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Child-resistant non-reclosable packaging for pharmaceutical products — Requirements and testing

Emballages à l'épreuve des enfants, non refermables pour produits pharmaceutiques — Exigences et essais

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This document was prepared by the European Committee for Standardization (CEN) (as EN 14375) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 122, *Packaging*, Subcommittee SC 3, *Performance requirements and tests for means of packaging, packages and unit loads (as required by ISO/TC 122)*.

There are no changes to the content of the EN 14375 document.

Introduction

Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. Various types of packaging are recognized as being child-resistant, based on performance testing against standards for specific product categories and packaging types.

Since child-resistant packaging was introduced, the incidence of accidental ingestion of potentially hazardous products by children under 5 years old has fallen. The degree to which this is due to the use of child-resistant packaging as opposed to other factors, such as greater public awareness of the hazards, is not easily assessed, but there is little doubt that child-resistant packaging has made a positive contribution to the reduction.

The use of child-resistant packaging needs to be confined to those products that are potentially hazardous, or for which any legislation makes its use mandatory, since, if used in other circumstances, there could be confusion over the degree of hazard posed by the product.

In any case, proper labelling and information by the manufacturer is important for the safe use of the product in the home.

Child-resistant packaging acts as the last line of defence if other barriers separating the child and hazardous product have failed. However, it should be recognized that it is unrealistic to expect that any functional packaging can be totally impossible for a child of 42 to 51 months inclusive to open and that child-resistant packaging cannot be a substitute for other safety precautions.

There has been an increasing use of child-resistant packaging, therefore it is desirable to achieve agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children.

The on-going development of non-reclosable packaging offers a significant area for innovation in packaging. The styles of non-reclosable packages can be wide-ranging in design.

This document aims to minimize the number of children “exposed to training” during panel testing. Since the introduction of performance testing much has been learned about the use of children for testing child-resistant packaging and attention has been focused on how the number of children involved can be reduced. Future development of standards based on mechanical test methods is needed to avoid unnecessary child panel testing and is essential in developing physical package attributes useable by manufacturers.

Child-resistant packaging is only the last in a series of protective measures, and does not release parents or guardians from their duty to keep medicinal products out of the reach of children.

Child-resistant non-reclosable packaging for pharmaceutical products — Requirements and testing

1 Scope

This document specifies performance requirements and methods of test for non-reclosable packaging that have been designated child-resistant. This document is intended for type approval only (see 3.5) and is not intended for quality assurance purposes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
child-resistant package
package which is difficult for young children to open (or gain access to the contents), but which is possible for adults to use properly

3.2
non-reclosable child-resistant package
child-resistant package (3.1) or part of a child-resistant package which, when all or part of the contents have been removed, cannot be properly closed again

3.3
substitute product
inert substitute resembling the product it replaces

Note 1 to entry: This is sometimes referred to as a placebo product.

EXAMPLE Powder, tablets or liquids (uncoloured water), etc.

3.4
unit dose
discrete quantity of any product to be removed from its immediate packaging in its entirety

3.5
type approval
procedure to certify as child-resistant a specific type of non-reclosable package, formed from a specified set of materials

4 Requirements

4.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this document, shall be capable of providing a satisfactory degree of resistance to opening by children (see 4.2.1) and a satisfactory level of accessibility to its contents by adults (see 4.2.2).

A non-reclosable child-resistant package, in addition to conforming to the performance requirements specified in this document (see 4.2), shall be appropriate for the contents, provide mechanical protection and function properly for the life of the content and packaging.

Manufacturers, component manufacturers, fillers and packers of such packages shall initiate and operate procedures to control the quality of packaging materials so that type approved packaging is in accordance with the requirements of this document.

NOTE ISO 9001 specifies requirements for quality management systems where organizations need to demonstrate their capability of supplying conforming products to customers.

4.2 Performance requirements

4.2.1 Child test

An individual child test shall be considered a failure in relation to unit, strip or blister packages if within 10 min the child accesses more than 8 unit doses from the packaging provided.

When tested in accordance with 5.3.2 and evaluated in accordance with 5.4.1.3, the packaging shall be deemed to be child-resistant.

NOTE The figure of eight units is based on existing national standards published by certain CEN members and does not address the issue of toxicity. Some pharmaceutical products on the market can cause harm to children by the ingestion of fewer than eight units. However, reliable data on child toxicity exists for few pharmaceutical products. A harmful dose can be established for some existing pharmaceutical products and a maximum safe dose can be established for all pharmaceutical products by one means or another. Such information is not currently available for all products and there is no central register where this information could be held. In the absence of European legislation on this topic, the drafters of EN 14375 acknowledge these concerns and believe that research and collection of data should continue with a view to considering the substitution of a toxicity based pass/fail criterion for the child panel test in a later revision.

4.2.2 Adult test

When tested in accordance with 5.3.3.2, at least 90 % of the adults shall be able to access at least 1 unit dose within the 1 min test period, without a demonstration.

To minimize the exposure of children to unnecessary testing, the adult test should be carried out before the child test.

5 Testing

5.1 Principle

Type approval for non-reclosable child-resistant packaging is obtained by a sequential test method or full panel test for children and a full panel test for adults. A test group of up to 200 children aged 42 to 51 months is divided into pairs. Each child is given a number of non-reclosable packages to be opened by whatever means they wish to use. If a child fails to gain access within 5 min, the method of opening is demonstrated by the supervisor and the child is given a further 5 min to open the package. The results are recorded sequentially, as obtained. The package is deemed child-resistant if the trail of results on the test charts passes into the acceptance zone or if at least 80 % of the children are unable to access more than eight unit doses within 10 min and at least 85 % of the children are unable to access more