

AGREED TEST METHOD: MENSTRUAL TAMPONS – ABSORBENCY – SYNGINA METHOD**1 SCOPE**

This standard method specifies a test procedure for the in-vitro measurement of absorbency of menstrual tampons by the Syngina method. It is a quality control test that is used in production sites for :

- a) determining conformance to internal manufacturing specifications, and
- b) for ensuring compliance to the EDANA Code of Practice for Tampon Labelling that has been agreed with the European Commission. It is important to note that this laboratory test is not intended to be used for predicting absorbency in vivo.

The protocol has been used by the tampon industry globally for more than 30 years and it is favoured by some regulatory authorities. It is applicable for products with an absorbency of up to 25 grams. The coefficient of repeatability has been estimated for an absorbency of around 10,5 grams to be less than 5%.

2 NORMATIVE REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of this standard method. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However parties to agreements based on this standard method are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. For undated references, the latest edition of the standard referred to applies.

ISO 5725, Precision of test methods

ASTM D 3492-83, Standard Specification for Rubber Contraceptives (Condoms)

ASTM D 3492-97, Standard Specification for Rubber Contraceptives (Male condoms)

3 TERMS AND DEFINITIONS

For the purposes of this standard method the following definitions apply:

3.1 Syngina

The term is derived from "Synthetic vagina".

3.2 Menstrual tampon/ tampon

A device to be inserted into the vagina to absorb menses.

4 PRINCIPLE

The principle is to simulate the vaginal environment in the laboratory by applying standard pressure to a tampon inside a flexible membrane (a certain type of condom) and then introducing defined amounts of fluid until the tampon leaks. The tampon weight is taken before and after the test to calculate the weight of fluid absorbed.

5 APPARATUS

5.1 Standard laboratory equipment

5.2 Syngina apparatus

The Syngina apparatus set-up is illustrated in Figure 1. This is designed to provide constant hydrostatic pressure of (180 ± 10) mm.

5.2.1 Syngina chamber, details of which are provided in Figure 2.

5.2.2 Infusion pump, set up to deliver (50 ± 2) ml/hour.

5.2.3 Thermostatic bath, with external circuit, set up to (27 ± 1) °C.

5.3 Straight unlubricated condoms having a tensile strength between 17 MPa and 30 MPa measured in accordance with ASTM D 3492-83 and ASTM D 3492-97 (Appendix X1).

Note: For condom installation and replacement: see Annex A (Normative)

6 REAGENTS

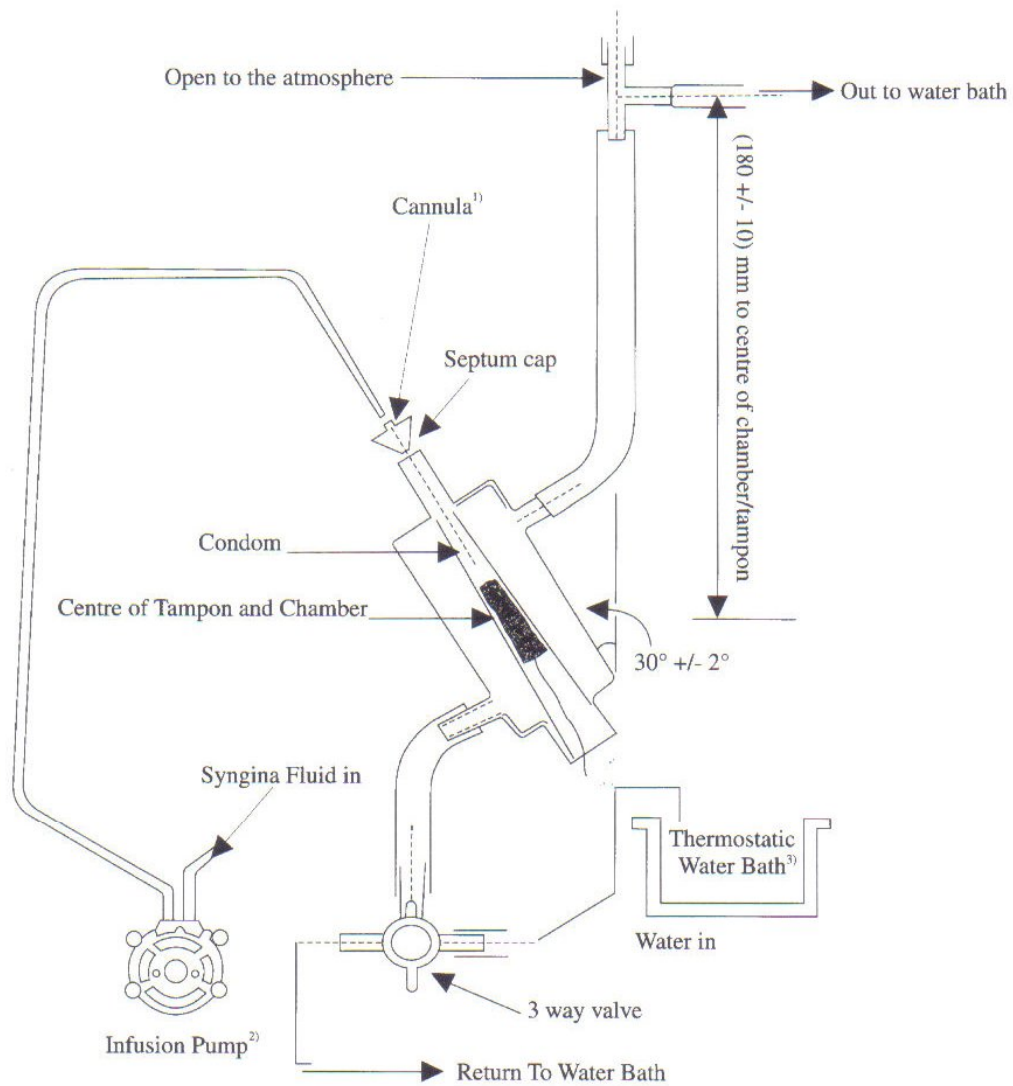
Syngina fluid

The formulation and preparation are given below:

- ↳ Distilled or de-ionised water.
- ↳ Sodium chloride (analytical reagent grade).
- ↳ Colour agent: acid fuchsin, Fisher F97 Certified Biological Stain, Colour Index N° 42685; Fisher Scientific Company or Fruchterot dye, E 144 or Ponceau Cochenillerot E 124 or FD&C Red #40.
- ↳ Sodium chloride solution: Dissolve 10 grams sodium chloride in 1 litre distilled or de-ionised water.
- ↳ Syngina fluid: Dissolve 0,5 gram colour agent in 1 litre sodium chloride solution.
- ↳ Syngina fluid should be regularly replaced to avoid microbiological contamination.
- ↳ Syngina fluid should be stored and used at room temperature.

7 PREPARATION OF TEST SPECIMENS

- 7.1 The test specimen (tampon) shall be removed from its wrapping and applicator, if applicable.
- 7.2 The test specimen shall be unwrapped immediately before testing.
- 7.3 The number of specimens per test, and sampling instructions, must be defined for each specific application.



¹⁾ min 100 mm long; (1,5 +/- 0,15) mm I.D.

²⁾ see 5.2.2

³⁾ see 5.2.3

Figure 1 – Syngina Apparatus

8 PROCEDURE

- 8.1 Weigh the tampon to be tested (including withdrawal cord) to the nearest 0,01 gram. Record the weight.
- 8.2 With the Syngina chamber empty, place the tampon within the condom so that the centre of the tampon is at the centre of the chamber and the withdrawal cord is positioned toward the bottom of the chamber. See Figure 1.
- 8.3 Insert the infusion needle (cannula) through the optional septum cap so that it contacts the top end of the tampon.
- 8.4 Fill the outer part of the chamber with water and adjust the flow such that water trickles over the head and back to the water bath. The liquid must not rise into the atmospheric vent.

Examine the position of the tampon and, if necessary, drain, re-centre and repeat steps 8.3 and 8.4.

- 8.5 Pump the Syngina fluid into the chamber.
- 8.6 The "end point" is defined by the first drop of liquid that exits the apparatus. Terminate the test by stopping the fluid flow.

Note: The test shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated.

- 8.7 Drain the water from the chamber, remove the tampon and weigh it immediately to the nearest 0,01 gram. Record the wet weight.
- 8.8 After the tampon has been weighed, carefully remove any residual fluid (with non-fibre shedding absorbent laboratory wipes) from the inside of each condom in preparation for the next test.

Note: If the test stand comprises more than one chamber, use tampons with the same absorbency, for parallel testing.

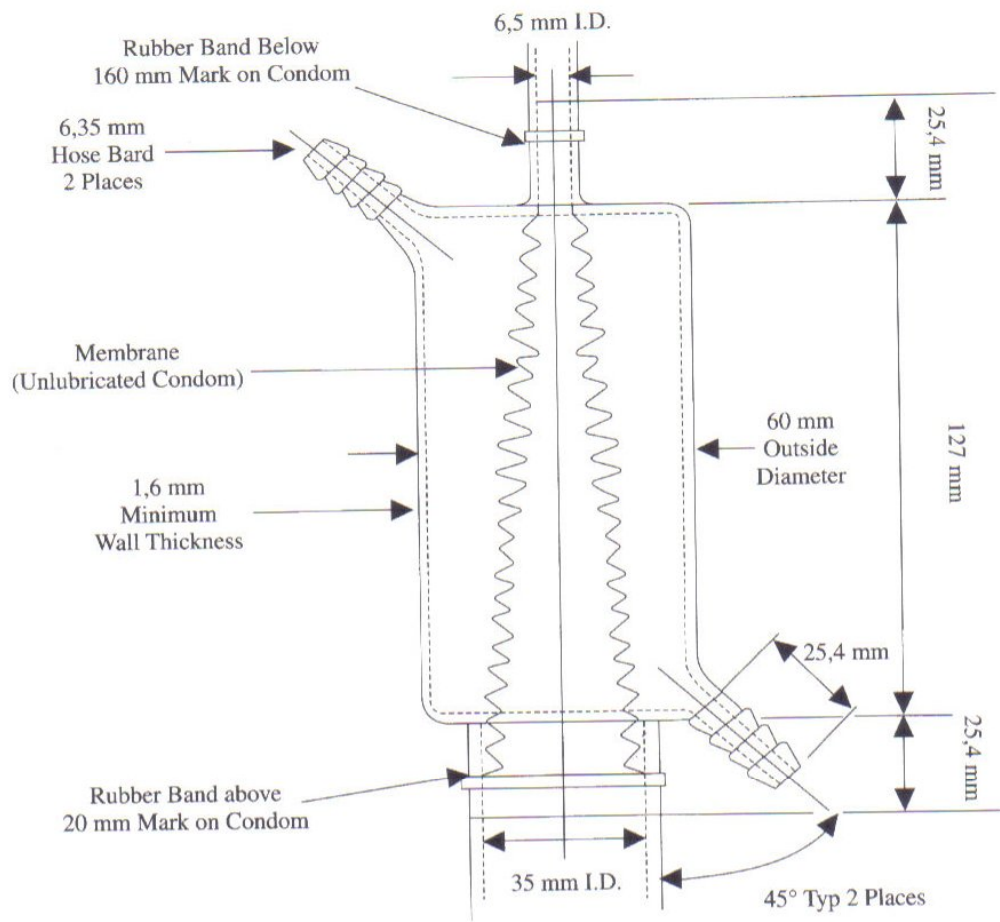
9 CALCULATION AND EXPRESSION OF RESULTS

- 9.1 Calculate the absorbency of each specimen tampon as follows:

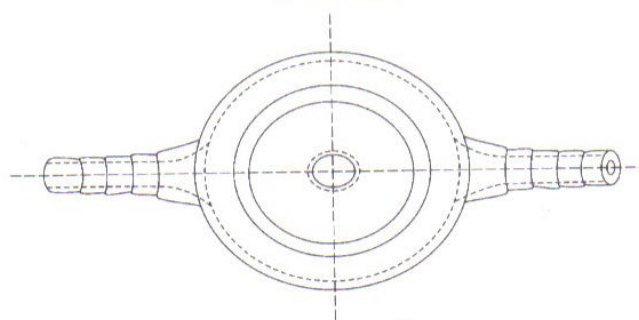
$$A = B - C \quad \text{where:} \quad \begin{array}{l} A = \text{Absorbency of tampon in grams} \\ B = \text{Weight in grams of saturated tampon} \\ C = \text{Weight of dry tampon in grams} \end{array}$$

and express the results to the first decimal.

- 9.2 Calculate the average absorbency of the total number of test specimens.



Top View



¹⁾ MATERIAL: Glass or transparent plastic.

Figure 2 – Syngina chamber

ANNEX A
(normative)

CONDOM INSTALLATION AND REPLACEMENT

Open and unravel a condom.

Mark the condom at 20 mm and 160 mm length from the open end (see Figure 3).

Insert the condom through the chamber with the aid of a rod so that the 160 mm mark rests on the edge of the smaller opening of the chamber (see Figure 2).

Cut the tip of the condom and secure with a rubber band, such that the 160 mm mark remains on the edge of the small opening of the chamber.

Draw the condom through the large chamber opening so that the 20 mm mark rests on the opening's edge (see Figure 2) and secure with a rubber band.

Replace condoms (a) if they leak, (b) after every tenth test or (c) daily – whichever applies first.

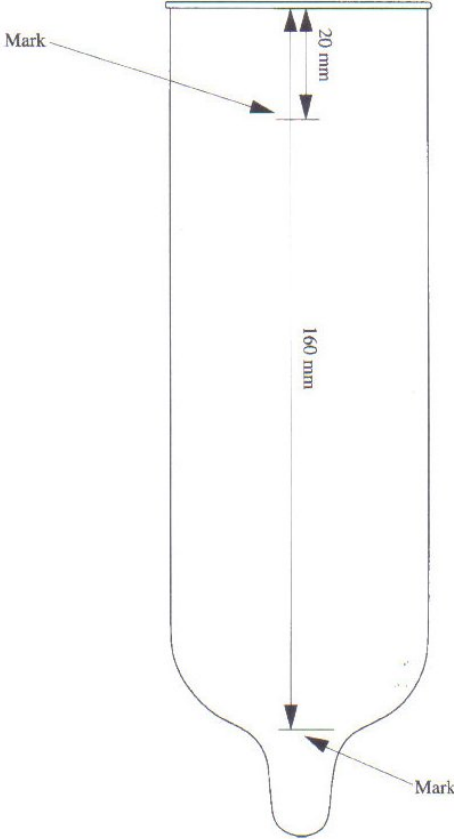


Figure 3 – Condom marking