

ICS 03.120.20

CCS A 00



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

GB/T 22275.5-2008

**Requirements of conduct for Good Laboratory Practice (GLP) --
Part 5: The application of the GLP principles to short term
studies**

良好实验室规范实施要求 第5部分：良好实验室规范原则在短期研究中的应用
(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 Main technical specifications
 - 4.1 Test organization and personnel agencies
 - 4.2 Quality Assurance Plan

Foreword

GB/T 22275 "to implement the requirements of Good Laboratory Practice" is divided into seven sections.

- Part 1. Quality Assurance and Good Laboratory Practice;
- Part 2. Good Laboratory Practice Research project leader roles and responsibilities;
- Part 3. Laboratory Supplier of Good Laboratory Practice Principles compliance;
- Part 4. Good Laboratory Practice principles in the field of applied research;
- Part 5. Application of the principles of Good Laboratory Practice in short term studies;
- Part 6. Application of the principles of Good Laboratory Practice in the computerized system;
- Part 7. application of the principles of good laboratory practice in the organization and management of multi-site studies.

This section GB/T 22275 Part 5.

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. 7. "GLP principles in short-term studies in the application" [ENV/JM/MONO (99) 23].

This part made the following editorial changes.

- Remove the foreword, introduction and catalog parts.

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 section GB/T 22275 specifies the organization and personnel of short-term studies of the testing facility, quality assurance programs, facilities, test system, Test samples and reference standard operating procedures, implementation and research results of the study report.

Except as expressly exempted national legislation, good laboratory provided for in this part of the normative principles (hereinafter referred to as GLP principles) applicable laws and regulations all non-clinical health and environmental safety studies required, including pharmaceuticals, pesticides, food additives and feed additives, cosmetics, veterinary drugs and Similar product registration or application for a permit, as well as industrial chemicals management.

2 Normative references

The following documents contain provisions which, through reference GB/T 22275 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 22275.1 good laboratory practice - 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 The terms and definitions apply to this part of the GB/T 22275 of.

4.1 Test organization and personnel agencies

Responsibilities 4.1.1 testing facility managers shall ensure that each study before start specified by the administrator with the appropriate qualifications, training and experience of the staff as a project manager. Negative items the person in charge should be replaced and documented in accordance with established procedures.

Note: The project leader is designated to ensure that research is a key factor in the proper planning, execution and reporting. Suitably qualified person in charge of the project depends more on experience rather than education.

4.2.1 General

Test body should have a written quality assurance program to ensure the implementation of the study followed the principles of GLP.

Note 1: The "quality assurance program" should be mentioned in this standard reference GB/T 22278-2008 and GB/T 22275.1 explained. For the physical - chemical research Studies, other published standards (such as ISO 9000 series) for "quality assurance" This definition is different.

Note 2: The quality assurance program shall include file-based research, facilities-based, process-based inspection description GB/T 22275.1 defined by. These settings Defined as follows.

--- Check-based research. this type of inspection in accordance with the progress of the study to arrange the examination schedule, usually first determine the critical phase of the study;

--- Check-based infrastructures. This type of inspection is not based on specific research, but covers general facilities and activities within a laboratory (Ann Equipment, support services, computer systems, training, environmental monitoring, maintenance and calibration, etc.);

--- Check-based process. This type of examination has nothing to do with a particular study. They are used to monitor the program or process having repetitive nature, usually