao Weilan Biotechnology Group Co., Ltd., Shandong Longkote Enzyme Preparation Co., Ltd., China Food Fermentation Industry Research Institute Co., Ltd., Novozymes (China) Investment Co., Ltd., Wuhan Xinhuiyang Biotechnology Co., Ltd., China Bio-fermentation Industry Association, Lianenzyme Trading (Shanghai) Co., Ltd., Amano Enzyme (Jiangsu) Co., Ltd. Shanghai Branch, Ningxia Xiasheng Industrial Group Co., Ltd., Guangzhou Puratos Food Co., Ltd., Hunan Hongying Biotechnology Co., Ltd., DSM (China) Co., Ltd. Beijing Branch, Baiyin Sino Biotechnology Co., Ltd., Angel Enzyme (Yichang) Co., Ltd., Zhejiang Huakang Pharmaceutical Co., Ltd., Zhejiang Yangshengtang Natural Medicine Research Institute Co., Ltd., Nanning Pangbo Bioengineering Co., Ltd., Shandong Academy of Pharmaceutical Sciences, Beijing Technology and Business University, Zhengzhou Xiangxueer Food Co., Ltd.

Zhongshan Hongli Health Food Industry Research Institute Co., Ltd., Zhongshan Nanfang Xinyuan Food Bioengineering Co., Ltd., Ocean University of China, Build Normal University and South China University of Technology.

The main drafters of this document are: Chen Nannan, Shao Jing, Guo Qingwen, Zhang Junyan, Xu Li, Wang Jin, Pei Jing, Wang Youyi, Shen Tao, Gao Tiecheng, Huang Shiqiao, Du Jianhua, Yu Feng, Ping Lei, Xu Jingjing, Huang Zhiming, Liu Hanling, Liu Fei, Wang Yanbo, Li Peiyu, Hu Zhigao, Liu Gaofeng, Huang Jianzhong, Wang Yonghua, Xu Xiaodong, Zhang Jie, Meng Hao, Wang Jinfeng, Zhou Ying, Wang Jie, Yuan Lin, Li Kangle, Tong Yuanyang, Yi Ming, Li Xiaoyi, Liu Xiaohan, Deng Juanjuan, Hu Changhui, Wang Xiaodong, Zhang Xiuhua, Zeng Hong, Xu Shenghua, Zheng Ping, Tian Tian'e.

The previous versions of this document and the documents it replaces are as follows.

- First published in 2009 as GB/T 23535-2009;
- This is the first revision.

## Introduction

With the rapid development of enzyme preparation industry, enzyme preparation types have diversified, product quality has been improved, product varieties have been enriched, and the industry has made great progress and development. GB/T 23527 "Quality Requirements for Enzyme Preparations" was formulated to regulate the product quality and testing of enzyme preparations.

The normalization and standardization of methods are the basic work to regulate the industry order of enzyme preparations and related products and promote industrial development.

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

- Part 1: Protease preparations. The purpose is to improve the product quality of the protease preparation industry.
- Part 2: Lipase preparations. The purpose is to improve the product quality of the lipase preparation industry.
- Part 3: Amylase preparations. The purpose is to improve the product quality of the amylase preparation industry.
- Part 4: Immobilized glucose isomerase preparations. The purpose is to improve the products of the immobilized glucose isomerase preparation industry quality.

With the innovative development of lipase preparation industry products, based on industry research and product solicitation, combined with the progress of domestic and foreign testing methods, and In order to meet the needs of industrial development, the enzyme activity determination method and conditions of GB/T 23535-2009 have been revised and improved in this revision.

Quality requirements for enzyme preparations Part 2: Lipase preparations

## 1 Scope

This document provides the product classification of lipase preparations, specifies technical requirements, inspection rules, marking, packaging, transportation and storage, and describes The corresponding test methods were developed.

This document applies to the production, inspection and sales of lipase preparations

produced by microbial fermentation.

## 2 Normative references

GB/T 191

GB/T 601

GB/T 602

GB/T 603

GB/T 6682

## 3 Terms and definitions

The following terms and definitions apply to this document.

### 3.1 Lipase

It can hydrolyze triglycerides (including natural oils) or fatty acid esters to produce mono- or di-glycerides or glycerol and free fatty acids.

An enzyme that can also catalyze ester synthesis and transesterification reactions.

### 3.2 Lipase preparations

A product made with lipase as the main catalytic active component through preparation and other processes.

Note. Excipients that aid in the storage, stability and use of the product may be added during the preparation process.

### 3.3 Lipase activity

The units of enzyme activity contained in 1g of solid lipase preparation (or 1mL of liquid lipase preparation).

Note 1.Expressed in U/g (or U/mL).

Note 2.Under certain temperature and pH conditions, lipase hydrolyzes substrate to produce 1  $\mu\text{mol}$  of titratable fatty acid per minute, which is one unit of lipase activity.

The corresponding enzyme activity unit can also be agreed upon according to the enzyme activity determination method adopted.