Male Latex Condom Testing Guidance
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Condom tests in ISO 4074:2015

The following tests are required in ISO 4074:2015:

- Biocompatibility
- Microbial contamination
- Quantity of lubricant
- Dimensions (length, width, thickness)
- Bursting volume and pressure
- Stability and shelf life
- Freedom from holes
- Visible defects
- Package integrity.
- Packaging and labelling
Condom tests in the WHO/UNFPA Male Latex Condom Guidelines 2013

□ In addition, the UNFPA guidelines also recommend the following are measured:
  □ Water-extractable proteins
  □ N-nitrosamines

□ Note: the Male Latex Condom Guidelines are being revised.
Testing laboratories

- This presentation is aimed at testing that can be carried out by condom manufacturers.
- Assessment of biocompatibility, microbial contamination, and the analysis of N-nitrosamines and water-extractable proteins will probably have to be outsourced.
- Specialist testing laboratories, accredited to ISO 17025, will have the procedures, equipment, skills and experience to carry out most of these tests.
General points to note.

- Follow the specified sample sizes.
- Randomize the sampling.
- Never use scissors or sharp instruments to open the condom pack (except possibly for lubricant determination).
- Ensure that the calibration of instruments is up to date.
- Ensure that the operators are adequately trained.
Two methods are specified in ISO 4074, both using a washing procedure.

- Propan-2-ol or a 5% solution of potassium laurate used.
- Points to note:
  - Ensure the washing process does not remove any identification on the condom and foil.
  - Note that propan-2-ol is flammable.
  - Ensure that constant weight is achieved.
  - The mass loss will include any powder.
Dimensions - length

- Length is measured by hanging the condom on a calibrated rod. Points to note:
  - Lubricated condoms are sticky: it is better to kill the tack by powdering, with or without removal of the lubricant.
  - Ensure that the bead of the condom is at eye-level to avoid parallax errors.
  - Measure the length at several points and record the minimum length to the nearest millimetre.
  - Automated measurement equipment is available.
Dimensions - width

Width is measured by hanging the condom over the edge of a ruler. Points to note:

- Lubricated condoms are sticky: it is better to kill the tack by powdering, with or without removal of the lubricant.
- Ensure that the condom hangs freely with the axis of the condom perpendicular to the ruler.
- Measure the width to the nearest 0.5 millimetre.
- Automated measurement equipment is available.
Dimensions - thickness

- Can use a micrometer gauge or the mass of a test piece from the condom. Points to note:
  - Lubricant is removed before the measurement.
  - Measure at three points (near the closed end, the open end and the centre of the condom).
  - With textured condoms measured with a micrometer, measure a smooth region as close as possible to the specified points, or use the mass method.
  - Condom cut open to measure as single-wall thickness.
Dimensions - thickness

• Micrometer foot pressure to be 22 ± 5 kPa.
• Ensure the shaft of the micrometer is clean.
• Ensure the foot is parallel to the platen.
Bursting volume and pressure measure important properties of a condom.

Several possible causes of variability.
- Loading of the condom.
- Incorrect inflation length.
- Condom slippage during inflation.
- Correct calibration of test equipment

Note that any condom showing an obvious leak must be removed and replaced.
Loading the condom

• The condom may be unrolled beforehand, or unrolled over the supporting rod/mandrel.
• The length to be inflated is 150 ± 3 mm., so
  – Do not stretch the condom over the rod/mandrel – this will shorten the tested length, and give lower burst volumes and higher pressures.
  – Do not hang the condom loosely over the rod/mandrel - this will increase the tested length and give higher volumes, lower pressures.
Check the equipment

- Described in Annex O of ISO 4074.
- Check at appropriate intervals, and include:
  - Confirmation of the correct inflation length.
  - Confirmation of no slippage of the condom.
  - Confirmation of no leaks in the system.
  - Confirmation of the calibration of the pressure gauge.
  - Confirmation of the calibration of airflow rate.
  - Confirmation of no sharp edges on the clamping mechanism.
Freedom from holes

• Like bursting volume and pressure, a critical property of condoms.
• Can be assessed by filling the condom with water and rolling over absorbent paper (“hang and roll”).
• Can also be assessed by looking for electrical leakage through the condom film.
• Includes an assessment of visibly open seals.
• The ASTM D3492 method (“hang and squeeze”) may also be used.
Freedom from holes - water leak test

- Inspect the condom packages for visibly open seals.
- Unroll the condoms and check for visible defects.
- Fill the condom with 300 cm³ of water (more water for extra large condoms).
- Observe for leaks.
- Remove the condoms, carefully twist the open end to seal and roll on absorbent paper.
Water leak test

Points to note.

- Wipe the condom before rolling to remove any water that may have splashed.
- Press the hand onto the condom so that the hand is 25 to 35 mm. above the paper.
- Roll through at least two full revolutions.
- Repeat, applying pressure to other parts of the condom.
- Hold the condom vertically, and press and rotate the closed end onto the paper.
Water leak test – things to avoid

• Do not
  – Roll the condom only a short distance. Ensure that the whole condom surface contacts the paper.
  – Compress the condom too much. The hand must be 25 to 35 mm. above the paper.
  – Stretch the condom.
  – Use absorbent paper held together with adhesive tape.
  – Squeeze the condom too much if using the ASTM test – see the standard for illustrations.
Water leak testing

No!

Yes!
Freedom from holes – electrical test

- Inspect the condom packages for visibly open seals.
- Unroll the condoms and check for visible defects.
- Load onto the test machine and fill with 300 cm³ of electrolyte (more electrolyte for extra large condoms).
- Apply a voltage of 10V dc and lower the condom into a bath of electrolyte.
- Check for current flow.
Water leak test

Points to note.

- Any condom failing the electrical test **must** be confirmed as holed using the hang and roll test.
- Ensure that the electrolyte level in the bath covers the condoms up to 25 mm. from the open end.
- Ensure the equipment is properly calibrated.
- Verify the equipment frequently, using condoms holed **before** testing.
Visible defects

- Include:
  - Adhesion of the internal surface of the condom.
  - Permanent creases or pleats.
  - Broken or missing beads.
  - Thin areas of the film.
  - Delamination.
  - Blisters or bubbles.
  - Large (>1 mm) embedded particles or coagulum.
  - Cracking of the film.

- The WHO/UNFPA guidelines contain a list and description of critical visible defects.
Package seal integrity

• Improved test being developed.
• Current test submerges the condom packs under water and holds them at a reduced pressure of 20 ± 5 kPa for 60 ± 5 seconds.
• The packs are opened after the test to confirm the absence of leaks.
• A low foaming surfactant may be added to the water to improve the wetting of the packs.
• A dye may be added to the water to improve the detection of any water in the pack.
Package seal integrity – points to note.

- Ensure the correct level of vacuum is used.
- The packs must be submerged at least 25 mm below the surface.
- Start observing the packs for escaping bubbles as soon as the vacuum is applied.
- Open the packs after the test to confirm leakage or no leakage.
- Do not overload the test chamber.
- Vacuums are potentially dangerous – use suitable protective equipment.