Annex 10

World Health Organization/United Nations Population Fund technical specifications for male latex condoms

Background

The report of the Fifty-third meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in 2018 (*1*) stated the following:

> *Ms Seloi Mogatle and Dr William Potter from the United Nations Population Fund (UNFPA) gave an update on the prequalification guidance for contraceptive devices and condoms. The UNFPA had contacted WHO to inquire how best to start a process to update the relevant texts that we adopted by the ECSPP and published in 2008 (2, 3). The Expert Committee agreed to the importance of updating these materials in view of the changes in the contraceptive field globally over the previous decade. The two organizations committed to work together to bring the documents up to date. It was suggested by UNFPA to separate out the current existing procedure for condoms to include the following aspects:*
>
> 1. *prequalification guidance for contraceptive devices;*
> 2. *prequalification programme for male latex condom and annexes;*
> 3. *technical specification for male latex condom and annexes;*
> 4. *male latex condom prequalification inspection aide memoire;*
> 5. *condom quality assurance and annexes;*
> 6. *guidance on testing male latex condoms;*
> 7. *condom storage and transportation;*
> 8. *post-market surveillance of condoms;*
> 9. *public assessment reports for contraceptive devices – condoms and intrauterine devices.*
>
> *UNFPA also raised the issue of specifications for lubricants (both water-based and silicon-based), which needs to be considered when developing the new guidelines.*
>
> *The Expert Committee supported the development of the relevant documents for prequalification of condoms in consultation with the WHO*

Secretariat and their preparation for public consultation and took note that they will be reported back to the Expert Committee.

As agreed at the ECSPP meeting in October 2018, UNFPA and WHO have separated out different aspects of the current procedure for contraceptive devices and condoms.

All related documents were restructured and revised in the first half of 2019, then sent out for public consultation in July 2019. Comments received were reviewed by a group of specialists in October 2019, before being presented to the ECSPP. This is one of the three adopted by the Fifty-fourth ECSPP meeting, to replace the previous guidance document.

1. Introduction 223

2. Glossary 225

3. WHO/UNFPA specification 227

3.1 General requirements 227
3.2 Performance requirements 234
3.3 Design requirements 239

References 246

Further reading 247

Appendix 1 International standards relevant to the Prequalification Programme for male latex condoms 249

Appendix 2 Alternate package seal integrity test 251

1. Introduction

This annex contains the World Health Organization (WHO)/United Nations Population Fund (UNFPA) specification that is suitable for the bulk procurement of male latex condoms for use in social marketing and public-sector programmes for family planning and prevention of sexually transmitted infections.

A specification is a statement of the buyer's requirements and covers all the attributes and features of the product. Many of these requirements, particularly the design features, may be unique to the buyer and not specified in the International Organization for Standardization (ISO) standard ISO 4074. The buyer's specification must be a detailed and unambiguous statement of the buyer's requirements and describe the means by which those requirements can be measured and assessed. The specification is generally attached to the bidding documents and forms part of the supply contract.

The WHO/UNFPA specification is based on the performance requirements for male latex condoms specified in the international standard ISO 4074 Natural latex rubber male condoms – requirements and test methods. This standard specifies the essential performance requirements that latex condoms are expected to meet and the test methods that are used to assess compliance with these requirements. This standard is based on extensive research and an ongoing consultation process, involving leading experts from around the world in all aspects of condom manufacturing, testing, research and use. The WHO/UNFPA specification described here incorporates the performance requirements of ISO 4074.

The WHO/UNFPA specification has been developed by consensus and is based on available evidence, details of which are given in Appendix 1. The WHO/UNFPA specification describes the general, design, performance and packaging requirements for the product and the methods of verification. It can be used unchanged, or adapted to the specific requirements of programmes. However, it is important to understand the points listed next.

- **General requirements** specify the safety of constituent materials and other characteristics, such as shelf-life. These properties should not vary from lot to lot and therefore do not need testing on a regular basis. Retesting is required following any significant change to the formulation, manufacturing process, equipment used or packaging. The general requirements detailed in the WHO/UNFPA specification **should not be changed**. They are listed in Section 3.1 of this document.
- **Performance requirements** specify the essential performance attributes of the condoms, established in accordance with ISO 4074. These must be tested on a lot-by-lot basis, since the quality of these

attributes may vary due to the manufacturing process. Laboratory tests are carried out to assess the barrier properties of the package, the integrity of the product and its ability to resist breakage. Performance requirements detailed in the WHO/UNFPA specification **should not be changed**. The only exceptions are:

- the possibility to include or exclude bursting volume and pressure testing after oven conditioning;
- the packaging integrity requirements, where the purchaser may choose to apply more stringent testing, especially if the condoms are to be delivered by air or to high-altitude locations (refer to the alternate package seal integrity test in Appendix 2).

The performance requirements are listed in Section 3.2 of this document.

- **Design requirements** are mainly concerned with the acceptability of the product to the end-user. These can be varied within certain limits to meet specific programmatic requirements. Special boxes have been provided in the WHO/UNFPA specification for changes to such design requirements as colour, length and width. For each design requirement, there is a means of verification. These are listed in Section 3.3 of this document.
- **Packaging requirements** are detailed in the WHO/UNFPA specification. Packaging materials and package shape should not be changed unless the impact on the shelf-life of the product has been confirmed by accelerated stability studies and real-time stability studies are in progress according to clause 11 of ISO 4074:2015. If consumer packaging is required, it is important to include detailed instructions in the specification and to discuss the design requirements with the manufacturer. The packaging requirements are listed in Section 3.2 of this document.

The WHO/UNFPA specification is based on:

- the international standard ISO 4074;
- a literature review of the available evidence;
- the recommendations of the WHO/UNFPA/Joint United Nations Programme on HIV/AIDS(UNAIDS)/Family Health International (FHI360) Male Latex Condom Technical Review Committee (May 2002, August 2007 and July 2008); and
- feedback from participants attending the WHO/UNFPA workshops to introduce the male latex condom specification and procedures for prequalification and procurement.

Where appropriate, reference is made to the current edition and corrigenda of the published international standard, ISO 4074 *Natural latex rubber male condoms* – requirements and test methods.

This WHO/UNFPA specification should not be considered nor used as a standard for regulatory purposes. For regulatory purposes, the applicable standard is ISO 4074 or the relevant local standard, depending on the country.

If used in conjunction with the WHO/UNFPA Prequalification Programme, the WHO/UNFPA specification will ensure that a quality-assured product is prequalified and later purchased and distributed to the end-user.

2. Glossary

acceptance quality limit (AQL). The quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling (ISO 2859-1). *Note*: Manufacturers should be consistently achieving a process average that is better than the AQL.

bead. The thickened ring formed at the open end of the condom.

bioburden. The population of microorganisms on a raw material, component, product, packaging or equipment.

CE mark. On condom packaging, a mark certifying that the product conforms to the essential requirements of the European Commission Directive 93/42/EEC on medical devices (*4*).

colony-forming units (cfu). A unit of measure of the level of microbial contamination of a product.

compliance testing. A regime of testing to verify that a lot complies with the specification.

condom. A medical device that is intended to be worn on the penis during sexual activity, for purposes of contraception and to prevent the spread of sexually transmitted infections. Condoms are usually made from natural rubber latex but may also be made from synthetic materials, such as polyurethane.

consumer pack. A wallet or carton into which one or more foil packages are inserted for marketing purposes.

date of manufacture. The date on which the condoms were dipped.

design requirements. Characteristics of the condom that are specified according to the buyer's requirements.

expiry date. The date at which the product is no longer considered acceptable for use.

exterior shipping carton. The container into which a number of inner boxes are packed.

general requirements. The general quality characteristics of condoms that are verified before supply commences and that are not expected to vary from lot to lot.

inner box. A box used to contain a convenient number of condoms in packages or consumer packs. Inner boxes typically contain 100–200 condoms; where a gross (144 condoms) is used as the unit of purchase, inner boxes are usually specified to contain one gross.

inspection level. The degree of examination of the lot, as specified in ISO 2859-1. The higher the inspection level, the more samples will be tested and, hence, the lower the risk of faulty products reaching the end-user.

length. The length of the condom measured from the open end to the tip, excluding any reservoir.

lot. A collection of condoms of the same design, colour, shape, size and formulation. A lot must be manufactured at essentially the same time, using the same process, same specification of raw materials, common equipment, same lubricant and any other additive or dressing, and be packed in the same type of individual container, using the same packaging materials.

lot number or code. A unique identifying alphanumeric code assigned to a lot.

Lowry method. A method for determining the water-extractable protein levels in latex products.

national regulatory authority. A regulatory body with authority in a specific country to control the importation and distribution of medical products. *See also* **regulatory authority**.

package. The foil sachet in which the condom is sealed after manufacture.

performance requirements. The critical tests of quality that all lots must pass in order to provide adequate consumer protection.

prequalification. The steps taken by the buyer to verify a manufacturer's suitability to provide condoms of the required quality. The WHO/UNFPA Prequalification Programme includes periodic assessment of manufacturing dossiers, testing of samples and factory inspection.

pre-shipment compliance testing. A regimen of compliance tests carried out before a shipment leaves the supplier's factory.

regulatory authority. A national or international body set up to oversee the safety, efficacy and quality of medical devices, including condoms, imported and distributed within a country or region.

reservoir. A narrow portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat.

shelf-life. The period of time after manufacture that the product is considered acceptable for use.

social marketing. The use of commercial marketing techniques to distribute, promote and sell products and services of social importance, often at a subsidized price.

specification. A detailed statement of a product's requirements as established by the buyer. Usually, a specification is based on an established standard.

standard. A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory authority.

viscosity. The resistance to flow of a fluid.

wall thickness. The thickness of the latex film.

width. The mean lay-flat width of 13 condoms measured in accordance with the relevant annex of ISO 4074 at a point 75 ± 5 mm from the closed end, rounded to the nearest 0.5 mm.

3. WHO/UNFPA specification

3.1 General requirements

Manufacturers shall include in their summary of technical documentation evidence to confirm that the condoms comply with the general requirements listed in Table A10.1. Verification of conformance to these requirements is assessed during prequalification.

General requirements cover the selection and safety of materials and the shelf-life of the product.

Table A10.1
General requirements for condoms

General requirements	Description
Lot definition	A lot is a collection of condoms of the same design, colour, shape, size and formulation. A lot must be manufactured at essentially the same time, using the same process, same specification of raw materials, common equipment, same lubricant and any other additive or dressing, and be packed in the same type of individual container, using the same packaging materials. All condoms comprising a lot will: • have an identical formulation; • have the same design, dimensions, colour, shape and surface texture; • be manufactured on the same production line; • be vulcanized under identical conditions; • be in the same packaging; • have the same lubricant; and • have the same date of expiry printed on the package. Lot sizes over 500 000 are not permitted.
Date of manufacture	The date of manufacture is generally the date that the condoms were dipped. The date of manufacture may be the date of packaging (i.e. sealing the condoms into the individual containers), as long as the storage period between dipping and packaging does not exceed 6 months and the unpackaged condoms are stored under controlled conditions as specified in Clause 11.1 of ISO 4074:2015. Storage conditions will be subject to assessment as part of the prequalification inspection.
Materials	The condoms shall be made of natural rubber latex. The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use.

Table A10.1 *continued*

General requirements	Description
Biocompatibility	Biocompatibility assessments shall be conducted on the whole condom, including any lubricants and dressing materials, in accordance with ISO 10993-1. Specifically, evaluations shall be conducted for cytotoxicity according to ISO 10993-5 and for irritation and skin sensitization according to ISO 10993-10. Manufacturers should choose accredited laboratories for these tests, and the results shall be interpreted by an accredited toxicologist or other suitably qualified expert. Expert reports should be available for review. The expert review report can be a separate document or can be included in the test report. Extraction conditions shall be at a temperature of 37 ± 1 °C, according to ISO 10993-12. Many latex products that have been established as safe, including condoms and medical gloves, can exhibit a positive cytotoxic response when tested according to ISO 10993-5. While any cytotoxic effect can be of concern, it is primarily an indication of potential for in vivo toxicity and a condom cannot necessarily be determined to be unsuitable for use based solely on cytotoxicity data. Manufacturers are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the countries in which the condoms are to be distributed. In accordance with ISO 10993-1, manufacturers may provide data on equivalent products. The International Agency for Research on Cancer (IARC, WHO) has classified 2-mercaptobenzothiazole (MBT) as probably carcinogenic to humans (*5*). MBT shall not be used as an accelerator in condom formulations
Water-extractable protein levels	It will be verified during prequalification that manufacturers determine the water-extractable levels of proteins in their products. The recommended levels for soluble protein, as determined by the modified Lowry method, should be less than 200 µg/g. Manufacturers should take steps not to exceed this level and should monitor production periodically, at least once a year and following any significant change to the latex formulation. The recommended interval is every 3 months.

Table A10.1 *continued*

General requirements	Description
	There is no specific standard for determining the protein levels in condoms. The methods described in ISO 12243 (*6*), EN 455-3 (*7*) or ASTM D5712 (*8*) for determining the protein levels in medical gloves can be modified for condoms.[1] Documentation recording protein levels should be available for review.
Bioburden levels	Condoms are not sterile devices, but nevertheless manufacturers should take steps to minimize the risk of contamination of the products with microorganisms. It will be verified during prequalification that manufacturers periodically determine bioburden levels. Documentation recording bioburden levels should be available for review. For prequalification, the manufacturer should be able to demonstrate that they are able to maintain bioburden levels on packed condoms below 100 cfu (colony-forming units)/condom and not exceeding 500 cfu/condom. There should be an absence of *Staphylococcus aureus* and Enterobacteriaceae, including *Escherichia coli* and *Pseudomonas aeruginosa*. For prequalification, bioburden levels should be determined periodically, e.g. at least quarterly (and following any significant change to the latex formulation), by extracting the condoms with a neutralizing medium and determining the total viable aerobic count using appropriate test methods. Further information on the rationale for the bioburden limits, methods of determining bioburden levels and general guidelines on controlling bioburden contamination during manufacture is given in ISO 4074:2015 Annex G.
N-nitrosamines	It will be verified during prequalification that manufacturers take steps to minimize the formation of *N*-nitrosamines. For prequalification purposes, the manufacturer should be able to demonstrate they are able to achieve levels below 50 ppb (parts per billion) measured as per ISO 29941 (*9*). Levels should be monitored periodically and at least once a year, and following any significant change to the latex formulation.

[1] For further information about latex allergy and protein levels, refer to the list of Further reading.

Table A10.1 *continued*

General requirements	Description
	Minimization of the formation of *N*-nitrosamines can be achieved by ensuring that condoms are adequately leached and washed; and by using minimum amounts of accelerators. It is recommended that, where possible, accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile (*10*),[2] are used in the formulation.
Dusting powder	A suitable dusting powder should be used to prevent the condoms from sticking together during manufacture. Acceptable powders are: • cornstarch; • magnesium or calcium carbonate; and • silica. Manufacturers may use other dusting powders, as long as they do not compromise the biocompatibility and safety of the condom. Talc or lycopodium spores shall not be used. It is recommended that manufacturers not use excess powder (maximum recommended is 50 mg per condom).
Shelf-life and stability studies	
Shelf-life	ISO 4074 describes the minimum stability requirements for condoms. These are considered the minimum requirements for placing condoms on the market. It can be assumed that condoms meeting these requirements have a minimum shelf-life of 2 years. Condoms shall comply with the performance requirements of this WHO/UNFPA specification throughout the stated shelf-life of the condom. The manufacturer shall determine the shelf-life based on the outcome of stability studies and measured from the date of manufacture. The claimed shelf-life shall be not less than 3 years and not more than 5 years.

[2] For further information about *N*-nitrosamines, refer to the list of Further reading.

Table A10.1 *continued*

General requirements	Description
	Variations Textured condoms made using the same latex formulation and processes as untextured condoms that have an established shelf-life based on real-time stability studies should be subjected to comparative accelerated stability studies extending out to 90 days and 180 days at 50 °C. Subject to satisfactory results, the specified shelf-life of the textured condoms may be assumed to be the same as for the equivalent untextured condom after 90 days, and confirmed after 180 days, without the need for a real-time stability study.
Stability studies – real time	Manufacturers **must** determine the shelf-life by real-time studies conducted at 30 +5/–2 °C (i.e. between 28 °C and 35 °C but with a target temperature of 30 °C), according to the relevant clause in ISO 4074. Pending the outcome of real-time studies, manufacturers may use accelerated ageing studies at 50 ± 2 °C to estimate a provisional shelf-life, as described in ISO 4074. The results of an accelerated ageing study, according to ISO 4074, must be available at the time of submitting an application for prequalification, and a real-time study must also be in progress.
Sampling	Condoms for stability studies shall be taken from three normal production lots. Sampling shall be done according Annex A or Annex B (preferred) of ISO 4074:2015. The sample size should be adequate for at least six separate tests for the three tests from ISO 4074.
Conditioning	Samples should be incubated in their individual sealed containers, according to the relevant annex of ISO 4074: one set for 168 ± 2 hours at 70 ± 2 °C, and another set for 90 ± 1 days at 50 ± 2 °C. At the end of the incubation periods, the condoms should be withdrawn and tested for airburst properties, freedom from holes and package seal. The incubation period at 50 ± 2 °C can be extended to 120 days or 180 days, in order to estimate a provisional shelf-life by accelerated ageing, in which case testing at 90 days is not necessary.

Table A10.1 *continued*

General requirements	Description
Testing requirement	Compliance with the requirements for bursting properties should be assessed at least annually for the full shelf-life of the product, and for freedom from holes and package integrity, as specified in the relevant clauses of ISO 4074, by the end of the testing period. All three lots of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and visible defects, including visibly open packaging seals and package integrity, as specified in the relevant clauses of ISO 4074, for the duration of the stability study. If all three lots of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of ISO 4074 for a period of 120 days at (50 ± 2) °C, a provisional shelf life of 3 years may be assigned. If all three lots of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of ISO 4074 for a period of 180 days at (50 ± 2) °C, a provisional shelf life of 5 years may be assigned. If at any time during the real-time studies, the manufacturer becomes aware that the shelf-life estimates made using the accelerated ageing studies are incorrect, the manufacturer must notify the procurers and regulators immediately.
Provisional shelf-life	Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life, using an accelerated ageing study.
Minimum stability requirements	Condoms shall comply with the minimum stability requirements defined in the relevant clause of ISO 4074. Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of 2 years.
Stability study report	The stability study report should indicate the time between dipping and foiling for the lots used for the study. If a manufacturer has not recorded the required information in the stability study report, then the default position will be that the manufacturer must use the dipping date as the date of manufacture.

3.2 Performance requirements

The performance requirements specified in Table A10.2 are based on the requirements of ISO 4074. These requirements cannot be altered. Verification of compliance with these requirements must be done as part of prequalification and the lot-by-lot pre-shipment compliance testing of the product. For prequalification purposes, the sampling plans specified in Annex B of ISO 4074 shall be used. Testing after oven conditioning may be required as part of prequalification, following a risk-based assessment.

Information on methods of monitoring quality is given in the condom quality assurance guidance document (*10*).

Table A10.2
Performance requirements

Performance requirements	Description
Bursting volume and pressure	
Sampling	In accordance with ISO 2859-1 General Inspection Level I (*11*). For prequalification testing, at least code letter M as specified in Annex B of ISO 4074:2015 shall be used.
Testing	In accordance with test method in the relevant annex of ISO 4074 and the relevant clause in ISO 4074.
Requirement	Minimum bursting requirements as listed below: **Acceptance quality limit (AQL) 1.5** **Volume:** • 16.0 dm^3 for condoms with mid-body widths ≥ 45.0 mm and < 50.0 mm • 18.0 dm^3 for condoms with mid-body widths ≥ 50.0 mm and < 56.0 mm • 22.0 dm^3 for condoms with mid-body widths ≥ 56.0 mm and < 65.0 mm • 28.0 dm^3 for condoms with mid-body widths ≥ 65.0 mm and < 75.0 mm **Pressure:** 1.0 kPa (for all widths) The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of ISO 4074 at a point 75 ± 5 mm from the closed end, rounded to the nearest 0.5 mm.

Table A10.2 *continued*

Performance requirements	Description
Freedom from holes and visible defects	
Sampling	ISO 2859-1 General Inspection Level I, but at least Code Letter M (*11*). For prequalification testing, at least Code Letter N as specified in Annex B of ISO 4074:2015 shall be used.
Testing	In accordance with the relevant annex of ISO 4074.
Requirement	In accordance with the test method in the relevant annex of ISO 4074. • **Freedom from holes: AQL 0.25** • **Critical visible defects: AQL 0.4** • **Visibly open package seals: AQL 0.4** ISO 4074 describes a limited number of critical visible defects. WHO/UNFPA specifies an extended list of critical visible defects and imperfections in Section 3.2.1 of this document. It is not possible to define all critical defects and imperfections, and it may be necessary to exercise some judgement about whether or not a particular visible defect is critical. (If you need assistance, contact qa-team-group@unfpa.org) If the visible defect may affect the performance of the condom, the defect is considered critical. If a defect not listed in Table A10.3 is considered critical by any party, then the procurer, test laboratory and manufacturer must consult with each other to agree on the classification of the defect concerned. Exact definitions of critical defects and imperfections should be reviewed and agreed upon during the contractual process.
Package seal integrity	
Sampling	ISO 2859-1 Inspection Level S-3 (*11*)
Testing	In accordance with the package integrity test method in the relevant annex of ISO 4074
Requirement	**AQL 2.5**

Table A10.2 *continued*

Performance requirements	Description
Alternative package seal integrity method (for condoms to be delivered by air shipment or to high-altitude destinations), to be specified in contracts; to be adopted and manufacturers given a transition period of 6 months to 1 year of publication of this specification	
Sampling	ISO 2589-1 Inspection Level S-4 (*11*), Minimum Code Letter H (80 samples)
Testing	Use the alternative package seal test specified in Appendix 2
Requirement	**AQL 0.65**

3.2.1 Types of visible defects

Some visible defects may adversely affect the performance of the condom, for example by increasing the risk of it breaking or slipping off in use. These defects are classified as critical and an AQL of 0.4 is applied to nonconforming condoms.

The most common critical visible defects are covered by ISO 4074. These defects include broken, missing or severely distorted beads and permanent creases with adhesion of the film. They are evaluated by visual inspection, as part of the procedure for testing for freedom from holes.

Other types of critical visual defects are occasionally seen, and they should be assessed for their potential effect on the performance and acceptability of the condom.

Some of the more common critical visible defects are described in Table A10.3 and imperfections that are not critical are listed in Table A10.4.

Table A10.3
Critical visible defects

Defect	Description
Pleat/crease	The film sticks to itself and the pleat/crease cannot be removed by gentle stretching of the adjacent film.
Blister/bubble	An obvious circular or teardrop-shaped thin area with a well-defined border in the film (such defects may break under pressure).
Embedded and surface particles	Any particle with any dimension of 1 mm or greater. These may be dirt, hair, insects, powder granules, coagulum, etc.

Table A10.3 *continued*

Defect	Description
Bead defects	Faulty, missing or severely distorted beads (as in ISO 4074).
Crack marks	Lines that penetrate the surface of the film, formed by shrinkage of the latex during drying. These do not include flow lines or marks from the mould.
Delamination	Areas where the individual layers of latex separate (condoms are formed by two or more dips in the liquid latex).
Thin areas	Small areas of the condom (including the teat) that are visibly thin. These can show up as bulges with well-defined edges on the freedom-from-holes test. Condoms that look asymmetrical when filled with water are not in this category (see Table A10.5).
"Cupping" (a concave region at the end of the teat)	An apparent indentation at the end of the teat, which is often caused by significant thickness variations around the teat. Very small concave areas (<2 mm) shall be treated as non-critical visible defects.

Table A10.4
Imperfections that are not regarded as defects

Phenomenon	Description
Micro-coagulum	Particles of rubber with dimensions <1 mm.
Flow lines	Lines of denser material in the film.
Small concave spot at the end of the teat	An apparent indentation caused during the withdrawal of the former (dipping mould) from the latex. Large concave spots (e.g. >2 mm) at the end of the teat shall be treated as thin areas (critical visible defect).
Distortion due to rolling	Apparent variations in condom width due to stretching during rolling.
Distortion when testing for freedom from holes	Distortion of the condom during the freedom-from-holes test that are due to small differences in thickness around the wall of the condom, caused by relative movement of the latex and the former (dipping mould) during dipping (bulges with well-defined edges should be treated as critical visible defects).
Uneven lubricant	The open end of the condom may appear dry, especially on new condoms. The lubricant penetrates the roll slowly.

Table A10.4 *continued*

Phenomenon	Description
Embedded and surface particles (small)	Particles with dimensions < 1 mm that are visible to the naked or corrected eye.
Faulty bead (minor)	Uneven and partially distorted beads.
Uneven colour	Minor streaking.

3.2.2 Packaging defects and ISO 4074

The main packaging defects are listed in Box A10.1. Additional defects are sometimes detected only after shipment. This section summarizes common types of packaging defects, including those detailed in the WHO/UNFPA specification.

Individual packages

The quality of the individual foil packages shall be assessed by visual inspection using a sampling plan in accordance with ISO 2859-1 Inspection Level S-3 (*11*). An AQL of 2.5 shall be applied to these defects collectively. Packaging defects are summarized in Box A10.1.

Consumer packs

There are no requirements for consumer packs included in the WHO/UNFPA specification. Procurers should fully specify requirements in accordance with programme needs. Compliance should be assessed by visual inspection, using a sampling plan in accordance with ISO 2859-1 Inspection Level S-3 (*18*). It is recommended that an AQL of 2.5 be applied to consumer pack requirements.

In cases where organizations repack condoms into consumer packaging, the quality of the consumer packaging is entirely at the discretion of the organization doing the repacking. The only requirements that can be specified are the labelling requirements for the consumer pack and information to be supplied to the user. These requirements are detailed in ISO 4074, although local requirements may apply as well.

Cartons and marking

Packaging requirements should be agreed in the purchase order. Compliance should be assessed by visual inspection, using a sampling plan in accordance with ISO 2859-1 Inspection Level S-3 (*11*). It is recommended that an AQL of 4.0 be applied to carton requirements.

Box A10.1
Packaging defects

Individual foil packaging defects, ISO 2859-1 Inspection Level S-3, AQL 2.5
- Empty package
- No lubricant
- Lubricant leakage
- Delamination of the packaging film
- Discoloured film and labels
- Missing manufacturer's name
- Incorrect/missing lot number
- Incorrect/missing date of manufacture
- Incorrect/missing expiry date

Consumer packs, ISO 2859-1 Inspection Level S-3, AQL 2.5
- Empty or partially filled packs
- Discolouration
- Delamination
- Missing manufacturer's name
- Incorrect/missing lot number
- Incorrect/missing date of manufacture
- Incorrect/missing expiry date
- Incorrect format of expiry date

Cartons and markings, ISO 2859-1 Inspection Level S-3, AQL 4.0
- Non-permanent marking
- Empty or partially filled cartons
- Damaged cartons that may affect the integrity or quality of the condoms inside
- Missing manufacturer's name
- Incorrect/missing lot number
- Incorrect/missing manufacture date
- Incorrect/missing expiry date

3.3 Design requirements

The design properties listed in Table A10.5 may be adapted, where appropriately indicated, to reflect the specific needs of the programme and population of intended users. Modification should be based on information about the target population. Verification of compliance with these requirements is to be done as part of the lot-by-lot compliance testing of the product.

If specific design changes are agreed between the manufacturer and procurer, then any appropriate testing procedures, sampling plans and compliance levels (AQLs) should also be agreed. Changes in condom design, such as different

shapes or the inclusion of pigments, can affect airburst properties and, in some circumstances, freedom from holes.

It is recommended that, where changes to the specification are made, dimensional requirements and design features should be subject to ISO 2859-1 Inspection Level S-2 (*11*) with an AQL of 1.0.

Appropriate reference samples should be maintained by the manufacturer and testing laboratory. The national regulatory authority and/or purchaser may also retain reference samples.

Table A10.5
Design requirements

Design requirements	Description
Shape and texture	
Verify by visual inspection	The surface of the condoms can be textured or non-textured. Texturing typically consists of a number of ribs or dots formed onto the surface of the condom. Condoms may be of any shape consistent with normal commercial practice and client requirements. If the condom is not parallel-sided and smooth, attach a dimensioned drawing with detailed description, which should be agreed with by manufacturer and procurer.
Integral bead	
Verify by visual inspection	The open end of the condom shall have a rolled ring of latex, called an integral bead, "rim" or "ring".
Colour, to be evaluated at prequalification	
Verify by visual inspection	Condoms can be translucent, pigmented or unpigmented. Pigments used with coloured condoms shall be suitable for use in medical devices and shall not degrade the rubber. The shelf-life of coloured condoms is to be verified by accelerated stability studies verified at 90 days and 180 days at 50 °C. If a pigment is required, indicate the colour and provide full details of the pigment, including a material safety data sheet (MSDS). Pigments and pigment dispersions or flavours used with coloured condoms shall be suitable for use in medical devices. A condom incorporating pigment, flavours and/or fragrances shall be subject to biocompatibility evaluation according to the relevant parts of ISO 10993.

Table A10.5 *continued*

Design requirements	Description
Odour and fragrance to be evaluated at prequalification	
Verify by visual inspection and smell	The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf-life of the product. It is recommended that manufacturers include odour assessment as part of their shelf-life studies. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened. A mild odour that dissipates quickly is acceptable.) Procurers may specify the addition of a suitable fragrance. Such fragrances must be non-toxic, non-irritant and not degrade the rubber. The manufacturer shall supply details of the fragrance used and the amount added to the procurer. Fragrances used with condoms shall be suitable for use in medical devices. The condom and fragrance shall be subject to biocompatibility evaluation according to ISO 10993-1. The shelf-life of any fragranced condom shall be verified as described in Section 3.1. If a fragrance is desired, the manufacturer should specify it and provide full details of the fragrance, including an MSDS.
Testing	If a masking agent or fragrance is used, odour testing should become part of the lot-by-lot pre-shipment compliance testing. Odour testing should be included in ageing studies.
Width	
Sampling	In accordance with ISO 2859-1 Inspection Level S-2 (*11*)
Testing	In accordance with the test method in the relevant annex of ISO 4074
Requirement	The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of ISO 4074 at a point 35 ± 15 mm from the open end, rounded to the nearest 0.5 mm. Standard widths within the public sector are 49 mm and 53 mm, with a tolerance of ±2 mm. **AQL 1.0** Other widths are available and may be more appropriate for specific target populations described in the list of Further reading. Users should select the appropriate width based on the best available data on the target population.

Table A10.5 *continued*

Design requirements	Description
Length	
Sampling	In accordance with ISO 2859-1 Inspection Level S-2 (*11*)
Testing	In accordance with the test method in the relevant annex of ISO 4074
Requirement	A minimum of 165 mm for condoms with nominal widths of < 50.0 mm A minimum of 180 mm for condoms with nominal widths from 50.0 mm up to 55.5 mm A minimum of 190 mm for condoms with nominal widths ≥ 56.0 mm **AQL 1.0**
Thickness	
Sampling	Test a sample of 13 condoms.
Testing	In accordance with the test method in the relevant annex of ISO 4074
Requirement	Unless otherwise specified, the nominal thickness will be 0.065 mm. If a different thickness is specified, then this must be agreed between the procurer and manufacturer. The thickness shall be stated in the specification and any purchase orders. The average single-wall thickness calculated for the 13 condoms tested shall be equal to the specified nominal thickness subject to a tolerance of: • ± 0.008 mm for condoms with nominal specified thickness of < 0.05 mm; • ± 0.01 mm for condoms with nominal claimed thickness ≥ 0.05 mm. **AQL 1.0** If a micrometer gauge is used, the thickness measurements are taken at three locations around the circumference of the condom at 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points. The condom thickness is reported as the mean of the nine measurements.

Table A10.5 *continued*

Design requirements	Description
	For partially textured condoms, the thickness shall be measured at points closest to those specified above where the surface is smooth. The locations of the points of measurement shall be noted. If it is not possible to locate a smooth region on the condom where thickness can be measured, then thickness shall be measured at the points specified above and the specification should be adjusted to allow for the effect of the texturing – for example, by reference to the manufacturer's specification. In such cases, the method of measurement should be specified (gauge or ring weight). It should be noted that, when used for textured condoms, the mass method gives the approximate average for thickness, as opposed to the micrometer method, which gives an estimate. *Condoms thicker than 0.080 mm are usually considered to be extra thick, whereas condoms that are thinner than 0.060 mm are usually considered to be thin. There is no evidence that extra thick condoms (sometimes called extra strong) provide additional protection.*
Quantity of lubricant including powder	
Sampling	In accordance with ISO 2859-1 Inspection Level S-2 (*11*)
Testing	In accordance with the test method in the relevant annex of ISO 4074
Requirement	The condom shall be lubricated with a quantity of silicone fluid having a nominal viscosity between 200 and 350 centistokes. *Other lubricants such as glycols and water-based lubricants may be used by agreement between the manufacturer and procurer. Oil-based lubricants* ***should NOT*** *be used.* The nominal quantity of lubricant, including powder, in the package should be in the range 350 mg to 600 mg. The quantity of lubricant may be varied depending upon local requirements. UNFPA recommends 450 mg as the nominal dose but lower quantities may be appropriate for some markets. The nominal quantity of lubricant must be agreed between the procurer and manufacturer. The agreed nominal quantity of lubricant shall be stated in the specification and any purchase orders.

Table A10.5 *continued*

Design requirements	Description
	The amount of lubricant, including any dusting powder, shall be equal to the specified nominal amount, within a tolerance of ± 100 mg. If no amount is indicated, the nominal amount of lubricant shall be 450 mg. **AQL 4.0**
Individual package materials and markings	
Definition	Sometimes referred to primary packaging, individual packaging or individual containers
Packaging requirement	The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to the specification for the purchase order. Unless otherwise specified, the individual packages shall be square or circular and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour and ultraviolet and visible light. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour and ultraviolet and visible light. If an alternative package shape is specified, then the shelf-life of the product in that package shall be confirmed as described in Section 3.1. **AQL 2.5**
Labelling requirement	The individual package shall have the following markings: • manufacturer's name; and identification(address) of manufacturing site* • lot number or lot identification code (printed at the time of packaging, not pre-printed); • expiry date: month and year in language(s) to be specified by the procurer. The year shall be written as a four-digit number and the month as a two-digit number (YYYY-MM) (printed at the time of packaging, not pre-printed). Other information, including texture, colour and fragrance can be agreed on between the manufacturer and procurer. In such cases, it is recommended that pre-printed foil is used. Manufacturing date: month-and-year manufacturing date can be added if required by procurer.

Table A10.5 *continued*

Design requirements	Description
	The lot numbers on packages must be printed at the time of packaging. * *Note*: If dipping of the condoms is done on one site and the naked condoms are packed and released for testing on another site, it is the manufacturer name and manufacturing site that did the final release testing that should be printed.
Sampling	In accordance with ISO 2859-1 Inspection Level S-2 (*11*)
Testing	The sample of condom packages is visually inspected to verify the required aspects of package quality.
Verified by visual inspection	Shape: unless otherwise specified, the individual packages shall be square or circular and shall not distort the rolled condom. The printing requirements, packaging and labelling can be verified by visual inspection.
Verified by supplier's data or independent test	Material: verified by manufacturer's data If it is not specified, packages should be constructed of a laminate that includes a layer of suitable impermeable flexible aluminium foil (recommended minimum thickness of 8 µm) and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing. The lot numbers on packages must be printed at the time of packaging. In addition, the following shall apply: • there shall be no evidence of leakage; • the outside surface of the package shall be clean; • there shall be no separation of the layers of laminate; • if the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals; • the package must be easy to open without damaging the condom.

Table A10.5 *continued*

Design requirements	Description
Alternative package materials	Alternative package materials can be accepted if they have barrier and strength properties comparable to those of the packaging recommended above or if there are real-time stability data to show that the condom in its pack has adequate shelf-life. If an alternative material is required, append the full specification. The lot numbers on packages must be printed at the time of packaging. In addition, the following shall apply: • there shall be no evidence of leakage; • the outside surface of the package shall be clean; • there shall be no separation of the layers of laminate; • if the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals; • the package must be easy to open without damaging the condom.

References

1. WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1019; https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1, accessed 17 December 2019).
2. Procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations agencies. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-second report. Geneva: World Health Organization; 2008: Annex 2 (WHO Technical Report Series, No. 948; https://www.who.int/medicines/areas/quality_safety/quality_assurance/ProcedureAssessingAcceptabilityMaleLatexCondomsPurchaseUNAgenciesTRS948Annex2.pdf?ua=1, accessed 17 December 2019).
3. Procedure for assessing the acceptability, in principle, of TCu380A intrauterine device for purchase by United Nations agencies. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-second report. Geneva: World Health Organization; 2008: Annex 3 (WHO Technical Report Series, No. 948; https://www.who.int/medicines/areas/quality_safety/quality_assurance/ProcedureAssessingAcceptabilityTCU380ATRS948Annex3.pdf?ua=1, accessed 17 December 2019).
4. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Brussels: European Commission; 1993 (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF, accessed 18 December 2019).

5. Some industrial chemicals. IARC monographs on the evaluation of carcinogenic risk to humans, volume 115. Geneva: World Health Organization; 2016.
6. ISO 12243:2003(en). Medical gloves made from natural rubber latex – determination of water-extractable protein using the modified Lowry method (https://www.iso.org/obp/ui/#iso:std:iso:12243:ed-1:v1:en, accessed 19 December 2019).
7. European Standards. CSN EN 455-3. Medical gloves for single use – Part 3: Requirements and testing for biological evaluation.
8. ASTM D5712-15. Standard test method for analysis of aqueous extractable protein in latex, natural rubber, and elastomeric products using the modified Lowry method. West Conshohocken (PA): ASTM International; 2015.
9. ISO 29941:2010(en). Water quality – Determination of total nitrogen after UV digestion – Method using flow analysis (CFA and FIA) and spectrometric detection (https://www.iso.org/obp/ui/#iso:std:iso:29441:ed-1:v1:en, accessed 19 December 2019).
10. Tinkler J, Gott D, Bootman J. Risk assessment of dithiocarbamate accelerator residues in latex-based medical devices: genotoxicity considerations. Food Chem Toxicol. 1998;36(9–10):849–66. doi:10.1016/S0278-6915(98)00037-4.
11. ISO 2859-1:1999(en). Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit(AQL) for lot-by -lot inspection (https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:ed-2:v1:en, accessed 18 December 2019).

Further reading

- Liss G, Sussman G. Latex sensitization: occupational versus general population prevalence rates. Am J Ind Med. 1999;35:196–200.
- Proksch E. Toxicological evaluation of N-nitrosamines in condoms. Int J Hyg Environ Health. 2001;204(2–3):103–10.
- Schumacher P. Über eine für die haltbarkeit von arzneimitteln maßgebliche klimaeinteilung [The impact of climate classification on the stability of medicines]. Pharmazeutische Industrie. 1972;34:481–3.
- Grimm W. Storage conditions for stability testing – long term testing and strength tests (Part 2). Drugs Made Ger. 1986;29:39–47.
- Grimm W. Storage conditions for stability testing in the EC, Japan and USA, the most important market for drug products. Drug Dev Ind Pharm. 2008;19(20):2795–830. doi:10.3109/03639049309050178.
- Grimm W. Extension of the International Conference on Harmonization Tripartite Guideline for Stability Testing of New Drug Substances and Products to countries of climatic zones III and IV. Drug Dev Ind Pharm. 1998;24(4):313–25. doi:10.3109/03639049809085626.
- Bó MC, Gerofi JP, Visconte LLY, Nunes CR. Prediction of shelf life of natural rubber male condoms – a necessity. Polym Test. 2007;26(3):306–14. doi:10.1016/j.polymertesting.2006.10.013
- Free MJ, Skiens EW, Morrow MM. Relationship between condom strength and failure during use. Contraception. 1980;22:31–7.
- Free MJ, Hutchings J, Lubis F, Natakusumah R. An assessment of burst strength distribution data for monitoring quality of condom stocks in developing countries. Contraception. 1986;33(3):285–99.

- Steiner M, Foldesy R, Cole D, Carter E. Study to determine the correlation between condom breakage in human use and laboratory test results. Contraception. 1992;46(3):279–88.
- Benton KWK, Jolley D, Smith AM, Gerofi J, Moodie R. An actual use comparison of condoms meeting Australian and Swiss standards: results of a double blind crossover study. Int J STD AIDS. 1997;8:427–31.
- Gerofi JP, Shelley GA. Condom inflation testing: strain distribution during test. J Test Eval. 1991;19(3):244–9.
- Van de Perre P, Jacobs D, Sprecher-Goldberger S. The latex condom, an efficient barrier against sexual transmission of AIDS-related viruses. AIDS. 1987;1(1):49–52.
- Minuk GY, Bohme CE, Bowen TJ, Hoar DI, Cassol S, Gill MJ et al. Efficacy of commercial condoms in the prevention of hepatitis B virus infection. Gastroenterology. 1987;93(4):710–14.
- Retta SM, Herman WA, Rinaldi JE, Carey RF, Herman BA, Athey TW. Test method for evaluating the permeability of intact prophylactics to viral-size microspheres under simulated physiologic conditions. Sex Transm Dis. 1991;18(2):111–18.
- Lytle CD, Routson LB, Cyr WH. A simple method to test condoms for penetration by viruses. Appl Environ Microbiol. 1992;58(9):3180–2.
- Voeller B, Nelson J, Day C. Viral leakage risk differences in latex condoms. AIDS Res Hum Retroviruses. 1994;10(6):701–10. doi:10.1089/aid.1994.10.701.
- Garside R. Condom shape: a neglected factor influencing use and acceptability? UK Family Planning Research Network. Int J STD AIDS. 1999;10(12):785–90.
- Macaluso M, Blackwell R, Carr B, Meinzen-Derr J, Montgomery M, Roark M. Safety and acceptability of a baggy latex condom. Contraception. 2000;61(3):217–23. doi:10.1016/S0010-7824(00)00097-4.
- Golombok R, Harding R, Sheldon J. An evaluation of a thicker versus a standard condom with gay men. AIDS. 2001;15:245–50.
- WHO/CONRAD Technical Consultation on nonoxynol-9 WHO, Geneva, 9–10 October 2001. Summary report. Geneva: World Health Organization; 2003 (https://apps.who.int/iris/bitstream/handle/10665/68510/WHO_RHR_03.08.pdf;jsessionid=3A2CB45DFC9C6BC17F7C7E2F57859589?sequence=1, accessed 18 December 2019).

Appendix 1

International standards relevant to the Prequalification Programme for male latex condoms

Various external documents form part of the WHO/UNFPA Technical Specification and Prequalification Programme and the buyer may wish to mention them in any invitation to bid or order sent to the supplier. In every case, the edition of the document is the one in force on the date of the invitation to bid. These are standards published by the International Organization for Standardization (ISO). The latest version of the standard should be used by manufacturers.

- ISO 4074. Natural latex rubber male condoms – requirements and test methods (2015; https://www.iso.org/obp/ui/#iso:std:iso:4074:ed-3:v1:en).
- ISO 16038. Male condoms – guidance on the use of ISO 4074 and ISO 23409 in the quality management of natural rubber latex condoms (2017; https://www.iso.org/obp/ui/#iso:std:iso:16038:ed-2:v1:en).
- ISO 13485. Medical devices – quality management systems – requirements for regulatory purposes (2016; https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en).
- ISO 2859-1. Sampling procedures for inspection by attributes. Part 1. Sampling schemes indexed by acceptance quality levels (AQL) for lot-by-lot inspection (1999; https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:ed-2:v1:en).
- ISO 10993-1. Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process (2018; https://www.iso.org/obp/ui/#iso:std:iso:10993:-1:ed-5:v2:en).
- ISO 10993-5. Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity (2009; https://www.iso.org/obp/ui/#iso:std:iso:10993:-5:ed-3:v1:en).
- ISO 10993-10. Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization (2010; https://www.iso.org/obp/ui/#iso:std:iso:10993:-10:ed-3:v1:en).
- ISO 10993-12. Biological evaluation of medical devices. Part 12. Sample preparation and reference materials (2012; https://www.iso.org/obp/ui/#iso:std:iso:10993:-12:ed-4:v1:en).

- ISO 14155. Clinical investigation of medical devices for human subjects – good clinical practice (2011; https://www.iso.org/obp/ui/#iso:std:iso:14155:ed-2:v1:en).
- ISO 14971. Medical devices – application of risk management to medical devices (2019; https://www.iso.org/obp/ui/#iso:std:iso:14971:ed-3:v1:en).

Appendix 2

Alternate package seal integrity test

1. Principle of the dry vacuum method

The condom packs are washed and dried, wrapped in coloured tissue, and put into U-shaped holders that prevent them from expanding. The U-shaped holders are placed in a vacuum chamber, which is evacuated for 20 minutes. The coloured tissue is examined for signs of staining. The packs are then examined, repacked and passed through the vacuum again, and the tissue re-examined.

Packs are considered to be leaking if:

a. a stain appears on the first examination, and the stain is found to be larger on the second examination; or
b. no stain appears on the first examination, and one appears on the second examination.

2. Equipment required for the dry vacuum

The following equipment is required:

a. ultrasonic cleaners with baths long enough to hold strips of 3 condoms (say, 200 mm). If the bath is not long enough, the strips can be gently folded to fit;

Note: It is necessary to ensure that the strips are submerged in the bath. This may be done by weighting the samples with a piece of metal (e.g. a large nut) or by using a frame that is part of the bath.

b. towels or tissues suitable for drying the packs;
c. isopropanol for washing (technical grade);
d. U-shaped holders for the condom strips;
e. coloured tissue suitable for wrapping the strips, in order to show leakage stains;
f. vacuum chamber (e.g. desiccator) capable of holding multiple U-shaped holders; and
g. vacuum pump capable of evacuating the vacuum chamber to 20 kPa (absolute).

Note: Manual washing may be used instead of the ultrasonic baths, provided that the process is shown to remove lubricant, which can be embedded in the stamping of the seals or in the serrations between packs.

3. Dry vacuum method

a. Select sufficient strips of 2 or 3 condoms from the lots to be tested, to give the required sample size (minimum 80).
b. Wash the strips in isopropanol in an ultrasonic bath for 10 minutes, and ensure they are submerged.

Note: The isopropanol can be re-used until it looks dirty on visual examination.

c. Remove the strips from the bath, and dry them with a paper towel.
d. Place the strips on a clean dry paper towel for to air-dry for at least 10 minutes.
e. Ensure the strips are dry.
f. Wrap each strip in coloured tissue then slide it into a U-shaped holder.
g. Place the U-shaped holders in a vacuum chamber and apply a vacuum of 20 ± 5 kPa (absolute). Hold at 20 ± 5 kPa (absolute) for 20 minutes and release the vacuum.

Note: if the laboratory is close to sea level, then 20 ± 5 kPa absolute is about –80 kPa gauge.

h. Remove the strips from the U-shaped holders one by one and check each tissue for stain marks.
   - Using a fine pen, mark the perimeter of each stain on the tissue.
   - Re-wrap the strip with the same tissue in the same place as before. Use the folds on the tissue to re-align the pack, or, if necessary, put guide marks on the tissue with a pen. Replace the strip in exactly the same orientation as it was before.
   - Record the leaking packages and the location of strip leaks.