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Advisory document of the working group on good laboratory practice(GLP)on the management, characterisation and use of test items

良好实验室规范(GLP) 管理、描述和测试项目的使用

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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:

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This document is proposed and coordinated by the National Standardization Technical Committee for the Management of Hazardous Chemicals (SAC/TC251):

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Introduction

This document refers to the Organization for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) Principles and Compliance Monitoring Document No: 19:

"Recommended Document of the Good Laboratory Practice Working Group on the Management, Description and Use of Test Samples" [ENV/JM/MONO(2018) 6], this document is a supplement and improvement to the already published GLP series of national standards:

This document is intended to provide guidance for the transport, receipt, identification, labelling, retention, handling, storage, description, archiving and disposal of test samples in

GLP studies: Provide guidance:

Since there are many test samples and the research objectives and stages of the test samples are different, the transportation, receipt, identification, labeling, and storage of test samples are difficult:

The information required to sample, process, store, describe, archive and dispose of may vary from study to study: Due to the diversity of test samples, GLP studies During the process, the "test facility manager" shall conduct an appropriate and proportionate risk assessment for the management, description and use of each test sample: Testing agency Personnel should obtain sufficient test sample information to control risks and evaluate whether sufficient test sample information has been obtained: Wind-based risk decision-making methods to ensure the realization of test sample research objectives:

This document consolidates existing requirements for test samples for studies conducted in compliance with GLP principles: This document is intended for compliance with Non-clinical research conducted under GLP principles provides guidance on the description of different types of test samples: Test samples can come in different sources such as chemical, biological, synthetic, natural, organisms, genetically modified organisms, items from complex industrial or biological processes, complex mixtures compound or part thereof: End uses of test samples include, but are not limited to, agrochemicals, industrial chemicals, pharmaceuticals (human and veterinary) (used), cosmetics, food/feed additives and medical devices:

Good Laboratory Practice (GLP) management, description and Use of test projects

1 Scope

This document sets out the responsibilities and requirements for the management, description, and use of test items in good laboratory practice:

This document is applicable to testing institutions that transport and receive test samples in accordance with the expectations of the National Good Laboratory Practice Compliance Supervision Department:

Collect, identify, label, retain samples, process, store, describe, archive and dispose of:

2 Normative reference documents

GB/T 22278

3 Terms and definitions

The terms and definitions defined in GB/T 22278 and below apply to this document: 3:1 test sampletestitem Objects that are the subject of research:

Note: The conclusion of the GLP study provides information about the properties of the test sample and is used to evaluate its safety risks to humans, animals or the environment: 3:2 batch A specific number of test samples:

Note: Products with uniform characteristics within a specific production cycle are considered to be from the same batch: 3:3 mediumvehicle A reagent that acts as a carrier: By mixing, dispersing, suspending or dissolving the test sample to facilitate administration and/or application to the test system: 3:4 dosage formformulation It is a combination of a test sample and different ingredients (such as excipients) in a form (such as tablets, capsules, solutions) that is different from the prototype of the test sample:

Combined administration and/or application to test systems: 3:5 Prepared test sample preparedtestitem A formulation (or mixture) containing a test sample or a test sample in a medium which can be prepared by diluting, mixing, dispersing, suspending, dissolving and (or) other processes intended to be administered to the test system:

Note: Provide test samples or test sample preparations to be reprocessed to the testing agency, or prepare test sample preparations for application or administration to the test system: like