

<sup>1</sup>[SCHEDULE R

[See Rule 125]

*Standards for condoms made of rubber latex intended for single use and other mechanical contraceptives.*

I-Condoms

1. *Description.* -Condoms consist of cylindrical rubber sheaths with one end open. The open end shall terminate with an integral rim. The closed end may have a receptacle. They may be supplied rolled and shall be free from tackiness and shall be capable of being unrolled readily.

2. *Materials.* - (1) Condoms shall be manufactured from good quality rubber latex and shall be free from embedded grit and shall be opaque or translucent prior to the application of dusting materials or lubricants;

(2) The rubber latex, colours used and any dusting materials or lubricants applied to the condoms shall neither contain nor liberate substances which are known to have toxic or other harmful effects under normal conditions of use. Any dusting material or lubricant or colour used shall not have deleterious effect on the condoms or be harmful to the users.

3. *Procedure for sampling during production.* - (1) Specimens constituting the test samples shall be taken at random successively from each quantum of production that is, from the quantity produced from the same finished rubber latex and under the same processing and finishing conditions of manufacture and samples from each quantum shall be tested separately to ascertain conformity of quantum with the specified requirements in accordance with the tests described in this Schedule.

(2) (a) The number of samples drawn from each quantum shall be not less than 0.5 per cent of the number.

(b) The number of samples drawn from each quantum shall be tested for Burst Volume and Pressure Test and Water Leakage Test in accordance with the method prescribed in paras 9 and 10 of this Schedule; 75 per cent of the samples drawn will be tested for Water Leakage Test and 25 per cent will be tested for Burst Volume and Pressure Test.

(c) The number of test samples 'N' and the number of rejected samples 'R' from a sequence of production quant a shall be recorded in a register. The cumulative total of test samples

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1Subs, by G.O.I. Notification No. GSR 495(E) dt 9.6.1995

'N' and the cumulative total of rejects 'R' from the test shall be recorded and the condoms shall be deemed to comply with the requirements if the cumulative total of rejects 'R' is not more than  $^2[0.0025N+3 \times \sqrt{0.0025N}]$  for Water Leakage Test, and  $^3[0.01N+3 \times \sqrt{0.01N}]$  for Burst Volume and Pressure Test.

- (3) Each unit of 100 test samples shall be distributed for the various tests and follows: -

25 for Burst Volume Pressure Test, and; 75 for Water Leakage Test

- (4) Where the number of test samples is a multiple of 100 the distribution scale mentioned above shall be prorated.

(5) If the cumulative total sample rejected exceeds the number of allowables at any point in the sequence of quanta, the quantum at which this occurs shall be liable to rejection. The assessment of quality of further production quanta shall include all previous test results starting from quantum number 1 and approval of production shall be in suspense until the condition required by the scheme is again fulfilled.

(6) At least one sample shall be taken at random from each production quantum not exceeding 10,000 condoms and shall satisfy all requirements regarding dimensions as specified in paragraph 8 of this Schedule.

4. *Procedure for sampling and testing of finished products by a manufacturer-*

A. *Water Leakage Test.*- (1) Statistical sampling for quality control assessment of the finished product in respect of Water Leakage Test shall be done in accordance with the plan set out in Annexure I to this Schedule.

(2) A test sample failing in the above test is to be considered as defective. If the cumulative total of rejects 'R' is found to be equal to or greater than the number shown against 'R' in Annexure-I, the batch or lot shall be declared as not of standard quality.

B. *Bursting Volume and Pressure Test.*- (1) Sample condoms shall be tested for Bursting Volume and Pressure Test. Statistical sampling for this test shall be done in accordance with the plan set out in Annexure III to this Schedule.

Condoms shall not leak or burst at a volume of less than that specified or at a pressure less than 1.0 kpa (gauge), when tested as per paragraph 9, both before and after oven conditioning as specified in annexure V. Bursting Volume minimum limit in litres shall be equal to  $\frac{[\text{mean condom width (mm)}]^2}{151.8}$  rounded to the nearest 0.5 litre.

(2) A test sample failing in the above test is to be considered defective. If the cumulative total of rejects 'R' is found to be equal or greater than the number shown against 'R' in annexure III, the batch or lot shall be declared as not of standard quality.

*C. Dimensions.* - At least 2 samples drawn from the lot or batch shall satisfy the requirements regarding Dimensions as specified in paragraph 8 of the Schedule.

5. *Procedure for sampling and testing of condoms by a purchaser.-*

A. *Water Leakage Test.*- (1) Statistical sampling of condoms by a purchaser for Water Leakage Test shall be done in accordance with the plan set out in annexure II to this Schedule;

(2) A test sample failing in the above test is to be considered as defective. If the cumulative total of rejects 'R' is found to be equal to or greater than the number shown against 'R' in the Annexure-II, the batch or lot shall be declared as not of standard quality.

B. *Bursting Volume and Pressure Test.*- Sample condoms shall be tested for Bursting Volume and Pressure Test. Statistical sampling for this test shall be done in accordance with the plan set out in Annexure III to this Schedule. If the cumulative total of rejects 'R' is found to be equal to or greater than the number shown against 'R' in Annexure III, the batch or lot shall be declared as not of standard quality.

Condom shall not leak or burst at a volume of less than that specified or at a pressure less than 1.0 kpa (gauge), when tested as specified in paragraph 9, both before and after oven conditioning as per specified in Annexure V. Bursting volume minimum limit in litres shall be equal  $[\text{mean condom width (mm)}^2]$  rounded to the nearest 0.5 litre.

151.8

*Dimensions.* - At least two samples from the lot or batch shall satisfy the requirements regarding dimensions as specified in paragraph 8 of this Schedule.

6. *Sampling plan for a Drugs Inspector.* - (1) Where an Inspector under the Act, desires to take for test samples from the premises of manufacturer or a distribution depot; twenty containers from each batch of production may be selected by him on a random basis and from each of these containers, five samples shall be taken. The hundred samples so selected shall be distributed for various tests as specified in paragraph 7 of this Schedule. In case the number of containers is less than twenty, the number of samples to be taken from each container shall be proportionately increased.

(2) Where an Inspector under the Act, desires to take samples from a sales premises, he shall take hundred samples from each batch of production in accordance with the procedure as specified in sub-paragraph (1).

7. Sampled condoms drawn under sub-paragraph (1) shall be distributed for various tests as follows: -

Two samples for thickness, length and width;  
Forty-five samples for Water Leakage Test;  
Forty-five samples for Bursting Volume and Pressure Test; and  
Eight samples as reserve.

The samples shall be declared as not of standard quality, if, - (i) the number of condoms found defective in the Water Leakage Test exceeds one; (ii) the number of condoms found defective in Bursting Volume and Pressure Test exceeds two; (iii) samples fail to conform to the requirements of dimensions as specified in paragraph 8 of this Schedule.

8. *Dimensions.* - (1) the length when unrolled (excluding teat) shall be not less than. -

(i) 170mm

(ii) 180 mm

(2) The width of a condom which laid flat and measured at any point within 85 mm from the open end shall be,

(i)  $49 \pm 2\text{mm}$  for 170mm length

(iii)  $52 \pm 2\text{mm}$  for 180mm length.

(3) The single-wall thickness of a condom when measured at three points, one at  $30 \pm 2\text{mm}$  from the open end,  $30 \pm 5\text{mm}$  from the close end excluding the reservoir tip and at the mid distance between these two point shall be from 0.045 mm to 0.075 mm.

NOTE 1. - The single-wall thickness shall be determined with a suitable micrometer dial gauge graduated in intervals of 0.01 mm.

NOTE 2. - Condoms shall, prior to the measurement of thickness, have the dusting powder or the lubricant or both removed by means of water or Isopropanol.

9. *Bursting Volume and Pressure Test.* - Determination of Bursting Volume and Pressure Test shall be done as specified in Annexure IV.

10. *Water Leakage Test.* - Unroll the condom and fit the open end on a suitable mount, the condom thus being suspended open end upwards. Fill it with 300ml water at room temperature and inspect it after a period of at least 1 minute for leakage up to 25mm from the open end because of distension of the condom the water does not extend to 25mm from the open end. If raise the closed end until the water level reaches this distance. After at least 1 minute, inspect the newly-wetted part of the condom for leakage. The condom shall be deemed to be defective if it bursts during test or shows any evidence of leakage or seepage of micro-droplets or does not hold 300ml water.

11. *Quantity of Lubricant.* -(1) The condoms shall be dressed with silicone lubricant. The quantity required on each individual condom should not be less than 200 mg and minimum viscosity shall be 200 centistokes.

(2) Lubricated condoms in individual foil packages shall be weighed on an Analytical Balance. Each condom shall be removed from its foil package and both condom and its foil package shall be washed in denatured ethanol or isopropanol, dried and then weighed again. All weights shall be recorded to the nearest milligram (mg.). Compliance with the requirement shall be determined by subtracting the weight of the washed and dried condom and its foil package from the weight of sample condom in individual foil package prior to the removal of lubricant. Washing and drying may be required upto a total of four times if the lubricant quantity is less than the required minimum.

(3) At least thirteen samples shall be drawn from the lot or batch and the samples shall satisfy the requirements regarding the quantity of lubricant.

12. *Colour Fastness.*- Not less than ten samples taken at random from each batch of coloured condoms shall pass the following test for colour fastness, namely :-

Thoroughly wet inside and outside of the condom 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 hours to 24 hours at room temperature. After removing the absorbent paper from the container, examine it visually the 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.

13. *Labelling, packing and storage.* - (1) The condoms shall be individually wrapped and sealed in laminates containing at least eight microns of aluminium foil. The individual condom shall be packed in square (non-squeeze condition) / rectangular aluminium foil. The packing shall protect the condoms from contamination and mechanical damage. The smallest packing offered to the consumer shall bear a clear permanent marking with the following particulars, namely: -

- (i) Manufacturer's name and address and the trade name of the condoms, if any;
- (ii) Batch number;
- (iii) Date of manufacture (Month and year only);
- (iv) Date of expiry (Month and year only) which shall not be more than thirty-six months from the date of manufacture;
- (v) The words "For single use only"

(2) The condoms shall be stored in a cool dry place away from heat and direct sunlight.

14. *Integrity of individual package seals.* - Sample condoms in individual packages shall be placed in a sealed, transparent container (such as a laboratory Bell jar) and subjected to vacuum of  $50 \pm 10$  kpa (gauge) for a period one minute.

Condom packages that do not inflate or remain inflated for the period of the test shall be deemed non-compliers. In doubtful cases, the test may be repeated, and both the inflation and deflation of packages may be observed on application and removal of vacuum. An AQL of 2.5 per cent will be applied in assessing the results of this test. Thirty-two samples of condoms for a batch size less than 5 lakhs and fifty samples of condoms for batch size more than 5 lakhs shall be tested for integrity test of individual package seals and compliance limit or acceptance number shall be not more than two or three condoms respectively.

## II- Other Mechanical Contraceptive

15. *Standards for other mechanical contraceptive* - Standards for 'Copper T' and 'Tubal Ring' shall be as laid down in Annexure VI.

\*[ANNEXURE I

[See Paragraph 4-A]

Sampling Plan for Quantity Control of Condoms at Manufacturer's Level.

### BATCH SIZE: 35,001 TO 1.5 LAKH.

Single Sampling Plan.			
Sample Size 200:	AQL	-	0.25
	AC	-	1
	R	-	2

### BATCH SIZE: 150001 TO 5 LAKHS

Single Sampling Plan.			
Sample Size 315 :	AQL	-	0.25
	AC	-	2
	R	-	3

\* Annexures I to III subs. by G.O.I. Notification No. GSR 353(E) dt 26-4-2000.

### BATCH SIZE: OVER 5 LAKHS

Single Sampling Plan.			
Sample Size 500:	AQL	-	0.25

AC	-	3
R	-	4

*Note :* AQL denotes Acceptance Quality Level;  
AC denotes Acceptance Number i.e. the maximum allowable number of defectives  
for acceptance of the Batch; and  
R denotes Rejection Number i.e., the minimum number of defectives for rejection  
of the Batch.

## ANNEDURE II

[See Paragraph 5-A]

Sampling Plan for Quality Control of Condoms at Purchaser's Level.

BATCH SIZE: 35,001 TO 1.5 LAKHS

Single Sampling Plan.		
Sample Size 200:	AQL	- 0.25
	AC	- 1
	R	- 2

BATCH SIZE : 15,001 TO 5 LAKHS

Single Sampling Plan.		
Sample Size 315:	AQL	- 0.25
	AC	- 2
	R	- 3

BATCH SIZE : OVER 5 LAKHS

Single Sampling Plan.		
Sample Size 500:	AQL	- 0.25
	AC	- 3
	R	- 4

*Note:* AQL denotes Acceptance Quality Level;  
AC denotes Acceptance Number i.e. the maximum allowable number of defectives  
for acceptance of the Batch; and  
R denotes Rejection Number i.e., the minimum number of defectives for rejection  
of the Batch.

## ANNEXURE III

[See Paragraph 4-B and 5-B]

Sampling Plan for Bursting Volume and Pressure Test.

BATCH SIZE: 35,001 TO 1.5 LAKH.

Single Sampling Plan.			
Sample Size 200:	AQL	-	1.5
	AC	-	7
	R	-	8
BATCH SIZE: 150001 TO 5 LAKHS			
Single Sampling Plan.			
Sample Size 315:	AQL	-	1.5
	AC	-	10
	R	-	11
BATCH SIZE: OVER 5 LAKHS			
Single Sampling Plan.			
Sample Size 500:	AQL	-	1.5
	AC	-	14
	R	-	15

**Note :** AQL denotes Acceptance Quality Level;  
AC denotes Acceptance Number i.e. the maximum allowable number of defectives  
for acceptance of the Batch; and  
R denotes Rejection Number i.e., the minimum number of defectives for rejection  
of the Batch.]

ANNEXURE IV

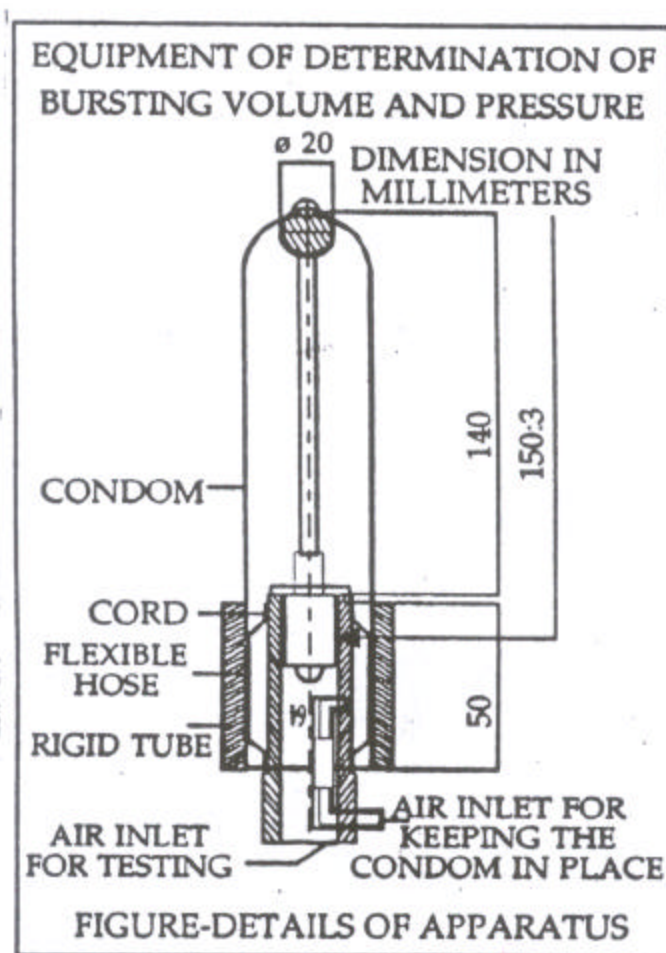
(See Paragraph 9)

*Determination of Bursting Volume and Pressure.*

1. *Principle.* - Inflation of constant length of the condom with air and recording the volume and pressure at the moment of bursting.
2. *Apparatus.* - (1) Apparatus suitable for inflating the condom with clean air at a specified rate and provided with equipment for measuring volume and pressure.  
(2) Suitable mount for fitting the condoms to the apparatus as shown in the figure annexed.  
(3) Rod, 140mm in length having a smooth sphere 20 mm in diameter at its top (see the figure) for hanging the unrolled condom when fixed to the apparatus.
3. *Procedure.* - (1) Unroll the condom, hang it on the rod (2.3), affix to the mount (2.2) and inflate with air at a rate of 0.4 to 0.5 litre/sec. (24 to 30 litres/min)  
(2) Measure and note the Bursting Volume, in litres rounded to the nearest 0.5 litre and the bursting pressure, in kilopascals rounded to the nearest 0.1 kpa.



4. *Test report.* - The test report shall include the following particulars.
- (a) the identification of the sample,
  - (b) the Bursting Volume and Bursting Pressure of each tested condom;
  - (c) the date of testing.



#### ANNEXURE V

[See Paragraphs 4(B) and 5 (B)]

#### *Oven Conditioning*

1. *Principle of the Method.* - The test consists in subjecting test samples to controlled deterioration by air at an elevated temperature and at atmospheric pressure after which Burst Volume and Pressure limits are measured.
2. *Apparatus.* - The air oven shall be of such a size that the total volume of the test samples does not exceed 10 per cent of the free air space of the oven. Provision

shall be made for slow circulation of air in the oven of not less than three changes and not more than ten changes per hour. The temperature of the oven shall be thermostatically controlled so that the test samples are kept within  $\pm 2^{\circ}\text{C}$  of the specified ageing temperature. A thermometer shall be placed near the center of the ageing test samples to record the actual ageing temperature.

*Note:* - Copper or Copper alloys shall not be used for the material of construction of the oven prescribed.

3. *Test sample.* - The foil laminations of individual packages should remain intact throughout all laboratory handling including over conditioning.

4. *Temperature of the oven* – Maintain the oven at  $70 \pm 2^{\circ}\text{C}$ .

5. *Duration of test.* - 96 hours.

6. *Procedure.* - Condition the requisite number of unopened packages of rubber condoms in the oven at  $70 \pm 2^{\circ}\text{C}$  for 96 hours. After heating, keep the packages at  $23 \pm 5^{\circ}\text{C}$  for at least 12 hours but not more than 96 hours. Open the packages and examine conditioned condoms for thickness, brittleness, or other signs of deterioration. Within 96 hours but not sooner than 12 hours after conditioning, do the Bursting Volume and Pressure Test as described in this Schedule.

## ANNEXURE VI

(See Paragraph 15)

1. *Standards for Copper T (200B) (IS-12418 (part 4)-1991-UDC 615.477.87.*  
- Contraceptive Device Copper T (200B) shall conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards.

2. *Standards for Contraceptive Tubal Ring (IS 13009 : 1990-UDC 615.472.6 : 611.656).*- Contraceptive Device Tubal Ring shall conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards.]

## <sup>1</sup>[SCHEDULE R-1

(See Rules 109-A and 125-A)

The following medical device shall conform to the Indian Standards specification laid down from time to time by the Bureau of Indian Standards: -

(1) Sterile Disposable Perfusion sets for single use only (Sections 2 and 3 of item 1 of IS 9824:1981 read with Amendment number 1).

(2) Sterile Disposable Hypodermic Syringes for single use only (IS 10258 : 1982).

(3) Sterile Disposable Hypodermic Needles for single use only (IS 10654 : 1991)]