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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21793-2025

Replacing GB/T 21793-2008

Chemicals - Test method of in vitro mammalian cell gene mutation

化学品 体外哺乳动物细胞基因突变试验方法

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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 21793-2008 "Chemicals in vitro mammalian cell gene mutation test method" and GB/T 21793- Compared with 2008, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- Added some content in terms and definitions (see 3.1, 3.9, 3.10, 3.11, 3.12, 3.13, 3.14, 3.15, 3.16, 3.17, 3.18, 3.19);

- Added abbreviations (see Chapter 4);

- Deleted the principles of TK mutation detection (see 3.1 of the 2008 edition) and the steps of TK mutation detection (see 3.1 of the 2008 edition) 4.3.2.2, 4.3.2.3);

- Deleted the chemicals that can be used as positive controls corresponding to the TK site (see 4.2.3.2 of the 2008 edition);

- Changed some of the contents in the "Solvents/Excipients" regulations, and made some adjustments to the establishment of solvents/excipients and test substance concentration ranges.

Supplement (see 5.2.1, 4.2.1 of the 2008 edition);

- Added general principles for the frequency of spontaneous mutations during test substance treatment (see 5.3.1.2);

- Added phenotypic expression time and mutation frequency detection (see 5.3.2);

- Increased laboratory testing capabilities (see 5.3.3);

- Added historical comparison data (see 5.3.4);

- Added test data acceptance criteria (see 6.2);

- Changed the judgment criteria for negative and positive test results in result evaluation and interpretation (see 6.3.1, 6.3.2, 6.3.3, 6.3.4, 6.3.5, 5.2 of the 2008 edition);

- Added calculation formulas for cytotoxicity and cell mutation frequency (see Appendix A).

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, North China University of Technology, and China Inspection and Quarantine (Tianjin) Inspection and Testing Co., Ltd.

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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 21793-2008;

- This is the first revision.

Introduction

In vitro mammalian gene mutation assays can be used to detect chemical-induced gene mutations. Cell lines that can be used include Chinese hamster cells.

CHO, CHL and V79 cell lines, mouse lymphoma cells L5178Y and human lymphoblastoid cells TK6, CHO-derived AS52 cells In these cell lines, the most commonly used genetic mutation detection indicator is the detection of hypoxanthine-guanine phosphoribosyltransferase HPRT mutation and xanthine-guanine phosphoribosyltransferase (XPRT) gene mutation.

XPRT is located on the autosomes and can detect genetic mutations that HPRT (located on the X chromosome) cannot detect, such as Fragment missing.

In in vitro mammalian cell gene mutation tests, established cell lines or cell strain cultures

can be used.

Cells are selected based on their growth ability and spontaneous mutation rate. In vitro experiments usually require an exogenous metabolic activation system.

The metabolic activation system cannot fully simulate the metabolic conditions in mammals, so measures are taken to avoid the occurrence of gene mutations that cannot reflect the in vivo Changes in pH and osmotic pressure or high cytotoxicity of the test substance may lead to false positive results, thus The results cannot reflect the actual situation of gene mutations in the body.

This test can be used to screen for mammalian mutagens and carcinogens. Positive results in this test are usually seen in carcinogens, but this test The relevance of the results to carcinogenicity is limited and depends on the mechanism of action of the chemical. The relevance depends on the type of chemical.

Carcinogens that act through non-genotoxic mechanisms or whose carcinogenic mechanisms are not readily detectable in these cells cannot be detected in this assay.

A positive result was obtained.

Chemicals In vitro mammalian cells Gene mutation test methods

1 Scope

This document specifies the basic principles, test methods, test data and reports for in vitro mammalian cell gene mutation tests on chemicals.

This document applies to the detection of chemical mutations in mammalian cells in vitro.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 mutation

A heritable change in the DNA base pair sequence of a gene or in the structure of a chromosome.

3.2

A substance that can cause the substitution of one or more base pairs in DNA.

3.3 The time required for the type feature to be detected

After treatment with the test substance, the genetic changes are fixed in the genome and the original gene products (such as enzymes or proteins) are fully consumed until the expression of

3.4 mutation frequency mutantfrequency

The proportion of mutant cells detected by selective medium (such as medium containing 6-thioguanine).

3.5 Cloning efficiency

The percentage of cells that can proliferate and form countable colonies relative to the total number of cells seeded.

NOTE. Cells are seeded at a low density, i.e., cells are dispersed and not touching each other.

3.6 Genotoxicity

All types of damage to DNA or chromosomes, including DNA damage, chromosome damage and gene mutation.

NOTE. Not all types of genotoxic effects result in gene mutations or stable chromosomal damage.

3.7 Cytotoxicity

The ratio of the cloning efficiency of the treated group cells to that of the negative control group was lower.