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(Continued on page 11)

Indian Standard

SPECIFICATION FOR RUBBER PROTECTIVE SHEATHS (CONDOMS)

(First Revision)

0. FOREWORD

- 0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 11 November 1958, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.
- 0.2 This standard was first published in 1966. As a result of experience gained since then, it has been found by the Committee that tensile strength and elongation at break before and after ageing gives better assessment of the quality of latex as compared to the bursting strength. Further colour fastness test has been included for coloured condoms. The Committee also decided to delete the reaction to aqueous extract test. The sampling scheme has also been modified.
- 0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with 1S: 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements, methods of sampling and test for rubber protective sheaths (condoms), for single use only. The sheath may be of natural colour or coloured.

2. REQUIREMENTS

- 2.1 Description The sheaths shall be provided with a receptacle at the closed end and a thin ring formed by rolling the rim at the other end (see Fig. 1).
- 2.1.1 Raw Material, Manufacture and Workmanship The sheathth shall be manufactured from natural rubber latex. It shall be free from

^{*}Rules for rounding off numerical ralues (revised).

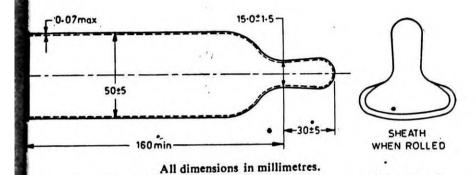


Fig. 1 Dimensions of Rubber Protective Sheath (Condom)
When Laid Flat

mbeded grit and foreign matter, and shall be transparent or translucent rior to the application of dressing material. The rubber later mix, compounding ingredients or the dusting powder shall not contain agredients known to be harmful or toxic.

2.1.2 The sheath shall be uniformly and properly shaped and shall ave a smooth surface. It shall be free from pinholes, wrinkles, cracks, reases, blisters, weak spots and other visible defects.

22 Dimensions

- 2.2.1 Length Length of the unrolled sheath when laid flat excluding he teat shall be not less than 160 millimetres.
- 2.2.2 Width The width of the sheath when laid flat measured at any point between 70 mm and 80 mm from the open end shall be 50 ± 5 mm.
- 2.2.3 Thickness The double-walled thickness when measured at any point between 70 mm and 80 mm from the open end with a micrometer dial guage graduated in intervals of 0.01 mm shall be not more than 0.14 mm. The sheaths which are lubricated shall, prior to measurement of thickness have the lubricant removed by means of water or isopropyl alcohol (propan-2-ol), in the case of dusted sheaths the dressing powder shall be wiped off.
- 2.3 Mass The maximum mass of the sheath shall be 1.6 g.
- 2.4 Water Leakage Test The sheath when subjected to leakage test described in 5.1 shall not show any leakage below 50 mm from the open end.
- 2.5 Tensile Properties When tested according to 5.2 the mean tensile strength and elongation at break each calculated after excluding the

lowest and highest of at least 5 test results shall apply with the following test requirements:

	Minimum Tensile Strength	Minimum Elongation at Break
Before ageing After ageing at	20 MPa	650 percent
70 ± 1°C for 96 h	+ 10 percent - 30 percent	+ 10 percent - 15 percent

2.6 Air Infiltration Test — Inflate the condom with air to a diameter of 150 mm. The inflated sample shall be examined for the presence of pin holes or foreign matter. No such defect shall be discernible. The examination of the inflated condom shall be completed within a minute. In case any foreign matter or any visual defect is observed in a condom during the air inflation test the condom shall be subjected to the water leakage test.

Note - Pin holes within 50 mm from the open end may be ignored.

2.7 Colour Fastness Test — Thoroughly wet inside and outside of the condoms with distilled water. Make no attempt to remove any dusting material or lubricant. Wrap the wet condom in white absorbent paper so that the largest possible surface area of the condom is in contact with the paper and seal the whole in a suitable container to prevent loss of moisture. Allow the container and its contents to stand for 16 to 24 hours at room temperature. After removing the absorbent paper from the container, examine it visually in natural daylight for any indication of staining. No part of the absorbent paper shall be stained. If there is any indication of staining of the absorbent paper by any colouring agent present in any of the condoms or any dusting material or lubricant, the entire batch shall be declared to be not of standard quality.

3. PACKING AND MARKING

- 3.1 Packing The sheaths shall be individually packed in air-tight packing which shall protect the sheaths from contamination and mechanical damage.
- 3.2 The smallest packing offered to the consumer shall be legible and indelible marked to include the following:
 - a) The name or trade-mark of the manufacturer or supplier,
 - b) Lot or batch number,
 - c) The month and year of manufacture and month and year of expiry which shall not be more than 36 months from the date of manufacture,
 - d) With the words at a prominant place 'FOR SINGLE USE ONLY', and
 - e) Store in cool and dry place away from sun light.

3.2.1 Each packet may also be permanently and visibly marked with the ISI Certification Mark.

Note — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

. SAMPLING

1.1 The scale of sampling and criteria for conformity of sheaths shall be as described in Appendix A.

5. TEST METHODS

5.1 Water Leakage Test — Fit the specimen on to the end of a suitable mount of about 45 mm diameter. Ensure that the outer surface of the specimen is in a dry state. Fill the condom with 300 ml of water at room temperature. After suspension for at least 1 min without visible leakages through the condom wall, remove the condom from the mount and close the open end by twisting the material near the rim.

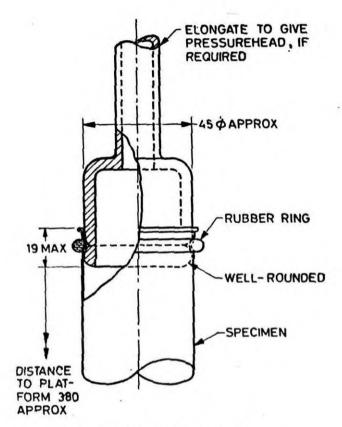
Roll any condom which has been treated with lubricant during manufacture over a separate sheet of absobent paper to remove surplus lubricant before subjecting the condom to the rolling procedure for the detection of leakage. Then roll the condom firmly at least twice over a sheet of the dry absorbent paper and inspect the paper for signs of leakage.

Note - Pin holes within 50 mm from the open end may be ignored.

5.2 Tensile Strength and Elongation at Break — Carry out this test as per 1S: 3400 (Part 1)-1977* using the thickness of the test piece as the single layer of the sheath. Accelerated ageing shall be done according to 1S: 3400 (Part 4)-1978† using air oven.

^{*}Methods of test for vulcanized rubber: Part 1 Tensile stress strain properties (first revision).

f Methods of test for vulcanized rubber: Part 4 Accelerated ageing (first revision).



All dimensions in millimetres.

FIG. 2 SUITABLE MOUNT FOR USE IN THE LEAKAGE TEST AND BURSTING STRENGTH TEST

APPENDIX A

(Clause 4.1)

sampling of rubber protective sheaths (condoms)

1. SAMPLING DURING PRODUCTION

- 1.1.1 Application of statistical quality control (SQC) methods will help achieving the desired quality and reliability of the sheaths during the rocess of manufacture. The need for SQC during production becomes if the more pressing when the nature of the finished product is such at non-conforming lot become a total loss because it is neither possible allow it into the market nor it is possible to screen and rework it.
- c1.2 Whenever there exists Indian Standard specification for raw aterials, the manufacturer may either obtain certificates from the uppliers guaranteeing the conformity of the raw materials to the specifications or get the raw material tested for conformity according to the rocedure given in the relevant specifications and keep a record of the sts.
- 1.3 For each production quanta, at least one percent sheaths shall be ken at random. Half the number of sheaths in the sample shall be sted for water leakage (see 2.4) and the other half for air inflation see 2.6).
- A-1.3.1 Sheaths produced from the same rubber latex and under the me processing and finishing conditions shall constitute a quanta.

-2. SAMPLING FOR ACCEPTANCE

-2.1 Scale of Sampling

A-2.1.1 Lot — In a single consignment all the rubber protective heaths of same dimensions, same mass and produced on the same line of production on the same day shall constitute a lot.

- A-2.1.2 Samples shall be tested from each lot separately for ascertaining the conformity of the lot to the requirements of this specification.
- A-2.1.3 Samples from the lot shall be selected at random. The required number of sheaths in the sample shall be obtained by selecting an approximately equal number from as many packages as possible. It is, however, recommended that for this purpose adequate number of packages may be selected so that about 10 sheaths are taken from each package to constitute the required sample size. The selection of packages and sheaths from a package shall be done at random.

Note — This recommendation is based on the information that 48 sheaths are packed in a package referred in A-2.1.3.

- A-2.1.4 In order to ensure the randomness of selection, procedures given in IS: 4905-1968* may be followed.
- A-2.1.5 The number of sheaths to be selected from a lot shall depend upon the size of the lot and shall be according to Table 1.

TABLE I SCALE OF SAMPLING AND PERMISSIBLE NUMBER OF DEFECTIVES

Number of Sheaths in the Lot	Sample Size	ACCEPTANCE NUMBER
(1)	(2)	(3)
Up to 3 000	126	3
3 001 to 10 000	200	.5
10 001 to 35 000	316	7
35 001 to 150 000	500	10
150 001 to 500 000	800	14
500 001 and above	1 250	21

A-2.2 Number of Tests and Criteria for Conformity

- A-2.2.1 Half the number of sheaths in the sample shall be tested for water leakage (see 2.4) and the other half for air inflation test(see 2.6). A sample sheath failing corresponding test shall be considered as defective. The lot shall be considered as conforming to the requirements for these tests if the number of defectives found in the sample is less than or equal to the corresponding acceptance number given in col 3 of Table 1.
- A-2.2.2 If the lot has been found in conformity with A-2.2.1, 32 sheaths shall be chosen afresh from the lot at random. Each of these sheaths shall be tested for visual and dimensional requirements as given

^{*}Methods for random sampling.

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in 2.1, 2.2 and 2.3 of this specification. Any sheath failing to meet one or more of these requirements shall be considered as defective. The lot shall be declared as conforming to these requirements if the number of defectives found in the sample does not exceed one.

A-2.2.3 The lot which has been found satisfactory according to A-2.2.2 shall be further tested for tensile properties (see 2.5) and colour fastness (see 2.7). Out of the sample sheaths found satisfactory according to A-2.2.2, 20 sheaths shall be used for testing tensile properties and 10 for colour fastness. The lot shall be declared as conforming to these requirements if no failure occurs; otherwise not.

(Continued from page 2)

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ISO 506: 1992

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Indian Standard
METHODS OF TEST FOR NATURAL

RUBBER LATEX

PART 7 DETERMINATION OF VOLATILE FATTY ACID NUMBER

(Second Revision)

ICS 83.040.10

468

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BUREAU OF INDIAN STANDARDS MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG NEW DELHI 110002



ISO 506: 1992

. Indian Standard

METHODS OF TEST FOR NATURAL RUBBER LATEX

PART 7 DETERMINATION OF VOLATILE FATTY ACID NUMBER (Second Revision)

1 Scope

This International Standard specifies a method for the determination of the volatile fatty acid number of natural rubber latex concentrate.

The method is not necessarily suitable for latices from natural sources other than Hevea brasiliensis and is not applicable to compounded latex, vulcanized latex, artificial dispersions of rubber or synthetic rubber latices.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 123:1985, Rubber latex - Sampling.

ISO 124:1992, Rubber latices — Determination of total solids content.

ISO 126:1989, Natural rubber latex concentrate — Determination of dry rubber content.

3 Definition

For the purposes of this International Standard, the following definition applies.

3.1 volatile fatty acid (VFA) number of latex concentrate: The number of grams of potassium hydroxide equivalent to the volatile fatty acids in latex concentrate containing 100 g of total solids.

NOTE 1 If substances have been added to the latex which produce volatile acids on acidification with sulfuric acid, the volatile fatty acid number is high and does not represent the volatile fatty acid content without correction.

4 Principle

A test portion is coagulated with ammonium sulfate and a portion of the resultant serum is separated and acidified with sulfuric acid. The acidified serum is steam-distilled and the volatile acids present in the test portion are determined by titration of the distillate with a standard volumetric barium hydroxide solution. •

5 Reagents

During the analysis, use only reagents of recognized analytical quality, and only distilled water or water of equivalent purity.

- 5.1 Ammonium sulfate, approximately 30 % (m/m) solution.
- **5.2 Sulfuric acid**, approximately 50 % (m/m) solution.
- **5.3 Barlum hydroxide**, standard volumetric solution, $c[Ba(OH)_2] = 0.005 \text{ mol/dm}^3$, standardized by titration with potassium hydrogen phthalate and stored in the absence of carbon dioxide.
- 5.4 Indicator solution: either bromothymol blue or phenolphthalein solution, 0.5% (m/m) in a mixture of approximately equal volumes of ethanol and water.

6 Apparatus

Ordinary laboratory apparatus and

ISO 506: 1992

6.1 Steam-jacketed distillation apparatus (Markham still), conforming essentially to figure 1. As an alternative to the one-piece apparatus illustrated, a ground-glass joint may be inserted between the distillation vessel and the condenser.

6.2 Steam-bath, or

- 6.3 Water-bath, capable of being maintained at a nominal temperature of 70 °C.
- 6.4 Pipettes, of capacity 5 cm³, 10 cm³, 25 cm³ and 50 cm³.
- 6.5 Burette, of suitable capacity.

7 Sampling

Carry out the sampling in accordance with one of the methods specified in ISO 123.

8 Procedure

- 8.1 If the total solids content and dry rubber content of the latex concentrate are not known, determine them in accordance with ISO 124 and ISO 126, respectively.
- 8.2 Into a beaker weigh, to the nearest 0,1 g, about 50 g of latex concentrate. Accurately add 50 cm³ of the ammonium sulfate solution (5.1) from a pipette (6.4), while stirring the latex concentrate. Either place the beaker on the steam-bath (6.2) or in the water-bath (6.3), maintained at 70 °C, and continue stirring the latex concentrate until it coagulates. Cover the beaker with a watch-glass and leave it on or in the bath for a total period of 15 min. Decant the serum which exudes through a dry filter paper. Transfer the coagulum to a mortar and press out more serum by kneading it with a pestle. Filter this serum through the same filter. Pipette 25 cm³ of the filtered serum into a dry 50 cm³ conical flask and acidify it by accurately adding 5 cm³ of the sulfuric acid solution (5.2). Mix well by swirling the flask.

With certain latex concentrates, in particular those preserved with potassium hydroxide, a fine precipitate may form during the acidification step. This precipitate shall be removed by filtration through a fresh dry filter paper before proceeding with the distillation process.

Pass steam through the apparatus (6.1) for at least 15 min. With steam passing through the outer jacket of the apparatus (steam outlet open), introduce into the inner tube 10 cm³ of the acidified serum by pipette (6.4). If foaming is a difficulty, 1 drop of a suitable antifoaming agent may be added. Place a

100 cm³ graduated cylinder under the tip of the condenser to receive the distillate. Partially close the steam outlet to divert steam into the inner tube. Pass steam gently at first, then fully close the steam outlet and continue distilling at a rate of 3 cm³/min to 5 cm³/min until 100 cm³ of distillate has been collected.

Transfer the distillate to a 250 cm³ conical flask and eliminate any dissolved carbon dioxide from the distillate by passing through it a stream of air free from carbon dioxide at a rate of 200 cm³/min to 300 cm³/min for approximately 3 min. Titrate with the barium hydroxide solution (5.3), using one of the indicators specified (5.4).

8,3 Carry out a duplicate determination (see 8.2) with a fresh 50 g test portion of latex concentrate.

9 Expression of results

Calculate the volatile fatty acid (VFA) number using the formula

$$\left[\frac{134,64cV}{m\,\text{TSC}}\right]\times\left[50+\frac{m(100-\text{DRC})}{100\rho}\right]$$

where

- is the actual concentration, expressed in moles per cubic decimetre, of the barium hydroxide solution (5.3);
- V is the volume, in cubic centimetres, of barium hydroxide solution required to neutralize the distillate;
- m is the mass, in grams, of the test portion;
- DRC is the dry rubber content, expressed as a percentage by mass, of the latex concentrate;
- TSC is the total solids content, expressed as a percentage by mass, of the latex concentrate;
- ρ is the density, in megagrams per cubic metre, of the serum¹⁾;
- 134,64 is a factor derived from the relative molecular mass of potassium hydroxide, its equivalence to barium hydroxide and those parts of the serum acidified and distilled.

Repeat the test if the results of the duplicate determinations do not agree to

 within 0,01 units when the actual VFA number is 0,10 units or less;

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 within 10 % when the actual VFA number is greater than 0,10 units.

10 Test report

The test report shall include the following particulars:

- a) a reference to this International Standard;
- all details necessary for the identification of the test sample;

- c) the results, and the units in which they have been expressed;
- d) any unusual features noted during the determination;
- e) any operations not included in this International Standard or in the International Standards to which reference is made, and any operations regarded as optional.

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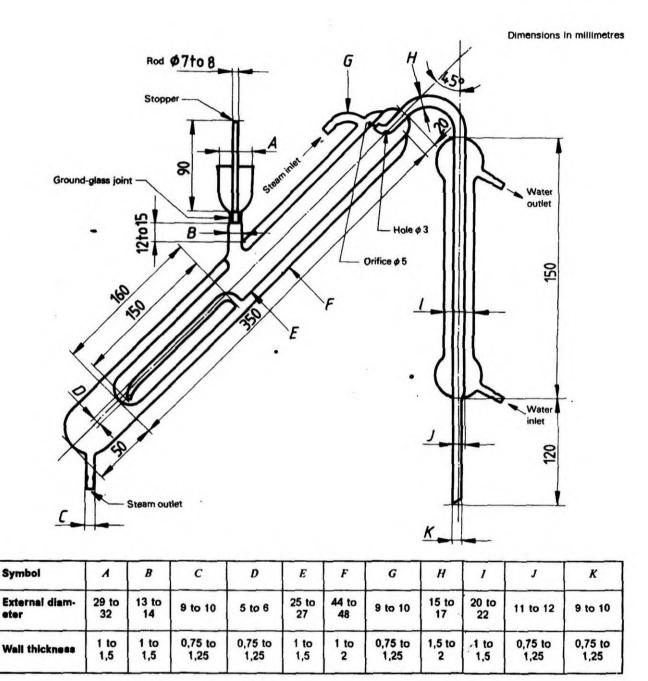


Figure 1 — Steam-jacketed distillation apparatus (Markham still)

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This Indian Standard has been developed from Doc: No. PCD 13 (2172).

Amendments Issued Since Publication

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NATIONAL FOREWORD

This Indian Standard (Part 7) (Second Revision) which is identical with ISO 506: 1992 'Rubber latex, natural, concentrate — Determination of volatile fatty acid number' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of the Rubber and Rubber Products Sectional Committee and approval of the Petroleum, Coal and Related Products Division Council.

The text of ISO Standard has been proposed to be approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

The Technical Committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards and has decided that they are acceptable for use in conjunction with this standard:

International Standard

Title

ISO 123: 1985

Rubber latex — Sampling

ISO 124: 1992

Rubber latices — Determination of total solids content

ISO 1264 1989

Natural rubber latex concentrate — Determination of dry rubber content

In reporting the results of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2: 1960 'Rules for rounding off numerical values (revised)'.