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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21750-2025

Replacing GB/T 21750-2008

Chemicals - Test method of toxicokinetics studies

化学品 毒物代谢动力学试验方法

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces GB/T 21750-2008 "Toxicokinetic Test Methods for Chemicals" and is consistent with GB/T 21750-2008.

In addition to structural adjustments and editorial changes, the main technical changes are as follows.

a) Added "Abbreviations" (see Chapter 4);

b) The content of "Basic Principles of Testing" has been modified (see Chapter 5, Chapter 4 of the 2008 edition);

c) The content of "Test Methods" has been changed (see Chapter 6, Chapter 5 of the 2008 edition), and the content of "Preliminary Tests" and "Experimental Animals" has been added. Content (see 6.1, 6.2);

d) Added "Clinical Observation" content (see 6.4);

e) Added the content of "Supplementary methods" (see 6.5);

f) The content of "Test Data and Report" has been modified (see Chapter 7, Chapter 6 of

the 2008 edition).

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document is proposed and coordinated by the National Technical Committee for Standardization of Hazardous Chemicals Management (SAC/TC251).

This document was drafted by: Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention, Capital Medical University, Liaoning Provincial Center for Disease Control and Prevention Control Center.

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The previous versions of this document and the documents it replaces are as follows.

- First published in 2008 as GB/T 21750-2008;

- This is the first revision.

Introduction

Toxicokinetic (TK) studies of chemical substances are aimed at obtaining a comprehensive understanding of their absorption, distribution, biotransformation (i.e. metabolism) and excretion.

To provide information to help relate the concentration or dose to the observed toxicity and to help understand the mechanism of toxicity.

Animals are exposed systemically to a test substance and reveal which molecules are circulating (parent substance/metabolites) to aid understanding of toxicology studies.

The essential TK parameters determined from these studies will also provide information on the potential accumulation of the test substance in tissues and/or organs and the potential for the test substance to accumulate in the tissues and/or organs as a result of exposure to the test substance.

information on the potential of substances to induce biotransformation.

TK data assist in assessing the adequacy and relevance of animal toxicity data for extrapolation to human hazard and/or risk assessment.

In addition, toxicokinetic studies can be used to determine the dose level (linear and nonlinear kinetics), the effect of the toxicity pathway, the bioavailability, and the Some types of TK data can be used to assess physiologically based toxicokinetics.

Development of the (PBTK) model.

Important uses of metabolite/TK data include indicating possible toxicity and mode of action

and their relationship to dose level and route of exposure.

In addition, metabolic data can provide information that helps to assess the toxicological significance of exposure to exogenous metabolites of the test substance.

Adequate toxicokinetic data will help support further acceptance and application of quantitative structure-activity relationships, analogies, or grouping approaches.

Application in Material Safety Assessment. Kinetic data can also be used to assess the toxicological relevance of other studies (e.g., in vivo/in vitro).

Unless otherwise specified, this document is primarily applicable to oral exposure routes.

1 Scope

This document establishes the basic principles of chemical toxicokinetic testing, describes the test methods, and specifies the test data and reporting requirements. Announcement content.

This document applies to toxicokinetic studies of chemicals.

2 Normative references

GB 14925

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Toxicokinetics

The science of studying the absorption, distribution, metabolism and excretion of a test substance in the body over time.

3.2 Atrioventricular compartment

A structure or biochemical unit of an organism, tissue, or cell that is separate from other parts.

3.3 absorption

The process by which the test substance or its metabolites enter the body or tissues.

3.4 distribution

The process of transporting the test substance that enters the systemic circulation to the body's distributable fluids, tissues, and organs.

3.5 metabolism

The process (usually enzymatic) by which a test substance is chemically converted into a different chemical substance in the body.

Note. Metabolism is also called biotransformation.

3.6 excretion

The process of transporting the test substance and (or) metabolites out of the body.

3.7 half-life

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