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

SN/T 2180-2014

Replacing SN/T 2180-2008

Toxicokinetics test

毒物代谢动力学试验

(English Translation)

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Table of Contents

Introduction

Introduction

1 Scope

2 Normative references

3 Terms, Definitions and Abbreviations

4 Method

4.1 Pre-Test

4.2 Animal Selection

4.2.1 Species

4.2.2 Age and line

4.2.3 Number and sex of animals

4.2.4 Rearing conditions

4.3 Test substance

4.4 Dose Selection

4.4.1 Pre-test

4.4.2 Test 3 official

4.5 Test substance exposure

4.6 Measuring

4.6.1 Mass Balance

4.6.2 Absorption

4.6.3 Bioavailability

4.6.4 Tissue distribution

4.6.5 Metabolism

4.6.6 Excretion

4.7 Time Course Test

4.7.1 Plasma/Hemodynamics

4.7.2 Other organizational dynamics

4.7.3 Enzyme induction/inhibition

4.8 Supplementary Methods

4.8.1 In vitro application information

4.8.2 Toxicity test using toxicokinetic data as supplementary information

4.8.3 Toxicokinetic model application

8 4.9 Other routes of exposure

4.9.1 Percutaneous route

4.9.2 Inhalation route

5 Data and Reports

5.1 Data Summary

5.2 Reporting format

5.2.1 Summary

5.2.2 Introduction

5.2.3 Materials and Methods

10 5.2.4 Results

5.2.5 Discussion and conclusions

Related terms in Appendix A (informative), Definitions and Abbreviations

References

Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

SN/T 2180-2008 "Toxicokinetics" modify the use of the United Nations Organisation for Economic Co-operation and Development (OECD) chemical testing means South No.417 "toxicokinetics Test" (1984). OECD 2010 Guidelines for the Testing of Chemicals No.417 "Toxicokinetics" (Toxicokinetics) (1984) have been revised. The technical content of the standard OECD Test Guidelines 417 chemicals "in metabolic power Science "(Toxicokinetics) (2010) are basically the same, therefore, also SN/T 2180-2008 "Toxicokinetics" has been revised. this Compared with mainly standard SN/T 2180-2008 "metabolic dynamics poison" following differences.

--- Increased introduction;

--- Age of experimental animals have clear requirements;

--- It should be clearly labeled using ¹⁴C radioisotope test, but canceled the determination of sensitivity, accuracy and precision Clear requirements of;

--- On the exposure dose and exposure pathways have a more detailed description of test methods and adds complementary;

--- Of the measure has been adjusted to cancel the test process dynamics model, increased the percentage of absorption and bioavailability Indicators and corresponding formulas;

--- Summary of the contents of the report and the results were refined.

This standard is proposed and managed by the National Certification and Accreditation Administration Committee.

This standard was drafted. People's Republic of China Ningbo Exit Inspection and Quarantine.

Introduction

Sufficient information excretion, which can be dose or concentration and the observed toxicity associated also help explore the mechanism of toxicity. By Comments Price exposure on laboratory animals to the test substance produced by the test substance and reveal whether cyclical (parent substance/metabolite), TK RESEARCH Study also helps to explore other toxicological studies. Basic TK parameters obtained from the above studies in the evaluation of tissue and/or organs of the test substance the possibility of accumulation and biotransformation likelihood of exposure to the test substance after aspect can provide valuable information.

TK data can help assess the adequacy and relevance of animal toxicity data extrapolation to humans hazards and/or risk assessment when. In addition, TK also for research to determine the toxicity of the dose level (linear and nonlinear dynamics), exposure pathways, bioavailability and the study design Some issues related to providing useful information. TK type of data that can be used physiologically toxicokinetic (physiologically based basedtoxicokinetic, PBTK) development model.

Metabolite/TK data has prompted important potential toxicity, the role model and the associated aspects of their dose levels and exposure pathways effect. In addition, data can also be used to evaluate the metabolic toxicologically significant exposure to exogenous chemical metabolites.

TK data can be sufficient enough for further QSAR acceptability and applicability, cross-references and material safety in Between the two groups on the evaluation to provide strong support treatment. The kinetic data are also used to measure other studies (such as in vivo/in vitro) toxicology Studies on the correlation.

Unless explicitly mentioned another exposure route (see 7.1, 7.2), this standard generally refers to oral administration of the test substance.

The competent authorities of different levels of chemicals (such as pesticides, fungicides, industrial chemicals, etc.) toxicokinetic parameters and measuring end Different requirements. Unlike most Test Guidelines (TestGuideline, TC) it is different, TK test described in this standard includes a plurality of measurement Amount and destination. In the future, OECD will be enacted several new testing guidelines and/or guidance documents (GuidanceDocument, GD) for each A test endpoints described individually and strive detail. Purposes of this standard, the test method or evaluation method in accordance with the special administrations Given the demand and/or need to make.

For administrative purposes, the evaluation of a chemical TK behavior, can be a variety of studies. But for some specific management needs or the status quo, not all studies can be used to evaluate chemicals. Sometimes, you have to be flexible in considering the technology in toxicokinetic study design Chemical properties. Sometimes, in order to solve chemicals-related hazards and risks concern the need to design a series of specific problems. In some cases, TK collected data can also be used as part of other toxicology assessment. In some other cases, the need for regulatory and/or of Chemicals assessment there are some new problems, the need for additional and/or more extensive study of TK.

To improve the quality of research and to avoid unnecessary use of animals, before such research should take full account of chemicals and related metabolites all the available information and the like, including access from other test methods (in vivo tests, in vitro tests and/or computer evaluation) the data. Physical and chemical characteristics, such as octanol - water partition coefficient (expressed in logPow), pKa, water solubility, vapor pressure, molecular mass and other research programs for the design and interpretation of results helps. These parameters by using OECD Test Guidelines method is obtained.

Potential This standard does not apply to certain special circumstances described, such as pregnant or lactating animals and their offspring, or comment after food animals Residues. However, the data obtained in this standard test method may provide background information for the design of these studies. This standard does not apply for testing nanomaterials. OECD pre-made nanomaterials suitability reports indicate that this standard does not apply to nanomaterials 1).

This test should be carried out to consider animal welfare. No. OECD19 guidance document 2) humane treatment of animals has significance. This standard all in vivo and in vitro studies are described in the recommended number OECD19 guidance document.

1) References [1].

2) Reference [2].

Toxicokinetics test

1 Scope

This standard specifies the terms and definitions chemicals toxicokinetic tests, laboratory animals, test methods, sample collection and results Evaluation.

This standard applies to chemicals toxicokinetic tests.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.