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**Nanotechnologies - Guideline on genotoxicity test methods for
nanomaterials**

纳米技术 纳米材料遗传毒性试验方法指南

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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. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document was proposed by the Chinese Academy of Sciences. This document is under the jurisdiction of the National Nanotechnology Standardization Technical Committee (SAC/TC279). This document was drafted by: China National Institute for Food and Drug Control, National Center for Nanoscience and Technology. The main drafters of this document. Wen Hairuo, Chen Liang, Shao Anliang, Xu Liming, Wu Xiaochun.

With the rapid development of nanotechnology and the emergence of a large number of nanomaterials, the chances of the human body in contact with nanomaterials are increasing. The safety evaluation of the drug has become a hot spot of great concern to the scientific community and the regulatory authorities of various countries. Genotoxicity test is an important part of non-clinical safety evaluation Content, through a series of tests to evaluate whether the test sample has genotoxicity, predict the carcinogenicity of the test sample, so as to reduce its harmfulness to humans Harm risk of group [5]. Nanomaterials may enter cells and interact directly or indirectly with cell genetic material (DNA or chromosomes). It induces DNA or chromosome damage through mechanisms such as oxidative stress or inflammation[20],[24-26]. Currently, the genotoxicity of nanomaterials Research has developed into a dedicated sub-branch of research "Nanogenetic Toxicology". National and international regulators such as the U.S. Food and Drug

Administration (FDA) and the Organization for Economic Co-operation and Development (OECD) have recognized Limitations of current standard genotoxicity combination assays when applied to genotoxicity risk assessment of nanomaterials [17]. OECD Nano Nanomaterials Products Working Group (WPMN) in 2014 in Nanomaterials Product Safety Series Document No. 43 "Genotoxicity of Nanomaterials Products General issues in genotoxicity evaluation of nanomaterials in the OECD expert symposium report (hereinafter referred to as "Document No. 43") [15] Seven consensuses were reached. This document is based on the research results of nanomaterials genotoxicity test and refers to the relevant international genotoxicity guidelines and The drafting of OECD Document No. 43 was approved by experts in the field of nanotechnology and genetic toxicology research, research and development of nanomaterials and related products. Consensus reached after discussions among agency representatives. This document provides a reference for the research and development, safety evaluation and supervision of drugs and medical devices containing nanomaterials. Nanotechnology Nanomaterials Genotoxicity Test Method Guide

1 Scope

GB/Z 42246-2022 is the Chinese national standard on nanotechnologies - guideline on genotoxicity test methods for nanomaterials, in the field of health care technology. The /Z suffix marks it as a guiding technical document: it does not prescribe requirements that can be certified against, but sets out the technique, the method or the state of the art that the standards bodies recommend following. It was issued on 30 December 2022 by the State Administration for Market Regulation; Standardization Administration of China. As a guiding technical document it carries no separate date of entry into force: it applies from publication. Classification: ICS 11.120, CCS C00. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document provides strategies for nanomaterial genotoxicity mechanisms of action, sample preparation and characterization, and in vitro and in vivo assay selection strategies. This document is applicable to the evaluation of genotoxicity potential of nanomaterials, drugs containing nanomaterials (nanomedicines) and medical device products.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

this document.

GB/T 16886.3-2019 Biological Evaluation of Medical Devices Part

3 Terms and Definitions

GB/T 16886.3-2019, GB/T 16886.12-2017, GB/T 30544.4-2019, GB/T 32269-2015 and The following terms and definitions defined in GB/T 41316-2022 apply to this document.

3.1 genotoxicity test genotoxicity test Use mammalian cells or non-mammalian cells, bacteria, yeast, fungi or whole animals to determine whether the test sample will cause genetic Tests for mutations, aberrations in chromosome structure, and other DNA or genetic changes. [Source: GB/T 16886.3-2019, 3.3]

3.2 nanomaterial nanomaterial A material in which any external dimension, internal or surface structure is at the nanoscale. NOTE. This generic term includes nanoobjects and nanostructured materials. [Source: GB/T 30544.4-2019, 2.3]

3.3 settlement A phenomenon in which the dispersed phase settles (separates) downward due to the density of the dispersed phase being higher than that of the continuous phase. NOTE. If the density of the liquid dispersed phase (emulsion) is greater than that of the continuous phase, the droplets will settle, as in a water-in-oil emulsion. [Source: GB/T 41316-2022, 3.13, modified]

4 Nanostructured Materials

GB/T 32269-2015 Terms and definitions of nanotechnology and nanoobjects Nanoparticles, nanofibers and nanosheets

GB/T 39261 Guidelines for Characterization of Physicochemical Properties of Nanotechnology Nanomaterials Before Toxicological Evaluation

GB/T 41316-2022 Guidelines for Stability Characterization of Dispersion Systems

12 Sample Preparation and Reference Materials

GB/T 30544.4-2019 Nanotechnology Terminology Part