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

GB/T 22274.3-2008

**Guidance for Good Laboratory Practice (GLP) monitoring
authorities -- Part 3: Guidance for the preparation of GLP
inspection reports**

良好实验室规范监督部门指南 第3部分：良好实验室规范检查报告的编制指南
(English Translation)

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Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Requirements

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 3.

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. 9. "Good Laboratory Practice guidelines for the preparation of inspection reports" [OCDE/GD (95) 114].

This section includes the following editorial changes.

- Delete the original text of the foreword and introduction.

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 22274 specifies the requirements under Good Laboratory Practice inspection reports, additional information and approval.

This part applies to the territory of our country in the establishment of 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 reference documents Member, all subsequent amendments (not including errata content) or revisions do not apply to this section, however, encouraged to reach under this section Parties to research agreement to use the latest versions of these documents. For undated references, the latest version applies to this section.

GB/T 22278 principles of Good Laboratory Practice

3 Terms and Definitions

GB/T 22278 in the terms and definitions apply to this section.

4 Requirements

4.1

The title of the report

4.1.1

There are many acceptable ways to organize an inspection report, but the key is to ensure that the reports contain the necessary information and can be filled Foot administration requirements. Typically, the title of the report includes a summary, description, narration, and the end of the appendix summarizes the discussion. Ministries Sub-heading of quality content to respond to the testing facility's compliance with the principles of GLP and optionally review the report to make an accurate description of.

4.1.2

descriptive title may contain the following information.

4.1.2.1 Summary

Summary of the report should appear first, it should provide background information about the trial bodies of GLP principles to check the type of execution, recorded Deviations, as well as testing facilities for the deviations response thereto. According to the actual situation in the country, the report may also include the real inspector Laboratory GLP compliance determination result.

4.1.2.2 Introduction

Introductory section should include the following information in some or all of the elements.

Objective and general description of a) checking, including legal powers of inspection and

as a basis for quality standards inspectors;

Identity b) inspectors and inspection to confirm the date;

c) a description of the type of inspection (inspection agency, study audits, etc.);

Identification information d) testing facility, including corporate identity, mailing address and contact (including telephone and fax);

e) a description of the relevant test body, including the identification of the test substance and test species ever undertaken and related facilities and layout Information situation of the persons;

Any date f) of the previous GLP inspection, GLP compliance status after the inspection, and testing facilities made since the previous inspection