

ICS 13.300; 11.100
CCS A 80



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

GB/T 27825-2011

Chemicals -- Test method for skin absorption -- In vivo

化学品 皮肤吸收 体内试验方法

(English Translation)

Issued on: December 30, 2011

Implemented on: August 1, 2012

Issued by: Standardization Administration of China

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

The Standards and Organisation for Economic Co-operation and Development (OECD) chemical testing methods No.427 (2004) "Skin absorption. in vivo test method" Unanimously (in English) of technical content.

The standard structure and made the following editorial changes.

--- Increasing the range a chapter;

--- The OECD427 original in the "Introduction" and "initial consideration" as part of this standard "Introduction";

--- The OECD427 original "Appendix" as part of the standard "2 Terms and definitions" content;

--- A unit of measurement unity to our legal units of measurement.

This standard is managed by the National Standardization Technical Committee chemicals dangerous (SAC/TC251) and focal points.

This standard was drafted. Chinese Center for Disease Prevention and Control of Occupational Health and Poison Control, People's Republic of China Hubei Entry-Exit Inspection Quarantine Bureau, China Chemical Technology Development Center.

Introduction

This standard mainly with reference to the technical content of the Organisation for Economic Co-operation and Development (OECD) Chemical Test Methods Guide No.427 (2004), this guide provides an in vivo test methods for chemical testing of skin absorption.

Human exposure to chemicals is the main route through the skin, and now the majority of

toxicological studies using experimental animals exposed by oral way.

This guide describes test methods for in vivo percutaneous absorption from the oral test extrapolated percutaneous exposure to chemical safety assessments inevitable contact.

Chemicals need to penetrate through layers of skin cells is available to reach the circulatory system. For most substances, the stratum corneum consisting of dead cells summary Given its skin penetration rate. Chemical permeation of the skin depends both on the chemical itself lipophilic, the thickness of the outer layer of the epidermis and the relative molecular mass of the matter concentration and other factors. In general, better than the rat and rabbit skin permeability of human skin, and guinea pigs, Pigs and monkeys is more similar to human skin permeability.

Test chemical method by percutaneous absorption include two kinds of in vitro in vivo. In vivo test method can provide different species of animals percutaneous absorption Good information. In recent years, in vitro test methods have also made progress. In vitro test for chemical substances mainly through full or partial thickness of animal or human skin reaches a predetermined liquid storage. Test Method for in vitro test method OECD guidelines as otherwise described separately [1].

Under certain circumstances, OECD skin absorption study guide [2] can be used as a reference to select the appropriate test method, which provided more information on body Within and in vitro test methods for applicability details.

In vivo test method described in this guide can test substance through the skin into the body parts of penetration is measured, the method has been widely Pan used for years [3-7]. Although many cases lower body Percutaneous absorption studies can be applied, but in some cases only through the study of in vivo tests it is available to provide the necessary data.

Advantages in vivo test method is that it uses physiological and metabolic complete systems, using a variety of toxicity studies in experimental animals generally applicable Species of the genus, and appropriate modifications can be applied to other species. Of course, this method also has its drawbacks. the use of live animals, required the use of isotopically labeled Marking material to obtain reliable results, it is difficult to determine the early stages of skin absorption and preferred species (rat) and human skin permeability there is a difference different. In general, animal skin permeability is better, so the test may overestimate human percutaneous absorption [6,8-9]. In addition, acid and other corrosive substances Also not suitable for live animals experiments.

Test methods for in vivo skin absorption of chemicals

1 Scope

This standard specifies the test methods for in vivo skin absorption of chemical terms and definitions, principles of testing, test methods, test data and reports.

This standard applies to test in vivo percutaneous absorption of chemicals.

2 Terms and definitions

The following terms and definitions apply to this document.

Not absorbed dose unabsorbeddose After exposure, rinse down from the surface of the skin and the amount of test substance in the cover means, including exposure during evaporate from the skin surface Amount.

Absorbed dose (in vivo) absorbeddose (invivo) After removal of the test site of the skin test substance, including urine, cages washing fluid, feces, exhaled air (if the test), blood, tissues (if There were collected) and the retention of the test substance in the body.

Absorbable dose After washing, the amount left in the skin surface or skin tissue test substance.

3 Test principle

Test substance (preferably isotopically labeled) was applied to the hair of an animal skin, a representative set of test one or more suitable agents Volume group. Within a predetermined exposure time, appropriate (non-closed, semi-closed or closed) covering means covering, the skin contact of the test preparation.

Before exposure, during exposure and after exposure, the test animals were reared in individual metabolic cages and collect animal waste and exhaled gas; exposure colorectal when the beam, removing the cover device with suitable detergent wash the skin, to retain the cover device and the cleaning fluid for analysis. Typically, each agent Set in the amount set several groups of animals. a group at the end of the exposure period that is sacrificed, followed by the other groups were killed after a predetermined time interval [2], end of sampling when the rest of the group of animals were sacrificed, blood was collected, remove the skin test sites were analyzed and analyzed to determine the amount of body excretion of the test substance is not.

Samples collected in an appropriate method of analysis and the percutaneous absorption of the test substance to assess the extent of [6,8-9].

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4.1 Animal selection

Rats are the most common species, can also be used with the human skin absorption rates more similar to strains of hairless series [3,6-9]. Generally used in experiments Common Room strain male healthy adult animals. When the trial began, animal weight difference does not exceed the average weight of $\pm 20\%$, for example, a large male Suitable for rats weighed 200g ~ 250g, especially in the upper part of this range.