

ICS 03.120.20

CCS A 00



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

GB/T 22274.2-2008

**Guidance for Good Laboratory Practice (GLP) monitoring
authorities -- Part 2: Guidance for the conduct of laboratory
inspections and study audits**

良好实验室规范监督部门指南 第2部分：执行实验室检查和研究审核的指南
(English Translation)

Issued on: August 4, 2008

Implemented on: April 1, 2009

Issued by: Standardization Administration of China

Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Test Institutions Examination
- 5 Checker
- 5.1 Pre-Trial

Foreword

GB/T 22274 "Good Laboratory Practice oversight Guide" is divided into three parts.

- Part 1. Good Laboratory Practice guidelines for compliance monitoring procedures;
- Part 2. perform laboratory inspections and study audits guidelines;
- Part 3. Guidelines for Good Laboratory Practice inspection reports.

This section GB/T 22274 Part 2.

This section is equivalent to using the Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practice (GLP) principles and a series of documents for compliance monitoring no. 3. "Good Laboratory Practice oversight Guide. Revised perform laboratory tests and research Audit Guide" [OCDE/GD (95) 67].

This section includes the following editorial changes.

- Remove the original (1) Foreword and Introduction; (2) the second part. with GLP principles and compliance monitoring of the relevant OECD Council Council Bills.

This part of the National Chemicals Management Standardization Technical Committee dangerous (SAC/TC251) and focal points.

The drafting of this section. Shandong CIQ.

1 Scope

This part of the testing facility GB/T 22274 specifies the supervision and inspection department, inspection procedures, study audits, inspections or study audits Completion.

This section applies to the territory of China established GLP supervision departments.

2 Normative references

The following documents contain provisions which, through reference GB/T 22274 in this section constitute provisions of this section. For dated references, all subsequent amendments (excluding corrections) or revisions do not apply to this section, however, encourage an agreement under this section Parties to study the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB/T 22274.1 good laboratory supervision departments specification - Part 1 Guide. Good Laboratory Practice guidelines for compliance monitoring procedures GB/T 22278 principles of Good Laboratory Practice

3 Terms and Definitions

The GB/T 22278 and GB/T 22274.1 terms and definitions apply to this section.

4 Test Institutions Examination

4.1

for regulatory purposes can be carried out in line with the principles of GLP check for any health or environmental agency issued the test data security. an examination Members may be required on the nature of the physical, chemical, toxic or eco-toxicity and other issues involving the substance or preparation of data for review. In certain cases , The inspector may require the help of special subject experts.

4.2

Inspectors will encounter a variety of institutions (the physical layout and management structure) and the type of research, which means that the inspector shall, in accordance Rely on their own judgment to assess the degree and extent of compliance with GLP principles. Nevertheless, inspectors evaluate a particular test or research institution when study whether the principles of GLP, should try to keep the consistency of assessment methods.

4.3

In the following of this section, the various aspects of the testing facility provides guidance, including the inspector is likely to be surveyed Rapporteurs and procedures; and a statement of purpose has a list of specific projects in each part of the organization during the test and a check may be considered.

The list is not inclusive, and do not misunderstand.

4.4

Inspectors should focus on scientific research and design or how to interpret the results of

impact studies on human health or the environment. These aspects are Management's responsibility, all of the data submitted to them for supervision.

4.5

pairs inspection test and research institutions audits inevitably affect their normal work. Inspectors should therefore carefully plan, such as If feasible, respecting the testing facility manager's willingness to access certain areas of the time schedule.

4.6

conducting research and testing facility inspection during the audit inspector will contact the confidential, commercially valuable information. They should ensure that only Authorized personnel to view the information. In the GLP compliance monitoring program also has responsibilities in respect of the provision made.

5.1 Pre-Trial

5.1.1

Objective. to provide inspectors familiar with the management structure, layout and scope of the study was to check the bodies.