INTERNATIONAL STANDARD

ISO 16037

First edition
2002-05-15

Rubber condoms for clinical trials — Measurement of physical properties

Préservatifs masculins en caoutchouc destinés aux essais cliniques — Mesurage des propriétés physiques

Reference number
ISO 16037:2002(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16037 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

Introduction

Clinical investigations of condoms involve many aspects, notably condom acceptability and failure. Useful studies require many condoms and subjects, which are expensive. Clinical studies often underestimate the potential influence of condom physical properties, whose laboratory testing is far less expensive. As physical properties may vary over time and from product to product, a lack of brand- and lot-specific data may well reduce the usefulness of a clinical investigation for improving condom quality and efficacy.

While some investigations may best be conducted using condoms of the participants' choice, it is usually appropriate to ensure that all participants use condoms having the same physical characteristics. In most cases, each clinical investigation will evaluate condoms of one or more types. Study condoms of each type should generally be from the same lot, in order to ensure that they are characterized by the same physical properties. If special properties are desired, independent test laboratories may be able to advise as to which laboratories or manufacturers should be contacted for assistance.

In most situations determination of these characteristics should be part of the study design. Assistance in this regard is available from a number of independent testing laboratories, and from some condom manufacturers. Laboratories should be experienced in, and accredited for, condom testing, in accordance with recognized standards.

It is believed that gathering as much physical information as possible about the condoms used is a sensible precaution. In principle, tests on physical properties should all be done at the beginning of the investigation, and some should be repeated at the end. In investigations running over more than six months, additional tests may be considered during the investigation to give a profile of the change in physical properties over the duration of the study.

While there have been several clinical investigations on condom failure, relatively few of these fully identify the physical characteristics of the condoms used. Thus, it is difficult to compare meaningfully the results of different investigations, or to build hypotheses about design or manufacturing factors that may affect condom efficacy.

Having developed an International Standard on the requirements and test methods for natural latex rubber condoms, (ISO 4074), ISO/TC 157 remains interested in further clinical validation of the physical requirements given, and in any data that may suggest a need for amendments to them. This document offers guidance on the measurement of physical properties characterizing condoms used in clinical investigations. Recommended sample sizes for laboratory testing in this document are in some cases intentionally larger than those in ISO 4074.

This document is written primarily for investigations on natural rubber condoms, but the principles apply to condoms of other materials also. It should not be expected that elongation properties of synthetic materials will be similar to those of natural rubber.

Rubber condoms for clinical trials — Measurement of physical properties

1 Scope

This International Standard is intended as a guideline for clinical researchers working with condoms. It suggests a series of laboratory tests to be conducted on the products to be used in any clinical investigation, so that it will be easier to relate the clinical results to the design and quality of the condoms used.

This International Standard is not applicable to the design of clinical investigations.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 4074, *Natural latex rubber condoms — Requirements and test methods*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 4074 apply.

4 Length

4.1 Measure and record the length of 13 condoms per lot, as described in ISO 4074. Calculate lot mean length and standard deviation (or confidence interval).

4.2 The length and width of any teat (reservoir) should also be measured (see also 5.2 below).

5 Width

5.1 Measure and record the flat width of 13 condoms per lot, as described in ISO 4074, at sections every 10 mm between 30 mm from the closed end and 30 mm from the open end (rim). For each section, calculate the lot mean width and standard deviation (or confidence interval).

5.2 Alternatively, a profile of the condom may be constructed by photocopying cleaned, dusted and flattened specimens alongside a transparent ruler.

6 Thickness

6.1 Determine the thickness of the condom in the transition area between the shaft of the condom and the reservoir (or closed end if there is no reservoir). Make this measurement as close as possible to the closed end, consistent with being able to flatten the rubber film on the micrometer anvil without excessive stretching.

6.2 Measure at least 13 condoms, using a micrometer dial gauge with a resolution of at least 0,010 mm, a foot diameter of (5 ± 2) mm and foot pressure of (22 ± 4) kPa. At each section, measure and record at least four evenly spaced single wall thicknesses.

6.3 Thickness may also be determined using the weighing method outlined in ISO 4074, on parallel-sided parts of the condom. This may be useful if any comparisons are made with condoms tested for compliance using ISO 4074, and a relationship between the two types of measurement is required.

Cut the test piece centred on the section concerned. Measure and record each test piece flat width to the nearest 0,5 mm and mass to the nearest 1 mg. Calculate the test piece thickness from the formula:

$$t = 0{,}026\ 8\, m/w$$

where

t is the thickness, expressed in millimetres;

m is the mass, expressed in milligrams;

w is the width, expressed in millimetres.

NOTE There is a systematic difference between the direct measurement and weighing methods, the latter giving higher values than the former.

7 Bead

From 13 condoms per lot, remove the bead (rim) by scissors or tearing, and cut it open. Measure and record each bead length (to the nearest 1 mm) and thickness at three sections (to the nearest 0,01 mm). Calculate the lot mean length and thickness, with standard deviation (or confidence interval).

8 Air inflation properties

Inflate at least 315 condoms per lot (but preferably 500), as described in ISO 4074. Measure and record each bursting pressure and volume. Data should be recorded to the maximum precision available from the equipment, rather than using the rounding specified in ISO 4074. Calculate lot mean bursting pressure and volume, with standard deviations (or confidence intervals); and report the number of defectives (specimens visibly leaking air, or bursting under ISO 4074 minimum pressure and/or volume).

Data may be summarized as histograms (or stem-and-leaf diagrams). The aim of the test is not only to determine whether the lot(s) of products being used in the investigation comply with ISO 4074, but also to reliably estimate the mean, range, standard deviation, and number of non-compliers. For a more reliable estimate of lot defectiveness, at least 2 000 condoms should be tested.

9 Tensile properties

9.1 Cut mid-body test pieces as specified in ISO 4074 from 20 condoms per lot. Measure and record for each test piece either:

a) length (to the nearest 0,5 mm), and thickness at four points (to the nearest 0,001 mm), or

b) flat width (to the nearest 0,5 mm) and mass (to the nearest 1 mg).

Test the test-pieces on a tensile tester as specified in ISO 4074. Measure and record each test-piece force (to the nearest 0,1 N) at 100 %, 300 % and 600 % elongation and at break, and the elongation at break (as percentage of original length).

9.2 Calculate lot mean elastic modulus at 100 %, 300 % and 600 % elongation, breaking force and elongation (strain), and tensile strength, with standard deviation (or confidence interval).

In case 9.1 b), stresses and tensile strength may be calculated from:

$$\sigma = \frac{0{,}935F \cdot w}{m}$$

where

σ is the stress, expressed in megapascals;

F is the tensile force at break, expressed in newtons;

w is the width, expressed in millimetres;

m is the mass, expressed in milligrams.

9.3 For non-isotropic materials, the tensile properties shall also be determined along the long axis of the condom. These tests shall be carried out using a dumbbell sample cut with an ISO Type I or Type II cutter as specified in ISO 37. The width of the test piece (nominally 20 mm) may be taken to be the width of the throat of the cutter. Measure and record the thickness of each test piece (to the nearest 0,001 mm) at four points.

10 Lubricant

On 32 specimens per lot, measure and record the mass of lubricant (to the nearest 10 mg) in each individual container, and that on each condom as removed from its individual container, using the method described in ISO 4074. Calculate the lot mean mass of lubricant on the condom and in the individual container, with the standard deviations (or confidence intervals).

11 Freedom from holes and visible defects

11.1 Test at least 315 condoms per lot for aqueous leakage, as described in ISO 4074 (specifying the method). Record the number of specimens with holes (over 25 mm from the rim), and the distance from the closed end of any hole detected, measured to the nearest 1 mm.

11.2 In the same sample, inspect each condom for visible defects (including holes). Record the number of visibly defective specimens, and the location and nature of any visible defect.

11.3 For a more reliable estimate of lot defectiveness, at least 2 000 condoms per lot should be tested for holes and visible defects.

12 Information from manufacturer

The manufacturer should be informed of the clinical investigation, and asked for a full technical specification of the condom type, including physical properties (as above), and data on stability (oven-treated and/or naturally aged condom bursting and tensile properties), dressing materials (including any spermicidal lubricant), toxicity, allergenicity, etc.

13 Follow-up studies

Condoms should be sampled and tested at the beginning of their clinical investigation. If the clinical investigation extends beyond six months, then air-inflation and tensile testing should be repeated every six months and at the end of the investigation. Re-tested condom sample sizes may be reduced appropriately.

Bibliography

[1] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[2] ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity*

[3] ISO 14155:1996, *Clinical investigation of medical devices*

[4] ISO 14971, *Medical devices — Application of risk management to medical devices*

ICS 11.200

Price based on 5 pages