AS 5014—2010

Australian Standard®

Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for pharmaceutical products (EN 14375:2003, MOD)

This Australian Standard® was prepared by Committee HE-016, Child-Resistant Packaging.
It was approved on behalf of the Council of Standards Australia on 4 June 2010.
This Standard was published on 28 June 2010.

The following are represented on Committee HE-016:

- ACCORD Australasia
- Australian Chamber of Commerce and Industry
- Australian Institute of Packaging
- Australian Paint Manufacturers' Federation
- Australian Self Medication Industry
- Consumers' Federation of Australia
- Department of Health and Human Services, Tas.
- Department of Health, SA
- Department of Health, Vic.
- Griffith University
- Pharmaceutical Society of Australia
- Queensland Injury Surveillance Unit
- The Children's Hospital at Westmead
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS 5014.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

Keeping Standards up-to-date

Australian Standards® are living documents that reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued.

Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments that may have been published since the Standard was published.

Detailed information about Australian Standards, drafts, amendments and new projects can be found by visiting www.standards.org.au

Standards Australia welcomes suggestions for improvements, and encourages readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to Standards Australia, GPO Box 476, Sydney, NSW 2001.

Australian Standard®

Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for pharmaceutical products (EN 14375:2003, MOD)

First published as AS 5014—2010.

Published by Standards Australia GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 0 7337 9625 8

PREFACE

This Standard was prepared by the Standards Australia Committee HE-016, Child-Resistant Packaging. Preparation of this Standard was commenced following requests from several state health departments that a Standard be prepared for non-reclosable child-resistant packaging for pharmaceutical products.

This Standard has been adopted with national modifications and has been reproduced from EN 14375:2003, *Child-resistant non-reclosable packaging for pharmaceutical products—Requirements and testing* and its Corrigendum 1 (2006), which is incorporated in the source text.

Variations to EN 14375:2003 and EN 14375:2003/Cor.1:2006 for application in Australia are set out in Appendix ZZ. A rationale for the variations is given in the Australian Foreword.

As this Standard is reproduced from a European Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this European Standard' should read 'this Australian Standard'.

(c) A full point should be substituted for a comma when referring to a decimal marker.

References to international Standards should be replaced by references, where appropriate, to the following Australian Standards:

Reference to European/International Standard		*Australian Standard*	
EN		AS	
862	Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products	5808	Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products
EN/ISO		AS/NZS ISO	
9001	Quality management systems—Requirements	9001	Quality management systems—Requirements
EN ISO/IEC		AS ISO/IEC	
17025	General requirements for the competence of testing and calibration laboratories	17025	General requirements for the competence of testing and calibration laboratories

Only references that have been adopted as Australian Standards have been listed.

AUSTRALIAN FOREWORD

The purpose of this Standard is to provide a method of assessing the resistance to opening by children of non-reclosable packaging that is intended to contain pharmaceutical products. It provides an objective test for defining such packaging as 'child-resistant'.

This Standard applies to non-reclosable packages that immediately enclose one or more unit doses of a pharmaceutical substance, each of which is individually sealed and can only be extracted individually. A product may have an external packaging that contains these multiple, individually-packaged unit doses, which may be joined (e.g. blister and strip packaging) or separate (e.g. sachets). This Standard sets out a test method for testing the packaging that immediately encloses the unit doses, not the external packaging.

Child resistance criteria for packages that enclose multiple dosage units intended for consumption on more than one occasion, where the dosage units are not individually sealed (normally considered to be reclosable packages) are set out in AS 1928—2007, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*. Products requiring reclosable child-resistant packaging should be packaged in accordance with AS 1928—2007.

It should be noted that the term 'child-resistant' is not synonymous with 'child-proof'. 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 hazardous products out of the reach of children. Child-resistant packages provide only the safeguard of delay in access, in the protection of children against accidental poisoning. Other precautions need to be taken by parents, legislators, educators and marketers to ensure the safety of children where these products are available.

The Committee recognizes that some forms of non-reclosable packaging, such as blister packs limit access to their contents, but such packagings cannot necessarily be assumed to be child-resistant.

The Committee also notes that some forms of non-reclosable packages such as blister cards that contain confectionary, toys or food, are deliberately designed to attract the attention of children. Similarities in appearance between such products and hazardous products packaged in a similar way can have the unintended consequence of encouraging children to access these hazardous products. The use of, or presentation of, a child-resistant package such that it resembles packages that contain confectionery, toys or food items, is discouraged.

In preparing this edition of the Standard, the Committee considered various international and regional standards that apply to child-resistant packaging and agreed that alignment with EN 14375:2003 was the preferred option for non-reclosable child-resistant packages for pharmaceutical products. Australian variations to the European Standard are largely based upon the practicalities of testing in the Australian situation, with a smaller population and limited testing capabilities. A detailed study of EN 14375:2003 was made, resulting in the following significant Australian modifications being made to EN 14375:

(a) The test methods given in EN 14375 have been adopted. The performance criteria of 8 unit doses specified in EN 14375 has been retained as a point at which testing is stopped and the package is deemed to have failed the child resistance test. Reporting requirements have been modified to provide for possible future development of graduated classifications in which the desired outcome is set to be less than 8 unit doses.

(b) The EN requirements for a maximum number of adults to be tested at any one site or by any one supervisor have been removed.

The age range for children in the child panel is 42 to 51 months. This is at the high end of the age range at which child poisoning is most common, so as to challenge the packaging with children most likely to have the ability to understand the instructions given in the test and the dexterity to succeed in opening the package. It is internationally recognized that this age range provides the best compromise between the at-risk age group and the practicalities of administering the test.

The age range for adults is 50 to 70 years, to reflect the age group that may have difficulties in opening child-resistant packages. While this group is not intended to represent the population as a whole, it covers adults who can read the instructions and would be expected to implement them with a high likelihood of success.

It is recognized that aged persons or those with disabilities may have problems in opening packages that comply with the Standard. Designers of such packaging should consider this when designing the package and preparing instructions for opening the packaging.

CONTENTS

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 standard 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 packaging—Requirements and testing procedures for non-reclosable packages for pharmaceutical products (EN 14375:2003, MOD)

1 Scope

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

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 862:2001 *Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products.*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 862:2001 and the following apply.

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

3.2
non-reclosable child-resistant package
child-resistant package 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, i.e. powder, tablets or liquids (uncoloured water), etc.

NOTE This is sometimes referred to as a placebo product.

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, which has met the requirements of this standard

4 Requirements

4.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this standard, 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 standard (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 standard.

NOTE EN 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 this European Standard 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.

NOTE To minimise 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 than eight unit doses within the first 5 min. The package's accessibility by a test group of 100 adults is also assessed. Each adult is given a non-reclosable package, any associated opening tools and written instructions, and is allowed 5 min to familiarize themselves with the packaging. The number of adults opening the package within a 1 min test period is recorded. The package is deemed to comply with the requirements of this standard if at least 90 % of the adults are able to access at least 1 unit dose in 1 min.

5.2 Samples and sample preparation

Sufficient packages shall be produced by the proposed manufacturing process to enable a representative sample to be selected by the supervisor for testing and to provide a reserve for reference purposes. Dangerous products shall not be used to fill the package to be tested; an appropriate substitute product shall be used. The material and design of the test samples shall conform to the technical specification and they shall be representative of an average batch of original packages.

Packages for the child panel test shall be unprinted.

In every test, a new package shall be provided for each member of the test group. For both the child and adult tests, there shall be at least 10 unit doses available for each participant.

Each sample package shall be checked for integrity before the test is conducted. The packages shall be presented to the children without the outer retail packaging, giving them access to the individual unit doses.

5.3 Procedure

5.3.1 General

The test procedure is carried out in two stages:

a) child test (see 5.3.2);

b) adult test (see 5.3.3).

5.3.2 Child test

5.3.2.1 Composition of child test group

The test group shall comprise no more than 200 children aged 42 to 51 months, inclusive, with approximately equal numbers of girls and boys. As far as possible, there shall be an even distribution of ages and sexes within the panel. The children shall be selected at random and shall have no apparent physical or mental disability which might affect manual dexterity. They shall not have taken part in more than one previous test and, in that test, a packaging of a different type and design shall have been used. If a child is used for more than one test there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as a part of the test group. Any children having been involved in a reported poisoning accident shall be excluded from the test.

NOTE Children should be selected to represent as closely, as is reasonably possible, the different social, ethnic and cultural origins or the population as a whole, and not just of the immediate district in which the test is carried out.

5.3.2.2 Test procedure

Testing shall be carried out in the presence of a test supervisor. The child test shall take place in an environment familiar to the children.

NOTE 1 Test personnel should visit the test location beforehand and become known by the children in order to gain their confidence. Only the supervisors should be present, parents being excluded from the test.

The test shall be carried out by a sequential procedure (see 5.4.1.1 to 5.4.1.3). The number of children tested will therefore depend on the results obtained, however, the age and sex constraints specified in 5.3.2.1 shall be adhered to.

Pairs of children shall be involved in the test, each pair being monitored by one supervisor. Should a child wander off during the test, action by the supervisor shall be limited to leading the child back to its place and requesting that he or she continue the test, without any additional instruction being given concerning the opening of the package; this fact shall be included in the report (see clause 6).

NOTE 2 If desired, a number of pairs (up to five) can undertake tests in the same room at the same time, provided that arrangements are such that they cannot distract other pairs. They can adopt any attitude or position that they find convenient

and should not be restrained. During the test children should be removed as far as possible from extraneous distractions. If other means of observation are used the supervisor can stand at a distance from the children.

Each child shall be given sufficient packages (see 5.2) with the request that they be opened by whatever means the child wishes to use; 10 min shall be allocated for this purpose. No attempt shall be made to prevent a child using its teeth or any other method of opening the package. However, no tools or implements shall be accessible which might be used by the child, other than those supplied by the manufacturer/filler or packer at point of sale.

Children failing to open or gain access to a minimum of 1 unit dose in the first 5 min shall then watch a single demonstration by the test supervisor of the package being opened, with no emphasis being placed on the actions of opening and with no verbal instructions. These children then have a further 5 min to open the package or gain access to its contents.

If a child leaves the test area during the test period (5 min or 10 min) or refuses to participate in the test despite encouragement, the result shall not be taken into account but the event recorded.

When tools are needed to open the package, but these are not supplied by the manufacturer, there shall be no demonstration. The test is therefore limited to the first 5 min test period.

NOTE 3 At the conclusion of each test, the children should be warned not to play with, or attempt to open, these types of packages.

NOTE 4 Annex A provides a summary of the requirements and guidance to be followed by test supervisors. If required by the regulatory body, an official observer will be present, but the guidance laid down in annex A still applies.

5.3.3 Adult test

5.3.3.1 Composition of adult test group

The test group shall comprise 100 participants. These shall be selected using a screening procedure in which potential participants shall be asked the following questions.

“Are you professionally concerned with the design, manufacture or use of child-resistant packaging?”

“Have you taken part in more than one previous child resistant packaging test within the last 6 months?”

Only those participants responding with negative answers shall be selected.

In order to elicit this information and, at the same time, to ascertain whether the individual is literate, this question shall be presented on a typed or printed form and given to the person to read.

Persons with obvious physical disabilities that might affect manual dexterity shall not be approached and those unable to understand the written opening instructions discounted.

The purpose of the test shall be explained but no demonstration shall be given.

The 100 participants shall be randomly selected between the ages of 50 and 70 in accordance with the requirements given in Table 1. Not more than 30 of the adults tested shall be obtained from or tested at any one site. No individual supervisor shall administer the test to more than 35 adults.

Table 1 — Composition of the adult test group

	Age range years	**Male** number of participants	**Female** number of participants	**Total** number of participants
	50 to 54	8 or 7	17 or 18	25
	55 to 59	7 or 8	18 or 17	25
	60 to 70	15	35	50
Total	—	30	70	100

5.3.3.2 Test procedure

NOTE 1 There is no need for the adults to be tested at any particular place or time. The test should be carried out by one person at a time and only the supervisor should be present.

Each adult shall be given a package, together with any associated opening tools that would be provided with the package at point of sale, and written instructions on how to open the package correctly, if any.

NOTE 2 These can be printed in or on the package when supplied to a consumer.

Each adult shall perform the test individually. No demonstration of how to open the package shall be given by the supervisor. A period of 5 min shall be allowed for the test participants to familiarize themselves with the package to be tested by reading the opening instructions and then attempting to open it correctly. Test participants shall not be allowed to consult either the supervisor or other participants in the test.

Participants who successfully open the test package within the 5 min period shall be given a new identical package and shall be requested to open this one as quickly as possible. A 1 min test period shall be allowed for the participants to open the new packaging.

If in this period of 5 min a panellist is unable to open the package being tested they will be given a screening test. This screening test consists of asking the panellist to open and reclose the following two conventional non-child resistant closures in one minute each:

a) a 28 mm diameter continuous screw thread closure applied at 1,1 Nm torque onto a 25 ml to 50 ml cylindrical plastic container;

b) a 28 mm diameter "push-off" closure applied to a 25 ml to 50 ml round plastic container.

Panellists unable to open and reclose both of these packages in the 1 min screening test are to be discounted from the adult panel results.

Panellists who are able to open and reclose both these packages are counted as a failure in the overall result.

5.4 Evaluation

5.4.1 Child test

5.4.1.1 General

The result of each test shall be recorded on the test charts given in Figures B.1 and B.2 in accordance with 5.4.1.2. The results shall be evaluated in accordance with 5.4.1.3.

NOTE The statistical parameters governing the sampling procedures for the test charts are given in annex C.

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

5.4.1.2 Test charts

As each result is obtained, plot it on the chart in either Figure B.1 or B.2 as follows:

a) Fill in a square immediately to the right of the previous result on the chart in Figure B.1 if the child failed to access more than eight unit doses in the first 5 min, and on the chart in Figure B.2 if the child failed to access more than eight unit doses by the end of the second 5 min period.

b) Fill in a square immediately above the previous result on the charts in both Figures B.1 and B.2 if the child succeeded in accessing more than eight unit doses in the first 5 min. Enter the result only on the chart in Figure B.2 if the child succeeded in accessing more than eight unit doses by the end of the second 5 min period.

NOTE In the case of the first result to be plotted, the blanked-out square is regarded as the previous result.

5.4.1.3 Expression of results

5.4.1.3.1

If the trail of filled squares on the chart in either Figure B.1 or B.2 enters the rejection or acceptance zone, discontinue testing and record the final result as follows:

a) Trail passing into the acceptance zone: The packaging shall be deemed child-resistant.

b) Trail passing into the rejection zone: The packaging shall not be deemed child-resistant.

5.4.1.3.2

If all 200 children are used to test the package, it shall be deemed child-resistant if the following requirements are met.

a) At least 85 % of the children in the test panel are unable to access more than eight unit doses within 5 min without a demonstration.

b) At least 80 % of the children in the test panel are unable to access more than a total of eight unit doses within 10 min (5 min without a demonstration and 5 min after a demonstration, if appropriate).

5.4.2 Adult test

When tested in accordance with 5.3.3.2, any adult who is unsuccessful in accessing at least 1 unit dose during the 1 min test period, apart from those who fail the screening test, is recorded as a failure.

5.5 Overall test result

Only packaging which satisfies both the child and adult test requirements specified in 4.2 shall be deemed to conform to this standard.

6 Test report

6.1 General

At least the following information shall be recorded:

a) name of the body carrying out the test;

b) date(s) on which the test was carried out;

c) name and address of the manufacturer and/or supplier of the package tested;

d) name(s) of the person(s) supervising the test;

e) material specifications comprising a composite package, drawing or photographs if appropriate and a complete description of the package tested;

f) list of the exact instructions given to the adults and children during the test by the test supervisor;

g) copy of the manufacturer's instructions on opening the package given to adults during the test;

h) description of the substitute product used in the test.

6.2 Child test

At least the following information shall be recorded:

a) test location(s);

b) number, age and sex of the children tested;

c) number of children, together with their age and sex, who successfully gained access to the contents of the package as defined in 5.4.1.1 to 5.4.1.3:

   1) before a demonstration;

   2) after a demonstration.

d) time required to open the package;

e) number of unit doses accessed by each child;

f) method of opening used.

6.3 Adult test

At least the following information shall be recorded:

a) number, age and sex of the adults tested;

b) number of adults who successfully opened the package during the 1 min test period;

c) number of adults who failed to open the package during the 1 min test period;

d) number, age and sex of adults unable to open the package during the 5 min test period;

e) time required to open the package;

f) reason for failure to open the package.

6.4 Additional (optional) information to be recorded

Any other information deemed to be useful in assessing the interpretation of the result should be recorded.

6.5 Overall test result

It shall be recorded whether the overall result was a success or a failure in accordance with 5.5.

Annex A
(informative)

Guidance for persons supervising tests with children

A.1 Parental/guardian consent

Parental or guardian consent should be obtained before the child is used as a part of the test group.

A.2 Surroundings and personnel

Surroundings and personnel should be familiar and friendly. For this reason, personnel should visit the test location beforehand and become known by the children in order to gain their confidence. Only the supervisors should be present, parents being excluded from the test.

A.3 Social circumstances of the children

Children should be selected to represent as closely, as is reasonably possible, the different social, ethnic and cultural origins of the population as a whole, and not just of the immediate district in which the test is carried out.

A.4 History of previous poisoning

Any children having been involved in a reported poisoning accident should be excluded from the test.

A.5 Avoidance of distractions

During the test children should be removed as far as possible from extraneous distractions.

A.6 Position of the children

They can adopt any attitude or position they find convenient.

A.7 Behaviour of the supervisor during the test

a) The supervisor should make the request to the children to open the package in an encouraging manner.

b) No opening instructions should be given other than the visual demonstration when there is a demonstration.

c) The children should not be restrained or distracted.

d) If the children lose interest in the test object the supervisor should repeat the request to open it.

e) If other means of observation are used the supervisor can stand at a distance from the children.

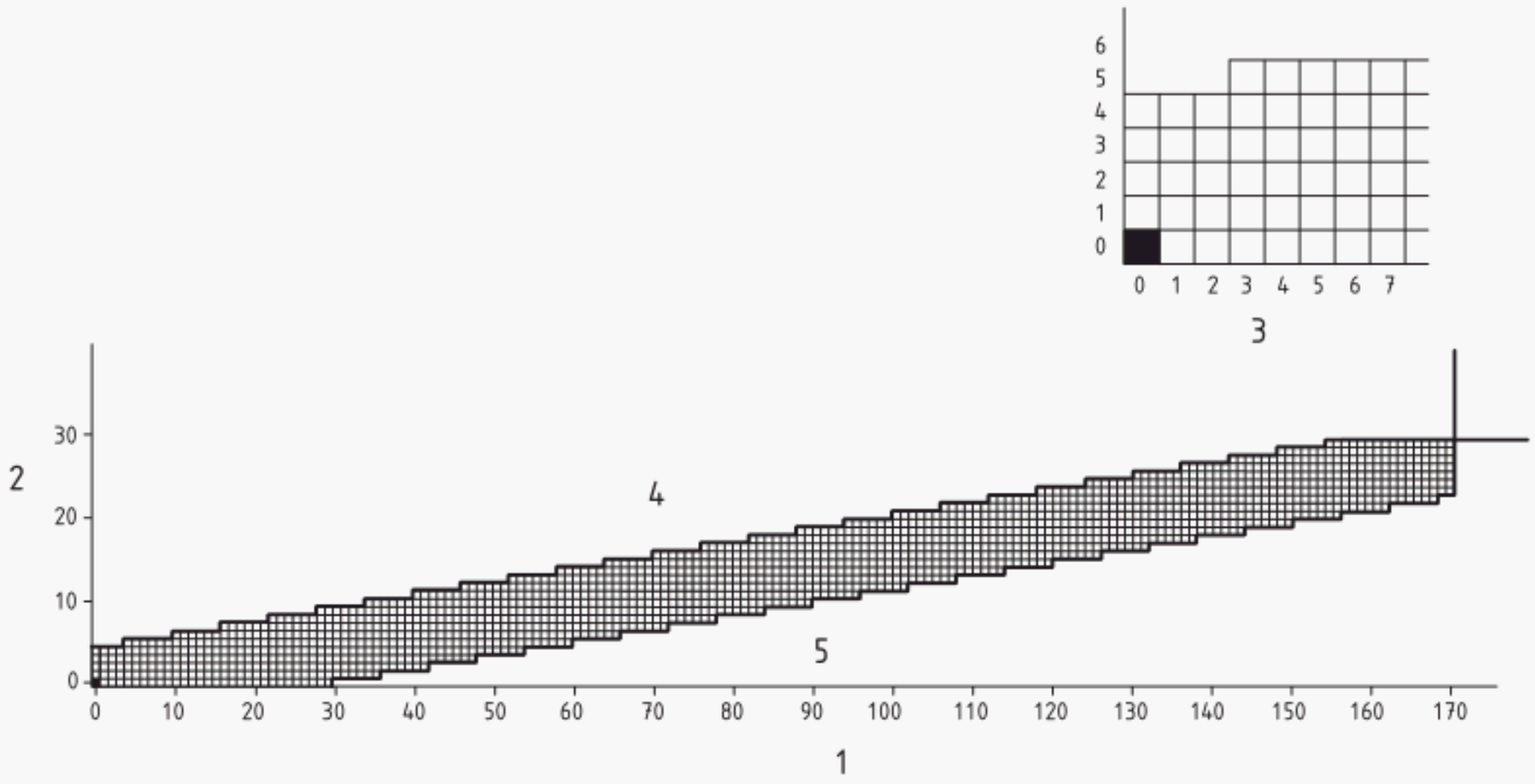
f) The supervisor should encourage the children to gain access to the contents by any means without mentioning any specific method.

g) At the conclusion of each test, the children should be warned not to play with, or attempt to open, these types of packages.

Annex B
(normative)

Test charts

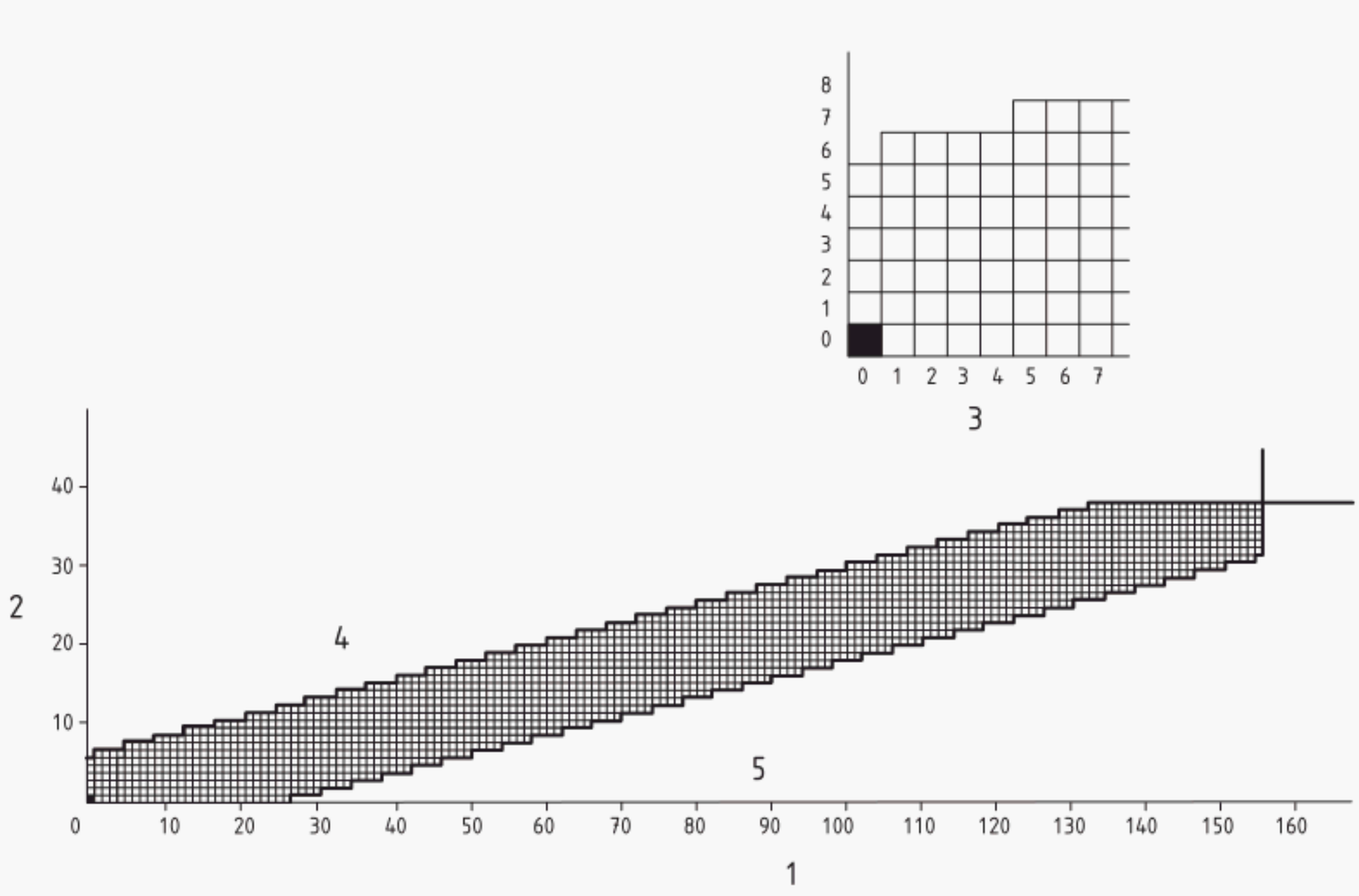
Results shall be entered on the charts in Figures B.1 and B.2 in accordance with 5.4.1.2.



Key

1 Number of packages not opened (Success)
2 Number of packages opened (Failure)
3 Enlargement of chart scale
4 Rejection zone
5 Acceptance Zone

Figure B.1 — Chart of a sequential child test procedure (after 5 min of test before demonstration)



Key

1 Number of packages not opened (Success)
2 Number of packages opened (Failure)
3 Enlargement of chart scale
4 Rejection zone
5 Acceptance Zone

Figure B.2 — Chart of a sequential child test procedure (Total test period)

Annex C
(informative)

Suitability of the sequential procedures chosen

The suitability of a sampling procedure is usually given by the coordinates of two points on its efficiency curve: the point for the producer's risk and the point for the client's risk. The AQL and LQ for the two sampling procedures given in this standard are the following:

— Children (before demonstration) (Figure B.1):

  — Acceptable quality level (AQL):p_A =producer's risk quality level = 10 % α = 5 %

  — Limiting quality (LQ): p_R= consumer's risk quality level = 20 % β = 5 %

— Children (after demonstration) (Figure B.2):

  — AQL = 15 % α = 5 %

  — LQ = 25 % β = 5 %

Where α = producer's risk and β = client's risk.

Although these values are sufficiently precise to give the sampling procedure chosen, they would not, however, be suitable for calculating a new set of acceptance and rejection figures. These figures, supplied in the charts and tables, also take into account other criteria and can, in practice, be considered to be standard.

Bibliography

EN ISO 9001, *Quality management systems — Requirements (ISO 9001:2000)*.

EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:1999)*.

APPENDIX ZZ

VARIATIONS TO EN 14375:2003 FOR APPLICATION IN AUSTRALIA

(Normative)

ZZ1 INTRODUCTION

This Appendix sets out the variations to EN 14375:2003 for the application of this Australian Standard.

ZZ2 VARIATIONS

The variations are as follows:

CLAUSE

3.1 *Delete* the Clause and *replace* with the following:

Child-resistant package

Package that, when tested in accordance with the requirements of this Standard, is difficult for children under the age of fifty-two months to open (or gain access to its contents), but which is not difficult for adults to use.

3.2 *Delete* the Clause and *replace* with the following:

Child-resistant non-reclosable package

Child-resistant package or part of a child-resistant package that, after it has been opened, cannot be properly closed again.

3.6 *Add* a new Clause 3.6 to define 'Prescribed number':

Prescribed number

The number of dosage units representing the performance criteria set by the party ordering the test, and is not more than 8 doses.

4.1 *Add* the following text after the second paragraph:

A package that complies with the human testing requirements of this Standard need not necessarily be retested in accordance with this Standard from batch to batch during production.

Add the following text after the last paragraph and before the Note:

The relationship and interaction of the products, the packaging components, and the packaging system, should be taken into account when developing an appropriate quality control program.

4.2.1 *Delete* the first paragraph and *replace* with the following:

An individual child test shall be considered a failure if within 10 min the child gains access to more than the prescribed number of unit doses from the non-reclosable packaging provided. Regardless of the prescribed number, the test shall be considered a failure if within 10 min the child gains access to more than 8 unit doses from the non-reclosable packaging provided. Testing shall be stopped at this point.

5.1 *Delete* the Clause and *replace* with the following:

Principle

Child-resistance of non-reclosable child-resistant packaging is tested by a sequential 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 gain access to the prescribed number of unit doses within 10 min and at least 85% of the children are unable to gain access to the prescribed number of unit doses within 5 min.

The package's accessibility by a test group of up to 100 adults is also assessed. Each adult is given a non-reclosable package, any associated opening tools and written instructions, and is allowed 5 min to become familiarized with the packaging. The number of adults opening the package within a 1 min test period is recorded. The package is deemed to comply with the requirements of this Standard if at least 90% of the adults in the full panel are able to access at least 1 unit dose in 1 min.

5.3.2.1 *Add* the following text after the last paragraph:

NOTE: Ethical aspects arising from the testing of child-resistant packages with children should be taken into account. For guidance, reference should be made to *ICH Guidelines for good clinical practice*.

5.3.3.1 In the last paragraph before Table 1, *delete* the last sentence which states 'No individual supervisor shall administer the test to more than 35 adults.'

5.4.1.1 (Para 2) *Delete* 'more than eight unit doses' and *replace* with 'the prescribed number of unit doses (to a maximum of 8)'.

5.4.1.2 Item (a) *Delete* 'more than eight unit doses' and *replace* with 'the prescribed number of unit doses (to a maximum of 8)' in both places.

5.4.1.2 Item (b) *Delete* 'more than eight unit doses' and *replace* with 'the prescribed number of unit doses (to a maximum of 8)' in both places.

5.4.1.3.2 Item (a) *Delete* 'more than eight unit doses' and *replace* with 'the prescribed number of unit doses (to a maximum of 8)'.

5.4.1.3.2 Item (b) *Delete* 'more than eight unit doses' and *replace* with 'the prescribed number of unit doses (to a maximum of 8)'.

Bibliography *Add* the following:

ICH Guidelines for good clinical practice

ISO/IEC Guide 23:1982, *Methods of indicating conformity with standards for third-party certification systems*

ISO/IEC Guide 50:2002, *Safety aspects—Guidelines for child safety*

ISO/IEC Guide 51:1999, *Safety aspects—Guidelines for their inclusion in standards*

Standards Australia

Standards Australia develops Australian Standards® and other documents of public benefit and national interest. These Standards are developed through an open process of consultation and consensus, in which all interested parties are invited to participate. Through a Memorandum of Understanding with the Commonwealth Government, Standards Australia is recognized as Australia's peak non-government national standards body. Standards Australia also supports excellence in design and innovation through the Australian Design Awards.

For further information visit www.standards.org.au

Australian Standards®

Committees of experts from industry, governments, consumers and other relevant sectors prepare Australian Standards. The requirements or recommendations contained in published Standards are a consensus of the views of representative interests and also take account of comments received from other sources. They reflect the latest scientific and industry experience. Australian Standards are kept under continuous review after publication and are updated regularly to take account of changing technology.

International Involvement

Standards Australia is responsible for ensuring the Australian viewpoint is considered in the formulation of International Standards and that the latest international experience is incorporated in national Standards. This role is vital in assisting local industry to compete in international markets. Standards Australia represents Australia at both the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Sales and Distribution

Australian Standards®, Handbooks and other documents developed by Standards Australia are printed and distributed under license by SAI Global Limited.

For information regarding the development of Standards contact:
Standards Australia Limited
GPO Box 476
Sydney NSW 2001
Phone: 02 9237 6000
Fax: 02 9237 6010
Email: mail@standards.org.au
Internet: www.standards.org.au

For information regarding the sale and distribution of Standards contact:
SAI Global Limited
Phone: 13 12 42
Fax: 1300 65 49 49
Email: sales@saiglobal.com

ISBN 978 0 7337 9625 8

This page has been left intentionally blank.