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Additional lubricants for male natural rubber latex condoms — Effect on condom strength

Lubrifiants supplémentaires pour préservatifs masculins en latex de caoutchouc naturel — Effet sur la résistance du préservatif

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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. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

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 corrected version of ISO 19671:2018 incorporates the following corrections:

— specifications for viscosity and specific gravity of positive control in 6.2;

— specifications for viscosity and specific gravity of positive control in Clause 9;

— "test substance" has been replaced by "lubricant" in A.3.3;

— subscript in Formula (B.4).

Introduction

Weakening of natural rubber latex is known to occur after contact with certain lubricants, particularly petroleum-based products. This procedure was developed as a screening method for lubricant manufacturers to determine whether or not a particular personal lubricant or topical medicine has a significant effect on the tensile and airburst properties of condoms. It is also applicable to topical medicines and other chemicals that might come in contact with vulval, vaginal or rectal tissues, and hence with condoms.

The method is designed for use on male condoms that meet the criteria of ISO 4074. While the test method can be effective for male condoms made of other raw materials, there is no evidence upon which to base pass/fail criteria for these materials.

This test method does not determine the safety of either the test substance or the condom.

This test method is to be used only to determine if the tensile or airburst properties of the condom have been significantly affected by the test substance.

Additional lubricants for male natural rubber latex condoms — Effect on condom strength

1 Scope

This document specifies a method of assessing the effect or compatibility of an additional or personal lubricant with lubricated male natural rubber latex condoms. It also applies to topical medicines and any other substances that come into contact with such condoms. It describes the measurement of changes in physical properties of the condoms after exposure to the test substance (i.e. lubricant, topical medicine, etc.) and specifies the pass/fail criteria for such changes.

This document is not applicable to the assessment of the compatibility of lubricants applied to a condom at the time of manufacture. It is not directly applicable to the assessment of the compatibility of a particular condom with lubricants or other substances. It is not directly applicable to tests using female condoms, although similar principles can apply.

The test methods are applicable to condoms made from natural rubber latex and from synthetic materials, but a pass/fail criterion is only stipulated for natural rubber latex.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4074:2015, *Natural rubber latex male condoms — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4074 and the following 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
personal lubricant
additional lubricant intended for application by the user at the time of condom use

3.2
positive control
test substance (3.3) which is known to cause deterioration in the physical properties of a condom

3.3
test substance
lubricant (3.1), *topical medicine* (3.4) or other material which is being tested for compatibility with condoms

3.4
topical medicine
medicine intended to be used vaginally or rectally, and which might come into contact with a condom in use

4 Principle

This test method measures the change in tensile properties and inflation properties of condoms, after 60 min of contact with a lubricant or other test substance to which this document refers. Force at break is the principal and most sensitive variable used in assessing the effect of test substances.

For tensile testing, rings cut from condoms are exposed to the test substance, heated to body temperature, cleaned of excess test substance, and tested for force at break and percent elongation at break in accordance with Annex A. Those properties are compared to control rings that are subjected to the same procedures using distilled water instead of the test substance.

For inflation testing, the parts of the condoms which are subject to inflation are exposed to the test substance and are then heated to body temperature. They are then subjected to inflation testing as prescribed in ISO 4074 or ISO 23409. The results are compared to control condoms that are subjected to the same using distilled water instead of the test substance.

5 Apparatus

5.1 Environmental chamber or oven, capable of maintaining (40 ± 2) °C.

5.2 Specimen containers for inflation testing, capable of holding one condom and sealing volatile components of the test substance, so they cannot escape into the atmosphere. The excess space in the container should be kept to a minimum.

NOTE A glass jar is a suitable container.

5.3 Specimen containers for tensile testing, capable of holding one tensile sample and sealing volatile components of the test substance, so they cannot escape into the atmosphere. The excess space in the container should be kept to a minimum.

NOTE A glass jar is a suitable container.

5.4 Tensile tester and roller grips, capable of testing ring specimens according to Annex A.

5.5 Ring-cutting die, mechanical press, and replaceable cutting surface, for cutting ring specimens from condoms, compliant with Annex A.

5.6 Mounts, suitable for holding ring samples while they are being coated with test substance. These mounts may be two cylindrical rollers about 15 mm in diameter, placed with their axes about 50 mm apart, over which the samples are stretched. Refer to Annex A.

5.7 Soft paintbrush, suitable for spreading the test substance on the condoms. A width of approximately 10 mm and thickness 5 mm to 10 mm, is recommended.

5.8 Cylindrical mounts, suitable for coating and storing condom samples for inflation testing. These can be glass test tubes 32 mm to 38 mm in diameter, or plastic rods with approximately hemispherical ends, mounted in such a way that the condoms can easily be unrolled onto them.

NOTE The tubes are intended to produce a smooth condom surface for applying the test substance, and also to allow easy removal of the condom after coating. The dimensions are not critical.

5.9 Inflation tester, suitable for testing condoms in accordance with ISO 4074:2015, Annex H.

5.10 Syringes or pipettes, for dosing 1,5 ml and 0,2 ml of the substance under test.

5.11 Small beaker or cylindrical container, about 30 mm in diameter, for storing the test substance and for moistening paintbrushes.

6 Materials

6.1 Condoms, complying with ISO 4074, to which the test substance is applied. The condoms shall be smooth and parallel-sided. The mean thickness of the condoms used, when measured according to ISO 4074 shall be between 0,055 mm and 0,07 mm. The mean force at break of the negative control condoms shall be between 70 N and 100 N.

6.2 Liquid paraffin, for positive control testing, meeting the current requirements of the US, European or British pharmacopeia, with a specific gravity of 0,83 to 0,85 at (25 ± 2) °C, and a kinematic viscosity of $4 \cdot 10^{-5}$ m^2/s to $5 \cdot 10^{-5}$ m^2/s at 40 °C. The liquid paraffin is expected to cause significant degradation in natural rubber condom physical properties when the test method is properly performed.

6.3 Cyclomethicone D5, for positive control testing, meeting the current requirements of the US, European or British pharmacopeia. The cyclomethicone D5 is expected to cause significant reversible, short-term degradation in natural rubber condom physical properties when the test method is properly performed.

6.4 Distilled water, for negative control testing.

6.5 Solvents, including water, isopropanol (IPA), and mild detergent, for cleaning laboratory equipment and supplies after each test substance group has been tested.

6.6 Cornstarch, or similar inert powder, to assist in dimensional measurements and tensile testing (optional).

6.7 Low-lint laboratory-grade paper towels, for removing test substance from test samples after oven conditioning.

7 Samples and tests

7.1 Sample overview

7.1.1 This test method shall be performed on three distinct, commercially available natural latex condoms made in different factories and belonging to different independent companies. The products shall be chosen from among leading brands in the country or countries where the test result is to be applied or, in the case of internationally branded products, three major international brands. The mean thickness for each product as determined in accordance with ISO 4074 shall be in the range 0,055 mm to 0,07 mm.

7.1.2 Each brand of condom should be lubricated, straight-walled, smooth condoms from a single finished lot.

7.1.3 All natural rubber latex condoms shall meet the requirements of ISO 4074.

It is acceptable to purchase condoms that are stated to conform to ISO 4074 from retail outlets or wholesalers.

7.2 Condom sample groups

7.2.1 Each of the three distinct brands of condoms shall be divided into two groups and tested for physical properties in the following order:

a) Control group: Condoms are tested according to 8.3 and 8.4, but the tensile samples/condoms are lubricated with distilled water. All other handling and testing of the control tensile samples/condoms shall be exactly the same as for the test substance group. There is no contact with the test substance in the control group.

b) Test substance group: Condoms are tested in accordance with Clauses 8 and 9 with a substance for which condom compatibility is unknown.

7.2.2 For staff training and for periodic re-validation of the method, a third group of products exposed to a positive control (with short or long-term effects) shall be tested, either instead of or after, the test substance group.

7.3 Sample size

The sample size for tensile testing shall not be less than 30 condoms per group.

7.4 Quantity of test substance

7.4.1 Inflation testing

a) Lubricants: Each condom shall be exposed to (1,5 ± 0,15) ml of lubricant.

b) Topical medicines: Each condom shall be exposed to one normal dose of the medicine. Where necessary to achieve even spreading over the sample, the medicine may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of up to 45 °C prior to application.

7.4.2 Tensile testing

a) Lubricants: Each ring sample shall be exposed to (0,2 ± 0,02) ml of lubricant.

b) Topical medicines: Each ring sample shall be exposed to (12 ± 1) % of one normal dose of the medicine. Where necessary to achieve even spreading over the sample, the medicine may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of up to 45 °C prior to application.

8 Procedure

8.1 General

The negative control test shall be performed first, and be followed immediately by the test on the test substance. Additional substances may be tested thereafter, provided all equipment is thoroughly cleaned of the previous test substance beforehand. Provision is made for testing positive controls, liquid paraffin and cyclomethicone D5, to train operators and validate techniques.

NOTE Some regulatory bodies might require positive control results to be submitted along with the results for the test substances.

Tests performed using natural latex condoms shall apply to claims of compatibility with natural latex condoms only.

Tensile testing shall be conducted in accordance with Annex A.

8.2 (Negative) control testing

For both inflation and tensile testing, a control test shall be conducted immediately before using the test substance. For negative control testing, distilled water shall be used in the same quantity as required for the test substance.

Condoms are tested according to 8.3 and 8.4, but the tensile samples/condoms are lubricated with distilled water. All other handling of the control tensile samples/condoms shall be exactly the same as for the test substance group. There is no contact with the test substance in the control group.

8.3 Inflation testing

For each of the product groups, mount 30 samples on suitable cylindrical mandrels. The mandrels should be marked with a line indicating 150 mm from the hemispherical top. If the mandrels are not so marked, or the mark is not clearly visible through the condom, make a mark on the condom itself, 150 mm from the top of the mandrel. Use a spirit-based marker.

If the test substance is too thick to spread easily on the condom, it may be heated to a maximum of 45 °C before application. Where necessary to achieve even spreading over the sample, topical medicines may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of up to 45 °C prior to application.

Wet the paintbrush with the test substance using the storage container, and drain it by brushing it against the lip of the container. Apply the required quantity of test substance or control substance using a syringe or pipette, while spreading it with the brush on the outer surface of the condom at the same time, between the closed end and the 150 mm mark. Immediately after application of the test substance, remove the condom from the mandrel by sliding the bead slowly upwards (this will wrinkle the condom), then place it in the specimen container. Seal the container immediately.

Syringes are more convenient to use where possible, but the seals may be affected by some test substances Pipettes or burettes may be used instead of syringes.

When a sub-group of condoms has been coated, place them immediately in an oven or environmental chamber at a temperature of (40 ± 2) °C. Leave the samples in the oven for (60 ± 5) min, then remove them.

Open one of the specimen containers and immediately wipe the condom contained in it with a fresh paper towel. Without delay, place the condom on the inflation tester and perform an inflation test on that sample. Repeat for all other condoms in the sub-group.

Cornstarch or similar inert powder may be used to assist in handling the condoms for testing after oven conditioning

Record the number of samples, the type of test substance or control substance applied, and the burst volume and pressure as required in ISO 4074.

Repeat the process until all condoms have been tested.

8.4 Tensile testing

Cut and measure a tensile ring sample from each of 30 condoms in accordance with Annex A. Place each sample on a suitable mount, so that the entire circumference of one side of the sample can be coated with the substance being tested. Wet the paintbrush with the test substance using the storage container and drain it by brushing it against the lip of the container. Apply the required quantity of test substance or control substance to the outside of the ring sample using a syringe or pipette, while at the same time spreading it with the brush.

Syringes are more convenient to use where possible, but the seals may be affected by some test substances. Pipettes or burettes may be used instead of syringes.