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

GB 15193.16-2014

Replacing GB 15193.16-2003

National Food Safety Standard -- Toxicokinetic test

食品安全国家标准 毒物动力学试验

(English Translation)

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Table of Contents

Foreword	
1 Scope	
2 Terms and definitions	
2.1 Test substance	
2.2 Toxicokinetics	
2.3 Absorption	
2.4 Distribution	
2.5 Metabolism	
2.6 Excretion	
2.7 Bioavailability	
2.8 Rate process	
2.9 Concentration - time curve	
2.10 Apparent volume of distribution	
2.11 Total body clearance	
2.12 Elimination half-life	
2.13 Peak concentration	
2.14 Peak time	
3 Test purposes and principles	
4 Instruments and reagents	
5 Test methods	
5.1 Basic information of the test substance	
5.2 Experimental Animals	
5.3 Dose	
5.4 Test procedure and outcome measures	
6 Data processing and evaluation of results	
7 Test report	
8 Explanation, trial	

Foreword

This standard replaces GB 15193.16-2003 "metabolic test." this standard compared with GB 15193.16-2003, the main changes are as follows.

- Standard name was changed to "national food safety standards toxicokinetics test";
- Modify the scope;
- Increasing the terms and definitions;
- Modified test purposes and principles;
- Modify the instruments and reagents;
- Increased test methods;
- Remove the biotransformation;
- Remove the isotope experiment precautions;
- Remove the test substances in biological samples analysis requirements;
- Remove the result of the determination;
- Increased data processing and evaluation of results;
- Increasing the test report;
- Expanded to explain the experiment.

National Food Safety Standard Toxicokinetics test

1 Scope

This standard specifies the basic technical requirements and test methods for toxicokinetic tests.

This standard applies to the evaluation of the test substance toxicokinetics process.

2.1 Test substance

Items for testing, refers specifically to meet the test requirements toxicokinetics the test.

2.2 Toxicokinetics

Test substance in the body absorption, distribution, biotransformation and excretion process time-varying dynamic characteristics.

2.3 Absorption

From the site of the test substance is usually administered biofilm transport outer or inner surface of the body's blood circulation to the process.

2.4 Distribution

After the test substance by absorption into the blood and body fluids in the body circulation and distribution process.

2.5 Metabolism

Test substance in the body through enzymatic or non-enzymatic reactions, the process of structural change occurs.

2.6 Excretion

The test substance and (or) its metabolites are cleared from the body process.

2.7 Bioavailability

The extent of the test substance is absorbed by the body.

2.8 Rate process

By the rate of change of the amount of poison dynamics of the test substance in unit time, usually with the amount of change per unit time through the process of representation Rate process. Rate process toxicokinetics, including zero order, first order and nonlinear three types.

2.9 Concentration - time curve

After administration of the test substance with time as the horizontal to the blood concentration of the test substance is made ordinate arithmetic graph reflects the test substance in the body Disposal within the state, the rate of change over time and content of the test, the area under the curve reflects into the systemic circulation of the subject matter content.

2.10 Apparent volume of distribution

When tested in vivo was partitioned Buda homeostasis hypothesis test substance concentration in the body fluid uniformly and plasma concentration of a test substance Thus, this body was dissolved test substance required amount of fluid volume is apparent volume of distribution. It was tested in vivo test volume and plasma concentration the ratio of representation.

2.11 Total body clearance

Test substance by metabolism and (or) excretion from the body to clear the way of speed; within per unit time in vivo clearance of the test substance is apparent from points Cloth

volume fraction.

2.12 Elimination half-life

Vivo blood test substance concentration required for half fall time, which is a parameter indicating the subject matter of the elimination rate.

2.13 Peak concentration

After administering the test substance in the blood to reach the maximum concentration.

2.14 Peak time

After the test is administered to achieve maximum blood concentration time.

3 Test purposes and principles

For a group or several groups of experimental animals, respectively, through the appropriate channels at once or several times within a specified time administration of the test substance. Then measured body Fluid, organ, tissue, fecal test substance and (or) change over time the amount or concentration of its metabolites. And then find the related poison power Parameters to investigate the toxicological significance.

4 Instruments and reagents

4.1

According to the test needs, with UV spectrophotometer, fluorescence spectrophotometer, thin layer chromatography, gas chromatography, high performance liquid chromatography Instrument, temperament or LC-MS and other equipment.

4.2

radiometric instruments.

4.3

commonly used laboratory instruments and reagents.

5.1 Basic information of the test substance

The test substance should provide the name, CAS number, batch number, source, purity, character, physical and chemical properties, storage conditions and preparation method, etc.

data.