

Technical Support Group – Condom Promotion

Department of AIDS Control

311-312, 3rd Floor, Competent House, F -14, Middle Circle, Connaught Place,

New Delhi - 110001

Tel: 011-43696600, Fax: 011-43696666

Dated: 17/12/2013

Request for Proposal

Condom Quality Audit

1. The Department of AIDS Control (DAC) has set up the Technical Support Group (TSG) - Condom Promotion to gear up its efforts towards increasing use of condoms and growth of market for social marketing condoms.
2. The success of condom promotion to prevent HIV/AIDS, STIs and unwanted pregnancy hinges directly on quality of condoms and therefore it is critical to know about the quality of condoms that are available in market.
3. In this regard, a need has been felt to to carry out quality audit nationally for different condom brands in order to determine the quality of condoms available at retail outlet for end users.
4. The bidder should have an average annual minimum turnover of Rs.50 Lacs during last three years.
5. The applying firm must have PAN (Permanent Account Number) and be registered with the Sales Tax / Value Added Tax, Service Tax and the documents for the same are to be provided.
6. Audited financial statements (Income & Expenditure Accounts and Balance Sheet) duly certified by Chartered Accountant of last 3 financial years have to be attached with the technical bid.
7. The agencies are expected to provide following information:
 - a. Name, address and facsimile number
 - b. Name of contact person and his/her contact details
 - c. Name and CV of proposed team members.
 - d. Capability statement (not more than 5 pages)
 - e. Ownership and organization structure of the agency
 - f. Audited statements for the last 3 financial years

- g. Information supporting their experience, capability and specialization in conducting similar kind of research studies
- h. List of major assignments of similar nature and in the area of public health undertaken (separate list for the studies for different domain)
- i. The information on adequacy and availability of resources to carry out the assignment
- j. Technical Proposal with detailed methodology and work plan for the audit
- k. Financial Proposal with detailed and bifurcated costing for Salaries, Field work & Other Expenditures. Please use the following template for financial quote.

Sl. No.	Name	Designation	Per day payout	No. of Days Involved	Total
<i>Salaries</i>					
<i>Field Work</i>					
<i>Other Expenses</i>					
Sl. No.	Activity		Price per unit/Day	No. of Units / Days	Total

8. The RFP shall be evaluated strictly based on the substantive information/credentials/documentary evidences submitted by the agency in support of the information (as suggested in point No. 5).
9. Based on the information submitted by the agencies in response to RFP, Technical Support Group-Condom Promotion, DAC will shortlist agencies who will be informed in due course.
10. HLPPT shall without prejudice to its other remedies under the contract, deduct from the Contract Price, as Liquidated Damages a sum equivalent to 2.5% of the contract price of agreed unperformed services or for delay of each day until actual delivery or performance, up to a maximum deduction of 20% of the contract Price. Once the maximum is reached, HLPPT may consider termination of the contract.
11. In the event of award of contract the bidder shall be able to start services immediately. If the services are not supplied within specified timeline penalty clause will be applicable.

12. Agencies who will obtain 70% marks or more in Technical evaluation only would be considered for further discussion.
13. The agencies not qualified in the technical evaluation by the committee will not be entertained for financial bid.
14. Points obtained by the Agency for both Technical as well as Financial Proposal would be clubbed for the final selection with 70% weight for Technical and 30% weight for Financials. The detailed breakup of points is as under,

Category		Max. Points
I. Understanding of the TOR		12
II. Relevant experience for the assignment	a) HIV/AIDS or family planning assignments	8
	b) Other public health assignments	8
	c) Non health related assignments (retail outlet studies)	4
	d) Large scale studies (Sample Size 10,000 and above)	4
III. Methodology proposed (especially work plan)		20
IV. Qualifications and experience of key staff proposed for the assignment		16
V. Organization capability (in terms of no. of years they are into business, annual turnover, number of branch or field offices, number of professional and field staff, management structure, etc.)-		8
VI. Presentation of Technical proposal#		20
Total Marks for Technical Component		100
VI. Financial Proposal*		100

**100 marks will be allocated to the lowest priced proposal. The financial scores of the other proposals will be in inverse proportion to the lowest price.*

Agency qualifying 50 marks and above (combining score of I to V) will only be invited for presentation.

15. Agency securing highest points after adding the points earned for Technical as well as Financial proposals would be considered for final selection & negotiation.
16. In case the negotiation fails with the agency ranked first, second ranked agency will be called for negotiation.
17. HLPPT reserves the right for extending or curtailing any activity at any point of time (if required) as per programme requirement.
18. Bid submitted by agencies in consortium will not be considered for evaluation.
19. HLPPT management reserves the right to shortlist more than two agencies for the said assignment/ empanelment. It may be noted that the agency have to submit **separate** Technical and Financial proposals (**all sealed**) to the above given address. The agency will be selected in accordance with the procedures set out in the procurement guidelines of Hindustan Latex Family Planning and Promotion Trust (HLPPT).
20. Agencies would not be allowed to further subcontract, partial/full of the work will be assigned to them.

21. HLPPT reserves the right to award the work order to the second highest scoring agency in the event the first highest scoring agency backs out after final discussions
22. The Agencies should also submit an undertaking (Annexure-1) duly signed & Stamped.
23. Payment will be made through local crossed cheque or NEFT only.
24. Management Reserves the right to cancel the contract awarded if the work is not performed as per the satisfaction of the management.
25. The interested agencies may obtain additional information or clarification from TSG office during office hours [9:30 AM to 6:30 PM] **latest by 23/12/2013.**
26. The technical and financial proposals should be delivered to the **Assistant Finance Manager** at the address given above latest by **18:00 Hrs (IST) on 26/12/2013.** Any proposal received after the closing date will not be considered.

Assistant Finance Manager

Annexure-1

UNDERTAKING FROM VENDORS

This has reference to the RFP emailed to us. In response to the RFP, we have submitted our technical & financial bids on..... at your office In connection with the above bids, we hereby declare as under:-

i- That we are neither related to any of your Trustees, Officers and other employees nor do we have any financial, commercial or other interests with any of the above persons in any capacity whatsoever.

ii- That we have submitted the bids in the name of M/S..... and declare that no other bids have been submitted by us in the name of any other firms/companies/proprietors/individuals which comes under the same management and related parties.

iii- We hereby undertakes that in case of any violations to the above declarations at any stage of the contract , HLPPT reserves the sole right to cancel the contract and recover the full value of the contract from us.

For and on behalf of

(Authorized Signatory with company seal /Stamp.)

Terms of Reference

Condom Quality Audit

Background

With sexual mode being the major cause of transmission of HIV/AIDS, significant efforts have been made to increase the awareness and usage of condoms to prevent the transmission of HIV/AIDS. Other than the free distribution via public health systems, social marketing condoms (GOI subsidized brands) and commercial condoms are being marketed through traditional (chemist) and non-traditional (other than chemist) outlets.

The need to use a quality condom is extremely pertinent to get protected from HIV/AIDS, STIs and unwanted pregnancy. The success of condom promotion to prevent HIV/AIDS, STIs and unwanted pregnancy hinges directly on quality of condoms and therefore it is critical to know about the quality of condoms that are available in market. During the routine field visits, TSG observed that there are cases of near expiry condoms available in market flooded with higher trade margins, which may get expired by the time it find its way to the user. Further the deterioration in quality is also caused by improper storage.

The condoms being manufactured in India are as per the Schedule R specifications of the Drugs and Cosmetics Act, 1940. In spite of the fact that the leading condom manufacturers in India follow standards conforming to Schedule R or WHO specifications, the quality of condoms available at retail outlets especially at the non-traditional outlets (NTO's) remain a matter of concern. This is due to the availability of spurious condoms which is repacked without labels passing, through improper storage within the supply chain.

A national level study has been undertaken by TSG during 2010 to determine the quality of condoms available at consumer's level. The study results clearly validate that the GoI condom brand such as Nirodh (free supply) and Deluxe Nirodh (socially marketed) are 'Reliable' complying with all quality parameters as per schedule R Drug and Cosmetics Act, whereas few commercial brands were found to be not complied on some of the quality parameters specified in Schedule R.

Since 2010, the overall condom market has grown significantly. Many new brands have been introduced in the market during last three years. Hence, it has become very important to carry out quality audit nationally for different condom brands in order to determine the quality of condoms available at retail outlet for end users.

Objective

The objective of the proposed study is to assess the quality of paid condoms available at retail outlets as well as free condom available at Targeted Intervention sites.

Methodology

The proposed study would be quantitative in nature. It will have three distinct dimensions into it:

1. Collection of condoms
2. Lab testing of the sample condoms
3. Reporting of results of testing

Field Work Approach

In this nature of study, the investigators might face difficulties in collecting samples of condom. Further, the method also should be non-threatening to retailers. We suggest to collect the brands using **Mystery Shoppers'** technique where the data collector will act as a costumer and purchase the required brands from the retail points.

Scenario: *An educated married man aged 20-25 years looking for condom. He is aware of different brands and variants. Hence, he is asking for the desired brand confidently.*

Based on the above scenario the agency needs to develop operational guidelines for the mystery shopper giving information about the role of the mystery shopper. The guideline should cover the potential problems and obstacles and how to overcome them. A simple script will be developed by the agency in consultation with TSG, which will be used to train the mystery shoppers.

As for free condom, it may be collected from randomly selected TI sites.

Study Area

The study will be carried out in selected states representing different geographical zones of the country.

Within state the sample collection needs to be carried out at the retail outlet level in the following areas:

- Retail outlets in and around the targeted intervention sites (TI)
- Retail outlets in and around truckers' halt points (THP)
- Retail outlets from non-TI/THP areas

The list of TI & THP areas will be shared with the selected agency.

Sample Size

In India around 350 condom brands / variants are available in the market. As discussed above other than the free distribution via public health systems, social marketing condoms and commercial condoms are being marketed. This study will focus on the following brands / variants.

- All social marketing brands covered in Targeted Condom Social Marketing Programme (Maximum top 2 variants of each brand)
- Top 10 commercial brands (Maximum top 3 variants of each brand)
- Top 5 IMFC (Indian Made Foreign Condoms) brands

(Note: Packaging will not be considered as a criterion for sample selection)

Nielsen retail audit data, 2012 will be used for this purpose. Relevant data will be shared with the selected agency.

In addition to the social marketing condom brands and commercial brands, samples of free supply condom "NIRODH" will also be collected from TIs /THPs.

Normally, **the testing is conducted by the Govt approved laboratory for at least a batch of 100 samples for each brand.**

Proposed Sampling

Selection of States

All DAC prioritize states will be considered under sampling frame for selection of states. The states will be grouped zone wise to ensure proper geographical representation of the country. Within group *percent share of condom sales volume to the all India sale volume during 2012 will be considered for selection of states*. Within zone states will be selected purposively in such a manner so that all major states in terms of population and both major and minor states in terms of condom sales volume get represented. We propose to select 12 states for the study. The following grid presents detailed process of state selection.

Categories	% Share of condom sales volume to the all India sale during 2012	No. of States Available	No. of States to be selected*	Selected States
North	45%	6	4	Delhi, Rajasthan, Uttar Pradesh, Punjab
South	12%	4	2	Tamil Nadu, Andhra Pradesh
East	16%	4	2	Bihar, West Bengal
West	26%	4	3	Gujarat, Madhya Pradesh, Maharashtra
NE States	1%	7	1	Assam

**Proposed No. of states is based on % share of condom sales volume to the all India sale during 2012. (percent share less than 10%-1 state; 10%-19%-2 states; 20%-40%- 3 states; More than 40%- 4 states)*

Data Source: Nielsen retail audit data, 2012

Selection of Outlets

The No of condom pieces to be selected from state by brand will be worked out based on Nielsen retail audit data, 2012. The required sample may be distributed proportionately across states. Relevant data will be shared with the selected agency.

Within a state prioritise districts which are high HIV prevalence and / or high fertility districts will be selected for the study. Minimum 3-4 districts will be selected keeping in view the type of areas (TI / THP) to be covered. As discussed above the sample collection needs to be carried out at the retail outlet level in the following areas:

- Retail outlets in and around the targeted intervention sites (TI) (within 2-3 km radius)
- Retail outlets in and around truckers' halt points (THP) (within 1-2 km radius)
- Retail outlets from non-TI/THP areas (Area not geographically adjacent to the TI/THP areas)

Further, the outlets will be selected randomly ensuring a proper geographical spread, coverage of both rural / urban areas and TO / NTO combination.

The research agencies are encouraged to suggest alternative methodology with proper justification to strengthen the proposed study.

Laboratory Tests

Testing of condoms is done during the manufacturing process on random samples, where strength and leakage are tested. Those passing the test remain reliable for up to five years if stored correctly (in a cool, dark place).

In order to ensure that the quality status of the condoms available at the retail outlets accessible to the end users, the quality tests needs to be carried out at Government of India approved laboratory (Annexure-I). The methodology for quality testing of condoms will involve the following checks on the sample condoms:

- Dimension; thickness, length and width
- Lubricant contents
- Water leak test
- Burst volume and burst pressure test
- Vacuum test for package seal integrity

The quality of condoms should conform to the following standards as per Schedule 'R' of the Drugs and Cosmetics Act, 1940 (Annexure-II).

Parameters	Quality Standards
	Schedule R, GoI
Thickness	0.045 – 0.075 mm
Length	170-180 mm
Width	49 +/- 2 mm – 52 +/- 2 mm
Lubricant type	Silicon oil
Lubricant quantity	200 mg on minimum
Water leakage test	300 ml for a minute
Burst volume and burst pressure test	0.4 to 0.5 litre/sec (24 to 30 liter /minute)
Seal integrity	vacuum of 50± 10 kpa (gauge) for a period one minute

All condoms collected need to be coded for the brand, outlet, outlet type, town, site from which it has been collected and other information available on packaging (Manufacturer's name & address; Manufacturing & Expiry date; Batch number; The words "For single use only"; etc). Subsequently, these condoms need to be sent by the agency to the laboratory for quality testing. **(Note: The cost incurred for laboratory tests will be reimbursed by TSG on actual basis. The agency needs to submit the original bills to TSG for reimbursement.)**

The data that would be returned by the laboratory after the tests need to be integrated with the initially coded data and further a detailed analysis of the same need to be conducted.

Normally, **the testing is conducted by the laboratory for at least a batch of 100 samples for each brand**. Therefore, any brand collected in less than 100 samples, should not be sent for testing.

As per Schedule R sampled condoms drawn 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
- Eight samples as reserve

Samples shall be declared as not of standard quality, if, -

- (i) the number of condoms found defective in the Water Leakage Test exceeds 1
- (ii) the number of condoms found defective in Bursting Volume and Pressure Test exceeds 2
- (iii) Samples fail to requirements of dimensions as specified above

About 10-14 day time is required by the laboratories for testing of proposed volume of condom. The laboratories need an advance intimation of 2 weeks to conduct the testing.

Research Instrument

A simple instrument should be used across all the states to collect the samples with identification particulars. The instrument will also have an observation checklist.

Research instruments will be developed by the research agency in consultation with TSG. The final approved instrument needs to be translated in regional language and used for data collection.

Data and Report

The agency requires to submit the clean data set in SPSS format to TSG.

The report structure and analysis plan should be submitted to TSG well in advance for feedback. The analysis of data will be done by the agency and findings will be reported in form of a report and Power Point presentation.

Deliverables

The selected agency has to provide the following deliverables during the course of the assignment:

- Draft research instruments
- Finalized instruments, sampling, briefing manual, etc.
- Training schedule and agenda
- Field movement plan
- Quality control mechanism
- Progress report /Monitoring updates
- Monitoring sheet and updates on testing
- Analysis plan including dummy tables
- Raw and Clean dataset (Quantitative data in SPSS format)
- Chapterisation plan
- Draft and final reports with recommendation and Power point presentations

Timelines

The entire audit needs to be completed within 6 weeks from signing of contract. Agencies are expected to present activity wise timeline in technical proposal.

Annexure-I

List of Govt. approved Laboratories for Testing of Condom Quality

Name of Company	Address	Contact Details
SGS India Pvt Ltd	28 B/1, 28 B/2 Second Main Road, Ambattur Industrial Estate, Chennai, 600058	91 87 5444 6594,
	SGS House, 4B Adi Shankaracharya Marg Vikhroli (West), Mumbai, 400083	91 22 6640 8829
Shriram Institute for Industrial Research	19, University Road, Delhi - 110 007, (India)	91)-(11)-27667267 / 27667860 / 27667436
	14-15, Sadarmangla Industrial Area, Whitefield Road, Bangalore - 560 048	91)-(080)-28410165/28410172
	76 D & E , Sector 18, Gurgaon	(91)-(0124)-2341128/ 2347485
PRK Pharmanlysts Private Limited	Flat No's: 201 - 204, Bluechip Arcade, Himayatnagar, Hyderabad- 500 029	040 - 23223805, 23225771
CIPET	T.V.K Industrial Estate, Guindy, Chennai - 600 032	044 – 22254780/701 - 705
SIPRA LABS LIMITED	7-2-1813/5/A, Adj. to Post Office, Industrial Estate, Sanathnagar, Hyderabad - 500 018, Andhra Pradesh	91-40 23802000

Annexure-II

SCHEDULE R

Standards for condoms made of rubber latex intended for single use

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 quanta shall be recorded in a register. The cumulative total of test samples

'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 audit 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 $\left[\frac{\text{mean condom width (mm)}^2}{151.8} \right]$ rounded to the nearest 0.5 litre.

151.8

(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 $\frac{[\text{mean condom width (mm)}^2]}{151.8}$ rounded to the nearest 0.5 litre.

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 container 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

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 ± 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.