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ESTABLISHMENT OF A DEVELOPMENT PLAN
FOR THE PHARMACEUTICAL INDUSTRY

UC/ALG/85/062

ALGERIA,

Technical report: Opportunities for
production of condoms in Algeria*

Prepared for the Government of the Democratic
and People's Republic of Algeria by the
United Nations Industrial Development Organization

Based on the work of Mr. S. Fujita

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INTRODUCTION

The notion of family planning was hesitantly and modestly introduced around 1965, but due to a lack of official endorsement and allocation of funds, was condemned to stagnation.

In the first five year plan of 1981-1984, as a demonstration of understanding and a political evolution, the subject was taken up in the form of stimulating the "birth-spacing", term employed in the second five year plan of 1984-1989. While it appears now that there is a genuine desire for a family planning programme to reduce the present average of about 6:7 children per family and to diminish the annual growth rate to acceptable averages, few practical recommendations and measures have been introduced, and few special efforts in this respect have been noticed.

Due to the predominantly young population of the country (57.3% of the population are below the age of 19), the acute crisis of living accommodation coupled with the realisation of a relative economic hardship for the large-sized families, there might be a tendency for delayed marriages and child births, as well as relatively reduced family sizes, facts which might have some impact on the long-term national efforts of family planning.

Whatever the case, in view of old family and religious traditions of tolerance and acceptance, the above-mentioned effects could produce only minimal results.

Furthermore, it should be noted, that until recently there was a prevailing thought concerning the future of the country's population. Being the second largest country in Africa and the tenth in the world, Algeria should continue to develop its human resources, essential for the long-term and growth prosperity of the country, a fact which if neglected could oblige the authorities to import labour at the horizon 2000. People, being the best asset of the nation - one should stimulate their development and not inhibit it.

The other school of thought, more pragmatic and probably more short to medium-term policy oriented, backed by a wide variety of politicians and government employees, maintains that without an increased "birth-spacing", there will be no real improvement in the quality of life of the population and no hope for a sustained future growth.

Table 1 gives a summary of the demography of the country.

The rapid population growth of 3.2% per year, from about 9 million at the time of the independence to 21.6 million in 1985 and a forecast of more than 35.5 million in the year 2000, is a major factor to be considered when evaluating the development of the national economy and the evolution of the consumption.

Table 1 - Population 1980-2010

Age group	1980			2010		
	TOTAL	Male	Female	TOTAL	Male	Female
0 - 4	3,308	1,687	1,621	7,507	3,821	3,686
5 - 9	2,827	1,439	1,388	6,738	3,422	3,316
10 - 14	2,432	1,239	1,193	5,964	3,022	2,942
15 - 19	1,993	1,016	977	5,241	2,648	2,593
20 - 24	1,583	808	775	4,490	2,262	2,228
25 - 29	1,304	655	649	3,775	1,896	1,879
30 - 34	921	435	486	3,158	1,592	1,566
35 - 39	598	315	383	2,711	1,366	1,345
40 - 44	691	325	366	2,306	1,161	1,145
45 - 49	634	294	340	1,869	937	932
50 - 54	500	233	267	1,448	724	724
55 - 59	404	189	215	1,150	565	585
60 - 64	335	156	179	770	354	416
65 - 69	268	124	144	535	233	302
70 - 74	218	100	118	452	203	249
75 - 79	126	56	70	317	138	179
80+	112	42	65	218	93	125

Source: ONS Algeria No. 5, Oct. December 1984

I. IMPORT AND DISTRIBUTION OF CONDOMS

According to ENEMEDI, the National Enterprise having the monopoly of import and distribution of medical equipment and products including condoms, the quantity of imported condoms was 1,944,000 pieces (13,500 gross) in 1984 and will be 2,736,000 pieces (19,000 gross) in 1985.

This quantity appears very small when compared with the total consumption of other contraceptive devices, such as the pill and the IUD. In accordance with Prof. M. Ladjali from the Ministry of Health (Bureau Central de la Protection Maternelle et Infantile), out of 100 women under contraception, only one would depend on condoms, 80 will take the pill and 19 will have an IUD inserted. However, this is certainly not an indication of a lack of interest or a strict preference. It seems that the absence of condoms in the market determines the demand and regulates the consumption "and should the supply be secured, the ratio of 1-19-80 could drastically change".

The main reasons for which the state Enterprise ENEMEDI is not active in this field are:

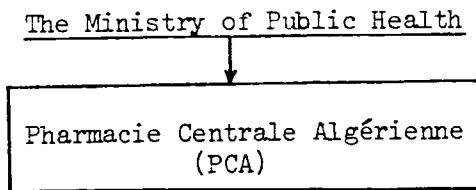
- The recent restructuring of the enterprise and the change of management.
- The priorities for importing medical equipment and its spare parts.
- The lack of data concerning the demand of condoms.
- The traditional inhibitions and hesitation for discussing the subject and for showing "excessive" interest.

There are neither specifications nor control when importing condoms in the country. Any condom from any origin, with any specification, is imported, provided the prices are competitive.

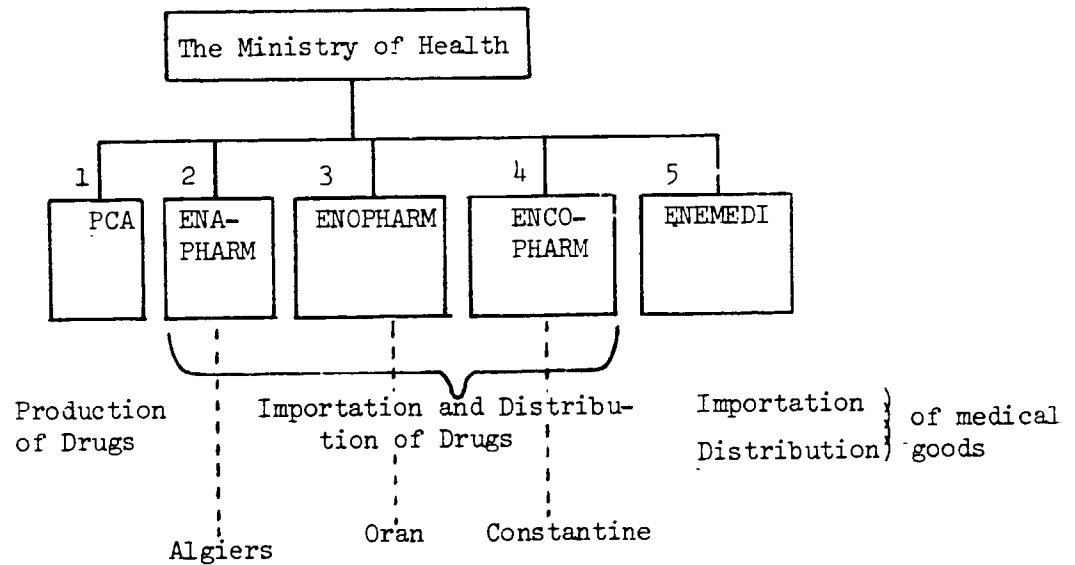
The condoms imported by international tenders from ENEMEDI are distributed through two channels - the private pharmacies and the state agents. The number of these outlets, according to the latest available statistics

Chart 1 RESTRUCTURING OF PCA

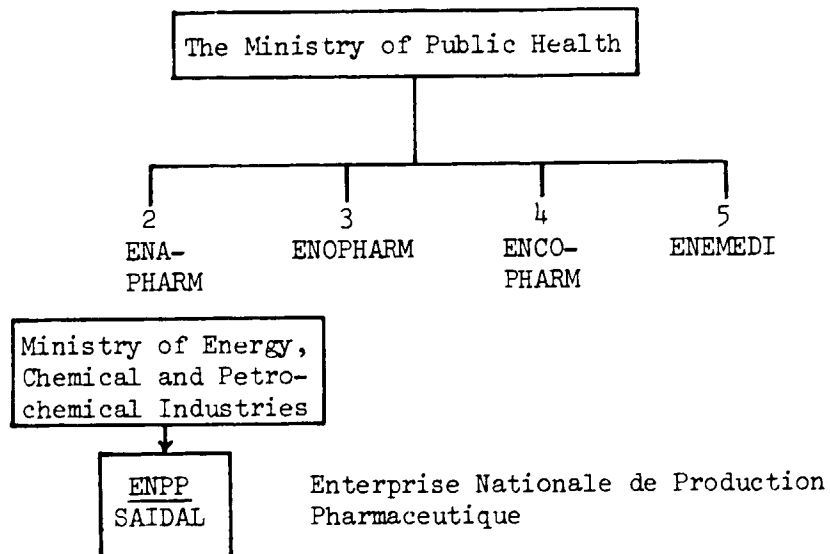
1982



1983



1984



for 1982 is 483 and 673 respectively, or a total of 1156 for the entire country. In other words, only about 16.5 gross are distributed per outlet per year, to a male population of about 7.1 million (age 20-65), representing roughly 2.5 condoms/man/year.

The scheme on the previous page (Chart 1) illustrates the various stages of the restructuring of the ex-PCA (Pharmacie Centrale Algérienne), which was originally in charge of importing and distributing condoms in the country.

Table No. 2 summarizes the usage of contraceptive methods in four developed western countries, where the preference for oral contraception is obvious. The contrary would be true in Japan, where the condoms represent 78.4% of the contraceptive methods used in 1984 (see table 3).

Table No. 2 - Percentage of Contraceptive Methods

Year	1971	1973	1975	1976
Country	<u>Austria</u>	<u>England (Wales)</u>	<u>Holland</u>	<u>U.S.A.</u>
Method				
Pill	38%	45.7%	66%	32.9%
IUD	8%	6.4%	6%	9.0%
Condom	9%	24.5%	14%	10.6%
Sterilization	?	7.4%	6	28.6%
Others	45%	16.0	8	18.9%
Total:	100%	100%	100%	100%

Source: United Nations, Fertility and Family Planning in Europe (1970-1976)

Table No. 3 - Contraceptive Methods in Japan (1973-1984)

Contraceptive Method	1973	1975	1977	1979	1984
Ogino Method (Rhythm)	29.7%	29.9%	27.0%	23.1%	19.1%
Sexual Interruption	6.2	6.7	5.1	5.2	4.0
Condoms	75.0	77.8	78.9	81.1	78.4
Washer	1.3	1.3	2.0	1.6	0.9
Tablets	4.2	3.8	3.0	2.3	1.0
Jellies	4.0	3.0	3.2	1.9	0.5
Diaphragm	3.6	2.4	1.9	1.1	0.4
Sponges	0.0	0.1	-	-	-
IUD's	9.0	8.6	9.1	8.3	8.1
Sterilization (Male)	3.6	4.7	1.3	1.1	4.7
Sterilization (Female)			4.0	2.9	8.7
Pill	2.4	3.0	3.3	3.2	3.5
Others	2.9	3.7	1.4	1.2	2.6
No response	2.3	0.0	1.8	1.2	2.5

Source: Research by the Newspaper "Mainichi" in 1984.

Remark: The excess over 100% is resulting from a double choice by some of the respondents.

II. CONDOM PRODUCTION

The manufacturing of condoms consists mainly of the following five processes: compounding, moulding, pinhole testing, packing and inspection. Today's condoms are manufactured from natural rubber latex, a milky liquid in a 60% concentration.

The production of condoms is complicated and difficult, and there are few manufacturing countries in the world, in spite of the high world requirements. It is estimated that about 40 million couples are using the condom as a method of contraception today.

The annual worldwide capacity of condom manufacturing is estimated at about 4,960 million units, out of which about 360 million are produced in Japan⁽¹⁾.

The cost of investment is rather high, as in the case of the Indonesian national project of approx. US\$ 9 million for a production facility with an annual capacity of 900,000 gross (excluding buildings) and the Vietnamese one with an annual capacity of 625,000 gross for a cost of approximately US\$ 4 million.

From the above-mentioned facts it is clear that the setting up of a condom manufacturing factory in Algeria today will be premature.

(1) It seems that on an annual basis, Pakistan, Bangladesh and Vietnam, for example, are using 500,000 gross of condoms.

III. PACKAGING OF CONDOMS

Due to rather high level of investment for a complicated condom production, many condom-consuming countries still depend on foreign supply.

However, if the consumption of condoms reaches from 100,000 gross to 300,000 gross per annum, several countries have installed packaging facilities with simple testing apparatus, such as Sweden, France, Switzerland, Thailand and Denmark.

Should the demand of condoms become of this scale, it is proven that a packing factory for bulk imported condoms will become feasible on a commercial basis.

The cost of bulk condoms on the international markets would be in the range of:

@US\$ 2.50 - 5.00/gross (ISO standard grade)
(These prices vary according to quantity, too).

The cost of a heat-sealing machine for packaging 5,000 gross to 10,000 gross per month will vary from US\$ 50,000 to US\$ 200,000.

The packing machines are of various types, but they normally include a lubrication apparatus. There are mainly two types of packing machines for packing in oblong and square strips.

For strip packing, polyethylene laminated cellophane tape and aluminium laminated cellophane tapes are used. From the point of view of cost, the oblong type and the polyethylene laminated cellophane are the lowest, whereas the square type aluminium laminated cellophane is the highest.

Anti-humidity treated laminated tape may not always be available in every country and should be imported.

The specifications of the packing tapes are given in Table No. 4.

Table 4 - Specification of Packing Tapes

Type	Material	Width	Quantity per gross
Aluminium tape	Cellophane PT No. 30		10 metre
	Polyethylene 15 micron	72mm	
	Aluminium 7 micron	or	
	Polyethylene 40 micron	144mm	
Poly-Cello tape	Cellophane PT No. 300	72mm	10 metre
	Polyethylene 50 micron	or 144mm	

Assuming that the bulk price of condoms is of US\$ 2.00/Grs, that the packing tape costs US\$ 0.50/Grs, that labour and other costs are @US\$ 0.50 and that the depreciation of the packing machine is of 5 years (the smallest scale and the most inexpensive type), the calculation could be as follows:

Bulk condoms (Tested)	@US\$ 2.00 x 20,000G = US\$ 40,000
Packing tape	@US\$ 0.50 x 20,000G = US\$ 10,000
Labour and other costs	@US\$ 0.50 x 20,000G = US\$ 10,000
Depreciation	@US\$ 0.50 x 20,000G = US\$ 10,000
<hr/>	
Total	US\$ 70,000 ⁽¹⁾

$$\text{US\$ } 70,000 : 20,000\text{G} = \text{US\$ } 3.50/\text{Grs.}$$

Compared with the present import costs of DM 7.90 = US\$ 2.53, it is not recommended to have a packing machine in case of a market demand of 20,000 gross.

When calculating the case of 50,000 gross and 100,000 gross on the base of the assumptions, the figures are as follows:

(1) In this calculation, the material for boxes of a dozen or a 1/4 dozen has not been taken into consideration, since generally free condoms from donor agencies do not require such luxurious packing.

	<u>50,000 gross</u>	<u>100,000 gross</u>
Cost of condoms	US\$ 100,000	US\$ 200,000
Tape cost	25,000	50,000
Depreciation	10,000	10,000
Labour and others	25,000	25,000
	<hr/>	<hr/>
	US\$ 160,000	US\$ 285,000
	+ 50,000	+ 100,000
	<hr/>	<hr/>
	US\$ 3.20/Grs	US\$ 2.85/Grs

From these figures it is clear that if the market demand could become over 100,000 gross, the production costs become comparatively smaller and lower than the ISO grade semi-packed condoms.

IV. REQUEST AND RECEIPT OF CONDOMS FROM DONOR AGENCIES, QUALITY CONTROL OF CONDOMS

Various international donor agencies, representing UNFPA, WHO, USAID, SIDE, IPPF and others, have supplied condoms free of charge to the family planning activities in developing countries for almost 20 years.

Until clear policies concerning the birth-spacing programmes are established, the proper budgets provided and the distribution channels organized, it is recommended to request the international donor agencies to participate in the family planning activities in Algeria also with condoms, as they do apparently with IUD's at present.

In any case, either through a direct purchase of condoms, or through a supply from donor agencies, assurance tests at the time of acceptance should be performed.

(Ref. Annex 1, International Condom Standard, ISO).

In this connection, it is recommended to have a small testing apparatus to carry out the inspection, after a short training in a reliable testing institute or a leading manufacturer.

- The testing apparatus required for the laboratory are as follows:
 - a) Rule
 - b) Balance dispenser
 - c) Dial gauge
 - d) Tensile strength tester
 - e) Dumb bell cutter
 - f) Ageing oven
 - g) Water filling apparatus
 - h) Bursting volume testing apparatus

- Space required for these tests is about 30 m² only.

- Cost required for these apparatus is approximately US\$ 46,000.

- Testing factors for the condoms are as follows:

A. Dimensions:

1. Length and Width

Measurement:

Prepare a measuring rule (the smallest calibrations in millimetres), 10 mm in width and 30 cm or longer in length, with its ends rounded.

Hold the test end of a test sample, and insert the rounded end of the rule into the sample from the rim part of the sample to its test end.

Unroll the test piece, read the calibration when the test piece is fully unrolled.

Measure the average length and record it on the test data sheet.

2. Thickness

Measurement:

In advance, adjust the point "O" of the gauge (calibration precision: 0.01 x 10 mm).

Put a test sample on the table. Measure the thickness between two opposing points 80 mm from the rolled end and record it on the test data sheet.

B. Elongation at break, tensile strength and elongation at break after ageing (JIS T9111)

Elongation at Break	Tensile Strength	Elongation at Break
<u>before Ageing</u>	<u>before Ageing</u>	<u>after Ageing</u>
No less than 600%	No less than 200 Kg/cm ²	No less than 540%

Measurement:

In advance, make sure that the test sample is not scratched. Put the test sample on the cutting table and cut it with a dumb bell cutter. Collect two test pieces from each sample condom.

Place a test piece flat on the table and mark index lines with a bench marker.

With a thickness gauge (calibration precision 0.01 x 10 mm), measure the thickness at three points between the index lines marked on the test piece. Consider the lowest value as that of the thickness of the test piece and write it on the test data sheet.

Read the length of the elongation and the load at break and write these values on the test data sheet. Repeat this procedure for the remaining test samples.

1. Ageing test:

Ageing conditions:

With a gear-type ageing tester, an air-oven ageing test is conducted at $70 \pm 1^{\circ}\text{C}$ for 72 hours.

Leave aged samples in room temperature for a full day and measure samples in the same manner as stated earlier.

Computation methods

$$\text{Elongation (\%)} = \frac{\text{Length of elongation at break} - \text{Original length}}{\text{Original length}} \times 100$$

Note: Original length = 2 cm

$$\text{Tensile strength (Kg/cm}^2\text{)} = \frac{\text{Load at break}}{\text{Cross-sectional area}}$$

Note: Cross-sectional area:
thickness x width (1 cm)

Summarization of test findings (with two test pieces)

$$T_B \text{ or } E_B = 0.9 S_1 + 0.1 S_2 \quad S_1 \geq S_2$$

2. Water leakage test (ISO)

Testing method

Put a test sample to the sample holder of a water leakage tester, and fill it with 300 ml of water.

Detach the test sample from the holder and twist the perimeter of the rim to fasten the rim.

Roll the test sample on a blotter at least twice to see if there is any leakage.

However, any leakage within 25 mm from the rim may be ignored.

Record the frequency of leakages on the test data sheet.

3. Bursting strength test (ISO)

Testing method

Inflate condom on the metering device until it bursts and read the meter to determine the volume of air at bursting.

An average air volume must be not less than 12 dm³ and minimum air pressure shall be 0.9 Kpa.

V. RECOMMENDATIONS

For a population of 21.65 million in Algeria, the quantities of imported condoms of 19,000 gross in 1985 is extremely small compared with other countries.

In order to promote family planning activities effectively, it is necessary to conduct a survey of the actual consumption of oral contraceptives, IUD's and condoms, throughout the country.

The first recommendation is to study and recognize the significant role of condoms and their safety and reliability, as well as their availability through donor agencies today.

The second recommendation is to set up a small scale testing laboratory for condom quality.

The third recommendation is that a packing factory of condoms may be installed after the consumption and demand for condoms reaches the level of 100,000 gross on an annual basis.

The consumption level of condoms estimated from the Algerian population should be more than 250,000 gross/year. Therefore, the said 100,000 gross can be achieved if and when the Algerian Government would seriously consider and carry out a pragmatic birth control policy.

ANNEX I

INTERNATIONAL STANDARD ISO/DIS 4074/1

Rubber condoms - Part 1: Sampling plans and requirements

A. Scope and Field of Condoms

This part of ISO 4074 specifies the sampling plan and requirements for rubber condoms.

Note: The efficacy of spermicidal and other active lubricant or material is not within the scope of this standard.

B. References

ISO 2859 Sampling procedures for inspection by attributes.

C. Definitions

1. Condom

A condom is a thin flexible sheath designed to be worn over the erect penis during sexual intercourse to prevent sperm from entering the vagina and to aid in the prevention of sexually transmitted diseases.

2. Inspection lot

Condoms produced in identifiable lots and manufactured under essentially the same conditions and at, essentially, the same time.

Each inspection lot shall consist of condoms of the same shape in one standard width, one standard length and one surface type.

The number of condoms in one inspection lot should not be more than 150,000.

D. Materials and Design Classification

1. Materials

Condoms shall be manufactured from any elastomeric compound that permits the condom to meet the requirements in this standard and shall be free of embedded grit or discoloration.

The condoms and any lubricant or powder applied to them shall neither contain nor liberate substances that are known to be toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of use. Any lubricant, powder or compounding materials shall not have a deleterious effect on the condom.

Note: Condoms may be transparent, translucent, opaque or coloured.

2. Design classification

Condoms included in this standard shall be of the following classes and types:

Class I	52 mm nominal width
Class II	49 mm nominal width
Type A	Smooth surface
Type B	Textured surface

The open end of the condom shall terminate in an integral rim.

Note: Condoms may be parallel sided or non-parallel sided, plain ended or reservoir ended, and either dry or lubricated.

E. Design Requirements

1. Sampling

Each inspection lot shall be sampled per ISO 2859, special inspection level S - 2.

2. Requirements

The design requirements shall be according to table 1.

Table 1 - Design requirements

Condoms		Minimum length (mm) in accordance with ISO 4074/2	Width (mm) up to 85 mm from the open end in accordance with ISO 4074/3	Maximum mass (g) in accordance with ISO 4074/8	AQL 1)
Class	Type				
I	A	160	52 ⁺ ₋₂	1.7	4.0
	B	160	52 ⁺ ₋₂	2.0	4.0
II	A	150	49 ⁺ ₋₂	1.5	4.0
	B	150	49 ⁺ ₋₂	1.8	4.0

Note 1) The AQL applies to the total number of condoms failing to meet any of the design requirements.

F. Physical Requirements

1. Strength

The requirements of this section can be met by either or both of the following two methods as agreed between the parties concerned which may include two or more of the following: Purchaser, standardizing body, regulating authority and supplier.

1.1. Option 1 - Tensile properties

1.1.1 Sampling

Each inspection lot shall be sampled in accordance with ISO 2859, special inspection level S - 2.

1.1.2 Requirements

The tensile properties for condoms as supplied shall be in accordance with table 2.

Table 2 - Tensile properties

Age of samples at time of testing	Minimum tensile strength (MPa) in accordance with ISO 4074/9	Minimum elongation at break (%) in accordance with ISO 4074/9	AQL 2)
Less than 12 months after manufacturing	17	650	2.5
12 months or more after manufacturing	15	600	2.5

Note 2) The AQL applies to the total number of condoms failing to meet any of the tensile properties.

For determining resistance to storage the condoms shall be tested in accordance with ISO 4074/7. The tensile strength shall be 15 MPa min and the elongation at break shall then be 600% min, in both cases utilizing a 2.5 AQL. (See note 2).

1.2. Option 2 - Bursting volume and pressure

1.2.1 Sampling

Each inspection lot shall be sampled in accordance with ISO 2859, special inspection level S - 4.

1.2.2 Requirements

The bursting volume and pressure for condoms as supplied shall be in accordance with Table 3.

Table 3 - Bursting volume and pressure

Age of samples at time of testing	Minimum bursting volume, (dm ³) in accordance with ISO 4074/6		Minimum bursting pressure, (kPa) in accordance with ISO 4074/6	AQL 3)
	Condom class I	Condom class II		
Less than 12 months after manufacturing	15	13	1.0	1.5
12 months or more after manufacturing	12	11	0.9	1.5

Note 3) The AQL value applies to the total number of condoms failing to meet any volume or pressure requirement.

For determining the resistance to storage the condoms shall be tested in accordance with ISO 4074/7. The bursting volume shall then be 12 dm³ min for class I and 1 dm³ min for class II and the bursting pressure shall be 0.9 kPa for both class I and class II condoms, in all cases utilizing a 1.5 AQL. (See note 3).

2. Freedom from holes

2.1 Sampling

Each inspection lot shall be sampled in accordance with ISO 2859, general inspection level I.

2.2 Requirements

When tested in accordance with ISO 4074/5 the condoms shall meet the requirements of ISO 2859, utilizing a 0.4 AQL.

If condoms are delivered from the manufacturer in bulk, they must be tested for holes after unit packaging.

3. Colour fastness for pigmented condoms

3.1 Sampling

Each inspection lot shall be sampled in accordance with ISO 2859, special inspection level S - 2.

3.2 Requirements

When tested in accordance with ISO 4047/4 the condoms shall meet the requirements of ISO 2859, utilizing a 4.0 AQL.

Note: This test must be carried out on condoms unit packaged as intended for supply.

G. Packaging and Labelling

1. Sampling

Each inspection lot shall be sampled in accordance with ISO 2859, special inspection level S - 2.

2. Requirements

2.1 Packaged condoms

When inspected in accordance with ISO 4074/10 the packaged condoms shall meet the requirements of ISO 2859, utilizing a 1.0 AQL.

2.2 Unpackaged condoms

When inspected in accordance with ISO 4074/10 section 3, clauses a) and b), the condoms shall meet the requirements of ISO 2859, utilizing a 1.0 AQL.

H. Acceptance or Rejection of Inspection Lots

Inspection lots of condoms which fail the requirements of this standard shall not be represented as meeting the ISO Standard for condoms. Condoms tested 12 months or more after manufacture must have passed the requirements of this specification when newly manufactured.