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

**GB/T 22275.4-2008**

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**Requirements of conduct for Good Laboratory Practice (GLP) --  
Part 4: The application of the GLP principles to field studies**

良好实验室规范实施要求 第4部分：良好实验室规范原则在现场研究中的应用

**(English Translation)**

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### Foreword

GB/T 22275 "good laboratory practice requirements" is divided into seven parts.

- Part 1. Quality Assurance and Good Laboratory Practice;
- Part 2. Tasks and responsibilities of project leaders in good laboratory norms;
- Part 3. laboratory suppliers on the principles of Good Laboratory Compliance;
- Part 4. Principles of good laboratory norms in the field of research applications;
- Part 5. good laboratory norms in the application of short-term research;
- Part 6. The application of good laboratory norms in computerized systems;
- Part 7. Good Laboratory Practice Principles in the organization and management of multi-site research applications.

This section GB/T 22275 Part 4.

This section identical with the Organization for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) principles and compliance monitoring series of documents no. 6. "The Application of GLP Principles in Field Research" [ENV/JM/MONO (99) 22].

This section made the following editorial changes.

- Remove the foreword and directory section.

This part of the National Standardization Technical Committee for the management of hazardous chemicals (SAC/TC251) proposed and managed.

This part of the drafting unit. Exit Inspection and Quarantine of Shandong.

## 1 Scope

GB/T 22275 provisions of this part of the field research organizations and personnel testing organizations, quality assurance programs, test facilities, equipment, Materials, reagents, test systems, test samples and references, standard operating procedures, reports of findings, records and storage and retention of materials.

In addition to the explicit exemptions from national legislation, the Good Laboratory Practice Principles (hereinafter referred to as GLP Principles) as set forth in this section apply to laws and regulations all required non-clinical health and environmental safety studies, including medicines, pesticides, food additives and feed additives, cosmetics, veterinary drugs and Registration of similar products or application for permits, and management of industrial chemicals.

## 2 Normative references

The following documents contain provisions that, through the reference in this part of GB/T 22275, become the provisions of this section. Any reference to the date of the citation all subsequent amendments (not including errata content) or revisions do not apply to this section, however, encouraged to be reached under this section the parties to the agreement examine whether the latest versions of these documents are available. For undated references, the latest version applies to this book section.

GB/T 22275.1 Good Laboratory Practice requirements Part 1. Quality Assurance and Good Laboratory Practice GB/T 22278-2008 Principles of Good Laboratory Practice

## 3 Terms and definitions

GB/T 22278-2008 Terms and definitions apply to this section.

### 4.1 Background

In 1981, the Organization for Economic Co-operation and Development (OECD) adopted the GLP principles. In 1997, the OECD revised it. GLP original Recommended test management standards are provided for a variety of studies for management purposes or for other purposes related to evaluation. The 1981 GLP original the OECD panel made clear in its reports the types of tests covered by the GLP principles.

- a) Physical and chemical properties;
- b) Toxicology studies (long-term and short-term) for evaluating the health effects on humans;
- c) Ecotoxicological studies (long-term and short-term) to evaluate environmental effects;
- d) Ecological studies (transport, biodegradation and bioaccumulation) for assessing the

environmental fate of chemicals.

The general classification of ecological studies also includes those used for the determination of residual pesticides, metabolites and for drug resistance and other dietary exposures. Test of the characteristics and quantity of his compounds. GLP principles are used to cover more chemical products, including pesticides, pharmaceuticals, cosmetics, veterinary drugs, food Additives, feed additives, industrial chemicals.

Oversight authorities in OECD member countries have received most of the GLP compliance oversight in the area of (non-clinical) toxicology testing. This is because these studies are traditionally considered to be the most important from a human health point of view. Many of the OECD member countries have been established. Compliance monitoring programs have evolved from the experience gained with toxicology laboratory tests. Laboratory character of ecotoxicological research. Integrity monitoring procedures have also been well developed.

Research programs, conditions, methods, techniques and developments in field studies of pesticides or veterinary drugs (eg residue studies, metabolic studies and ecological studies)