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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21772-2025

Replacing GB/T 21772-2008

Chemicals - Test method of mammalian bone marrow chromosome aberration

化学品 哺乳动物骨髓染色体畸变试验方法

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Standardization Administration of the PRC

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting.

This document supersedes GB/T 21772-2008 "Test Methods for Chromosomal Aberrations in Mammalian Bone Marrow Using Chemicals", and is consistent with GB/T 21772-2008.

In comparison, aside from structural adjustments and editorial changes, the main technical changes are as follows.

a) The term and definition of "mitotic index" have been added (see 3.5);

b) A new chapter on "Abbreviations" has been added (see Chapter 4);

c) The definitions of "chromosomal aberration," "chromatid aberration," "internal replication," "polyploidy," and "structural aberration" have been revised (see 3.1).

3.2, 3.3, 3.7 and 3.8 (2008 editions 2.1, 2.2, 2.3, 2.6 and 2.7)

d) The temperature and humidity ranges of the experimental animal housing environment were changed (see 6.1.2, 4.1.2 of the 2008 edition);

e) Added requirements for the number of animals per cage and specific animal marking methods (see 6.1.2, 6.1.3);

f) Increased the routes of exposure for different types of test substances (see 6.1.4.1);

g) Added the option to select specific names of common solvents/excipients (see 6.2.1);

h) The names and CAS numbers of cyclophosphamide and cyclophosphamide

(monohydrate) have been changed (see 6.2.2.3, 4.2.2.2 of the 2008 version), and The name and CAS number of methyl methanesulfonate have been added (see 6.2.2.3);

i) The maximum volume for gavage and injection administration has been changed (see 6.3.4.3, 4.3.5 in the 2008 edition);

j) Added requirements for smear marking (see 6.3.8.1);

k) An "Observation" section has been added (see 6.3.6);

l) Added specific methods for chromosome preparation (see 6.3.7);

m) The "Test Report" has been revised, providing more detailed specifications for the contents that should be included in the test report (see 7.3, 2008 version). 5.3).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Technical Committee on 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; Qingdao University; and the Ministry of Ecology and Environment, Solid Waste Management Department.

With the Chemicals Management Technology Center.

The main drafters of this document are: Yu Dianke, Xu Lin, Li Bin, Ma Yan, Yang Li, Chen Xiao, Jin Yuan, and Zhao Kunming.

The release history of this document and the document it replaces is as follows.

- First published in 2008 as GB/T 21772-2008;

- This is the first revision.

Introduction

This experiment was used to detect and evaluate the effect of test substances on chromosomal structural aberrations induced by the test substance in the bone marrow of rodents. Chromosomal structural aberrations can have...

There are two forms. chromosomal aberrations and chromatid aberrations. Increased polyploidy may indicate that the test substance causes chromosomal number aberrations.

Potential effects. Most chemical mutagens induce chromosomal aberrations as chromatid abnormalities, but chromosomal aberrations can also occur.

Mutations in the body and related events are the cause of many human genetic diseases, and there is ample evidence that oncogenes and tumor suppressor genes are responsible

for these diseases.

Altered chromosomal aberrations and related events are associated with the development of cancer in humans and laboratory animals.

This experiment routinely uses rodents. Bone marrow is the target organ in this experiment because it is rich in blood vessels and contains a large amount of material that is easy to isolate and process.

Rapidly circulating cells. Other species and target organs are not the subjects of this experiment.

Chromosomal aberration assays are particularly suitable for evaluating chromosome aberrations that require consideration of factors such as in vivo metabolism, pharmacokinetics, and DNA repair processes.

The resulting genotoxicity, although the factors mentioned above may vary between different animal species and tissues, requires in vivo testing for further investigation.

The study investigated the genotoxicity detected in in vitro experiments.

If there is evidence that the test substance or its active metabolites cannot reach the target organ, this test is not suitable.

Chemicals and mammalian bone marrow chromosomal aberrations Test methods

1 Scope

This document describes the experimental method for testing chromosomal aberrations in mammalian bone marrow.

This document applies to mammalian bone marrow chromosomal aberration testing.

2 Normative references

GB 14925-2023

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Chromosomal type aberration

Chromosomal structural damage caused by chromatid breakage or breakage and rejoining between chromatids.

3.2 Chromatid-type aberration

The phenomenon of chromosomal structural damage caused by the breakage or rejoining of two chromatids at the same site.

3.3 Internal copying endoreduplication

After the S phase of DNA replication, the cell nucleus begins another S phase without undergoing mitosis.

Note. The result is that the chromosomes have 4, 8, or 16 times the amount of chromatin.

3.4 Crack gap

Unstained damage smaller than the width of the chromatid, accompanied by very small misalignment of the chromatids.

3.5 mitotic index

The ratio of the number of cells undergoing mitosis to the total number of cells.

Note. This is an indicator used to measure the number of cells in a proliferating state.

3.6 Numerical aberration

The change in chromosome number is different from the normal chromosome number of the cells used.

3.7 polyploidy

Cells or individuals with two or more sets of chromosomes.