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

GB/T 22273-2008

**Advisory document for good laboratory practice (GLP): The
application of the principles of GLP to in vitro studies**

良好实验室规范建议性文件 良好实验室规范原则在体外研究中的应用

(English Translation)

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Foreword

This standard is identical with the Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) principles and a series of documents for compliance monitoring no. 14. "In vitro studies using GLP principles" [OECDENV/JM/MONO (2004) 26, the English version].

This standard made the following editorial changes.

--- Remove the OECD's Background and Introduction.

This standard is managed by the National Standardization Technical Committee chemicals dangerous (SAC/TC251) and focal points.

This standard was drafted. Chinese Academy of Inspection and Quarantine, China Petroleum and Chemical Industry Association.

Drafters of this standard. Falls Apart, Yu Wen Lin, Wang Xiaobing, Mei Jian, Sun Xin.

Good Laboratory Practice Good Laboratory recommendations document Application of normative principles of in vitro studies

1 Introduction

Experimental studies in vitro systems have long been used to obtain chemical safety data for human health and the environment. The law in many countries Legal requirements, research on aspects of human health and the environment should be in accordance with good laboratory practice (GLP) requirements to carry out. Traditionally, in vitro methods Mainly used for genetic toxicity tests, mainly with reference to data from an in vitro study experimentally obtained risk assessment. Given the current emphasis on reducing the the use of animals in safety testing, in vitro methods increasingly prominent role, has become an alternative or complement in vivo safety tests. In addition, as Development of toxicogenomics, toxicological proteomics, metabolomics and other toxicological chips as high-throughput screening of in vitro safety testing the growing importance.

Plan GLP principles for security research, management, recording, reporting and archiving requirements, no different from other types of research. therefore, GLP principles describe all non-clinical health and environmental safety studies, including requiring in vitro studies, and provide a means to implement these studies Guiding principles. To facilitate application of the principles of GLP in vitro, there is a need for further clarification and guidance.

Objective 2

This standard aims to promote the correct application and interpretation of the principles of GLP in vitro studies on the organization and management; while on the principles of GLP in vivo Proper use of external research for test bodies (including management, quality assurance, project leaders and researchers) and national GLP compliance monitoring Governor department to provide guidance.

This standard is intended to GLP regulations require registration in principle to provide guidance for the purpose of in vitro studies of the use and guidance. The standard Registration in accordance with the principles of GLP order of the different parts of the organization, for easy reference and use.

3 Range

This standard is applied in principle GLP non-clinical safety testing of in vitro studies. These non-clinical safety test sample comprising. medicine, Pesticides, cosmetics, veterinary drugs and food additives, feed additives, and industrial chemicals. Test samples are usually synthetic chemicals, but there are or natural substances of biological origin, sometimes they may be living organisms. Purpose of the implementation of these tests is to obtain the characteristics of the test substance and (Or) safety data for human health and the environment.

Unless legal immunity, GLP principles apply to all non-clinical health and environmental safety studies required by regulation, including. pharmaceuticals, pesticides, Food additives and feed additives registration application for a permit or cosmetics, veterinary drugs and similar products, and industrial chemicals management.

4 Normative References

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB/T 22275.3-2008 implementation requirements of Good Laboratory Practice Part 3.
Laboratory Supplier of Good Laboratory Practice original of the compliance Part 5 GB/T 22275.5-2008 implementation requirements of Good Laboratory Practice. Good Laboratory

Practice principles to short term studies Applications GB/T 22278-2008 principles of Good Laboratory Practice