Technical Specifications for Tampons

1. General Description and intended use:

Tampons are made of absorbent materials that are inserted into the vagina to absorb menstrual fluid. Once inserted correctly, a tampon should be held in place by the vagina and expands as it soaks up menstrual fluid.

2. Product components:

Consisting of a pledget made of absorbent materials, an overwrap (cover), a removal string and with or without an applicator. All tampons shall be provided with a suitably attached removal string to ensure safe, comfortable, and efficient removal.

Shall be supplied as unscented and for single use only.

3. Materials

The absorbent core of the tampons shall be made of materials such as cotton, viscose rayon or a blend of the two or equivalent materials that are proven to be absorbent and biocompatible. Manufacturers are encouraged to use 100% organic cotton for the construction of tampons and weightage will be given to the use of 100% organic cotton.

The overwrap is made of nonwoven material or perforated film to facilitate insertion and removal of the tampon, keep the tampon fibres intact, and aid the absorption of fluid.

The materials used in the construction of the string may be cellulosic or synthetic fibres or a blend of both. Examples include polyester, cotton, viscose, rayon or blend of any.

A chlorine-free bleaching (TCF) is required for the fibres used in tampons. Suppliers shall provide proof of the chlorine free bleaching process for the fibres used in the construction of the tampons.

Restricted materials in the construction of tampons include polyester foam, carboxymethylcellulose (CMC), acrylate modified rayon etc due to the reported toxic effects.

Any addition of chemicals such as fragrances, odour control chemicals, antimicrobial agents shall be declared.

For all component materials present in a tampon, the manufacturer shall provide detailed chemical identity for all components. Any change in raw material from the bid submission shall be informed to UNFPA and the supplier is deemed to resubmit the biocompatibility data for the new raw materials as well as the finished product.

4. Requirements

Visual inspection: Product shall be free from any kind of dust, particulate, and foreign matter.

Biocompatibility: The tampons, in its final form, shall be non-irritant and non-sensitizing and the results of the biocompatibility shall be established by employing tests ISO 10993-parts 5 &10. The sensitization tests shall include intracutaneous irritation and G. pig maximization study.

Linting: The tampons shall be resistant to linting and shall not leave any residual fibres in the vagina after removal.

Removal string: The strength of the removal string shall be enough to withstand the withdrawal force applied by the user. When the string is hanging free from the tampon the length of the string should be no less than 80mm long. The removal string must also meet minimum standards for water repellency and pull strength of the cord (Annexure I). With respect to water repellency, the withdrawal cord shall not sink completely beneath the surface of the water when tested as per Annexe I. The pull strength of the removal string and its attachment point shall be such that the mean force required to break or detach the cord shall not be less than 28 N. No value for an individual string shall be less than 22.4 N when tested at a constant rate of 200± 25 mm/min using a tensile tester or equivalent.

Dangerous chemicals: Tampons, in its final form, shall be free from chemical residues 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)/2,3,7,8-tetrachlorofuran dioxin (TCDF) and any pesticide & herbicide residues. Tampons, in its finished form, shall be free from formaldehyde, heavy metals, polycyclic aromatic hydrocarbons (PAHs), phthalates, dioxins, acrylic monomers, reproductive & developmental toxins and other suspected carcinogens.

Wear time: 4-8h only.

pH: The pH of the tampons shall not harm the vaginal flora. Recommended range is 5.5-8.5 when tested as per ISO 3071:2020 Textiles — Determination of pH of aqueous extract or equivalent.

Size: Size shall correspond to absorbency of the tampons to manage light, moderate and heavy flow.

Product integrity: The user shall be able to remove the tampons without losing its integrity while removal.

Absorbency: The absorbency tests shall be measured by the Syngina Method when tested as per Code of Federal Regulations21CFR801.430, Sec. 801.430 User labelling for menstrual tampons Revised as of April 1, 2020, or equivalent test method.

Ranges of absorbency in grams	Corresponding term of absorbency
6 and under	Light absorbency (very light to light flow)
6 to 9	Regular absorbency (light to moderate flow)
9 to 12	Super absorbency (moderate to heavy)
12-15	Super plus absorbency (Heavy flow)

Microbiology: The total viable microbial/bacterial species count including but not limited to mesophilic bacteria, Anaerobic Bacteria, Fungi (moulds) and yeasts, Coliforms, Escherichia

coli, Staphylococcus spp, Candida albicans, Pseudomonas aeruginosa etc, shall not exceed 10 CFU per gram when determined in accordance with EN ISO 6887-1 or equivalent.

The tampons in its finished form shall be free from Enterobacteriaceae (E. coli), Staphylococcus aureus, candida albicans, Pseudomonas aeruginosa, yeast, and fungi.

Product comes in close contact with skin and mucosa hence, the tampons shall not harm vaginal flora, shall not enhance the growth of Staphylococcus aureus and shall not increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1). The detection and enumeration of the above-mentioned microorganisms shall be tested as per internationally accepted test methods for food or cosmetics such as ISO or equivalent. The supplier shall submit test reports for microbiology for finished good for three recent batches that they have manufactured and marketed.

Applicator: The applicator, if provided shall be a sustainable option that is plastic-free and residual-chlorine free such as cardboard or similar and shall be non-irritant and non-sensitizing. The bidder shall submit the specification for the applicator such as length and diameter, weight of the applicator, applicator click and separation force, and applicator collapse force, expulsion force (between 350g - 600g, indicative figures only) etc to show the applicator meets the purpose intended. There shall be no premature expulsion and shall not cause any damage to the vagina during the insertion process. Bidder shall also provide evidence for ease of use and comfort.

Compostable and biodegradable claim: A claim on the compostability for plastics in the product or packaging shall be accompanied with independent third-party certification as per applicable ISO/EN 17088-2021 standards or EN 13432 respectively. A claim on environmental excellence over the life cycle of the product such as biodegradability shall also be accompanied with independent third-party certification from accredited labs.

The bidder shall furnish an engineering drawing of the tampon and applicator including its shape, length and diameter, weight of the product under offer, and a detailed list of ingredients.

The bidder shall provide valid test reports that the tampon, in its final manufactured form, meets the stated requirements in section 4, does not enhance the growth of Staphylococcus aureus and other microorganisms, and does not contain dangerous & restricted chemicals listed as per section 4. The test reports shall be from third-party testing lab accredited as per ISO 17025.

The bidder shall certify that the tampon, in its final manufactured form, does not contain any dangerous substances including but not limited to substances mentioned above, and is fit for use by human beings in accordance with international standards and regulations as applicable.

5. Instructions For Use (IFU)

Each primary pack must enclose an instruction leaflet which gives clear advice and guidance on the use and disposal of the product. It must be multilingual: English, Arabic, French, Spanish as mandatory at the time of bidding. The bidder shall be ready to provide IFU in other official UN languages as per instructions at the time of order. Instruction for use and care shall be printed as pictograms and as a QR code, if applicable.

IFU shall contain the following information:

- To instruct the user to follow all labelled instructions.
- Inform the consumer to use only one tampon at a time.
- Instruct the user on the method for insertion and withdrawal of the tampon with or without an applicator.
- Instruct the user on the wear time (4-8h).
- Instruct the user on disposal method or as per local regulations.
- Instruct the user to wash hands before and after inserting and/or removing a tampon.
- Advise the user to ensure the removal of the last tampon once menstruation has finished.
- Advise the user to select the tampons of the lowest absorbency for her needs. If you can wear one tampon up to eight hours without changing it, the absorbency may be too high and hence, it is advised to use the lowest absorbency type for your periods.
- To warn the user not to flush tampons, applicator tubes or wrappers.
- To warn the user not to use tampons during sexual (vaginal) intercourse.
- To warn the user not to use tampons for bleeding soon after or within the first 24h after IUD insertion, for vaginal discharge, during vaginal medication, and during any kind of vaginal infections or irritation.
- To avoid toxic shock syndrome (TSS), limit wear-time per tampon to no more than 8 hours and advise against the use of tampons "overnight.
- Include a warning statement on toxic shock syndrome (TSS).

  "Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious illness that may be fatal and refer to leaflet for more information. If you have pain, fever or other unusual symptoms from using tampons, you should discontinue use and consult a medical professional." This statement should be prominent on pack and should have at least a minimum font size equivalent to Arial 7.

  To inform consumers about Toxic Shock Syndrome (TSS). Inform the user in the TSS statement that the illness can be fatal. To provide a full description of the symptoms of TSS to include the following: a sudden high fever usually over 39°C (102°F), vomiting, diarrhoea, muscle aches, a sun burn like rash, sore throat, dizziness and/or fainting. Optional to include severe flu-like feeling.

  To instruct the user that if symptoms of TSS occur, to remove the tampon, consult a health specialist urgently and inform health specialist that a tampon has been used.

- To provide a full description of absorbencies available within a brand's product range, including Syngina absorbency in grams e.g., 6 – 9g, 9-12g etc. and linking to menstrual flow via the primary and secondary descriptors and droplets with droplet size 3mm minimum. Instruct the user to use the lowest absorbency for their flow as it changes throughout their period.

Droplets	**Grams**
1 droplet	<6
2 droplets	6-9

3 droplets 	9-12
4 droplets 	12-15

- If an allergic reaction or irritation occurs from using tampons, you should discontinue use and consult a medical professional.
- To advise the user to alternate between tampons and towels/pads, liners from time to time during their period.
- To include brief details of the absorbent materials in the product.

6. Unit pack and Primary Packaging:

Unit Pack: Each tampon shall be individually wrapped with suitable material such as the tearable paper pouch to ensure that the hygienic quality of the products is maintained throughout the shelf life of the product. The packaging shall ensure the product free from moisture and microbial contamination during storage and transportation and proof of the same shall be provided as the shelf life studies for the product under offer. Use of single use plastic including those from oxo-degradable plastics is strictly not recommended.

Primary package: A pack of 15–40-unit pack of tampons per pack. Includes the IFU leaflet.

The required number of unit packs shall be packed in a primary pack, which is adequately robust to protect the tampons against damage during transport and storage. The material of the primary package shall be made of paper or paper laminates and only minimal use of plastic is recommended for the primary package. The primary pack shall be properly sealed to avoid tampering.

Weightage shall be given to manufacturers who uses the environmentally sustainable options for packaging.

7. Labelling on the primary package:

a. Printing on primary packing shall have product name, Manufacturer's name and address, Tampon's type (by droplet method from syngina absorption testing or equivalent), Lot/batch No, Date/month/year of manufacture, Expiry date/year, number of tampons, Manufacturing license No., and List of ingredients.

b. Instruction for use and care shall be printed primarily as pictograms. QR code may be printed on the primary packaging, if applicable.

The following information on the primary package shall be in prominently and legibly at least a minimum font size equivalent to Arial 7, to render the information likely to be read and understood by the ordinary individual:

c. To instruct the user to follow all labelled instructions.

d. For single use only.

e. Inform the consumer to only use one tampon at a time.

f. Pictograms for absorbency recommendation

g. Instruct the user to wash hands before and after inserting and/or removing a tampon.

h. Instruct the user on the method for insertion and withdrawal of the tampon with or without an applicator (to be provided as per the product under offer).

i. Use tampons only when you have your period.

j. Instructions on disposal.

k. To warn the user to ensure the removal of the last tampon once menstruation has finished.

l. To warn the user not to flush tampons, applicator tubes or wrappers.

m. To warn the user not to use tampons during vaginal sexual intercourse.

n. To warn the user not to use tampons for bleeding soon after IUD insertion, for vaginal discharge, during vaginal medication, and during any kind of vaginal infections or irritation.

o. Include a warning statement on toxic shock syndrome (TSS) on the primary package. e.g., sudden fever (usually 102 °F. or more) and vomiting, diarrhoea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn; including the need to remove the tampon at once and seek medical attention immediately.

p. To reduce your risk of TSS, use the lowest absorbency tampon necessary, wear a tampon for not more than 8 hours, and advise against the use of tampons “overnight”. Advise user to alternate between pads and tampons.

q. The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

Use pictograms for use and disposal instructions is recommended to accommodate all the above the information on the primary package. The warning statements from “k to q” shall be in multilingual.

8. Secondary packaging:

Marked as per contract. Number of units in the secondary packaging. Printing on secondary packaging shall include Generic name of product, Manufacturer's name and address, Lot/Batch No, Date, month and year of manufacture.

9. Regulatory and conformity Requirements:

Applicable QMS standards ISO 9001 minimum. ISO 13485 will be an added advantage.

ISO 13485 - Medical Devices - Quality Management Systems

10. Safety and Product Standards, must comply with following standards:

Test reports showing biocompatibility as per ISO 10993 Part-5&10: Evaluation and Testing to assess the safety.

Absorbency testing carried out as per - NWSP 350.1 OR Code of Federal Regulations 21CFR801.430 Revised as of April 1, 2020, or equivalent

REACH Regulation (Annex XVII)

Detection and enumeration of bacteria, fungi etc as per ISO test methods for food or cosmetics

- ISO 6888 Horizontal methods for the enumeration of coagulase-positive Staphylococci
- ISO 21149, Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria.
- ISO 22717, Cosmetics — Microbiology — Detection of pseudomonas aeruginosa.
- ISO 22718, Cosmetics — Microbiology — Detection of staphylococcus aureus.
- ISO 18416, Cosmetics — Microbiology — Detection of candida albicans

Third party test report for the product in the final form shall be conducted at labs accredited as per ISO 17025.

11. Classification:

Class II as per FDA 884.5470 Unscented menstrual tampon.

As per EU regulation, tampons are expected to meet the General Product Safety Directive (EEC Directive 2001/95/EC) and the EU Tampons Code of Practice, updated as of Dec 2020.

12. Environmental Requirements:

Preferrable to have Environmental Management system certification as per ISO 14001.

Use of single use plastics including those from oxo-degradable plastics is not recommended. Manufacturers may be aware that as per the single-Use Plastic Directive (EU) 2019/904, the marking specifications for four product groups including feminine hygiene pads and tampons are established which includes the labelling to inform consumers about the presence of plastic in the products to avoid inappropriate waste disposal by consumers.

Certifications such as FSC, EU ecolabel (as per 2014/763/EU) for absorbent hygiene products is highly recommended

FSC certification for the fibre raw material suppliers and packaging may be advantageous.

Meeting one or more of the above requirements shall be given weightage during the bidding and evaluation.

13. Special instructions

The information and data relevant to the product that are shared with UNFPA will be treated as confidential.

Manufacturers are encouraged to use environmentally sustainable options for the construction of tampons, the claim for which shall be accompanied by third party test reports or third-party certifications.

Weightage will be given manufacturers who are using compostable raw materials, environmentally sustainable packaging, and meeting one or more of the requirements listed in section 12.

For applicator, only the sustainable options with third party test reports for all the requirements as detailed in section 4 will be considered for bid evaluation process. In the absence of such applicators, bidders are encouraged to bid for digital tampons (insertion with fingers).

All the test reports submitted for the product as proof for the specification requirements shall have the manufacturer name, the name & picture of the product under offer with packaging and SKU of the product (the product under offer shall be the same as the one in the test report) and shall be from labs accredited as per ISO 17025 or equivalent.

Manufacturers are encouraged to share the post market report / market feedback study for the item under offer which involves studies involving consumers.

The bidder shall be able to provide the IFU in six official languages of UN namely, Arabic, Chinese, English, French, Russian and Spanish

14. Instructions to CO: Instructions for IFU in the official UN languages may be communicated at the time of placing the order.

15. References:

Guidance for Industry and FDA Staff Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) Document issued on: July 27, 2005.

Absorbency: Code of Federal Regulations21CFR801.430, Sec. 801.430 User labelling for menstrual tampons Revised as of April 1, 2020

Edana Code of Practice for Tampons

AS 2869—2008 Australian Standard® Tampons—Menstrual

Guidance on the tampons in Australia Version 3.0, April 2019, Therapeutic goods Administration

Annexure I - Test method for water repellency and pull strength of the cord (Adapted from Annex B and C of KS 1534-2021 & Australian standard 2869-2008)

Pull strength of the cord: The apparatus used shall be a tensile testing machine capable of testing at a constant rate of 200 ± 25 mm/min. Condition the wrapped tampons for not less than 12 h at 20 ± 2°C and 65 ± 5% relative humidity. The tampon is placed in a holder having internal diameters of 26 ± 1 mm and the cord is pulled through the base of the hole in the holder and then attached to the lower jaw of the tensile machine. Place the flange on the holder into the upper jaw of the tensile testing machine making sure to extend the cord so that there are no kinks in it. Start the test at a constant rate of extension of 200 ± 25 mm/min and and record the force required to either break the cord or detach it from the body of the tampon. Repeat and note the average of 6-9 readings.

Repeat the test in the wet state which is as follows. Place the tampon in the 1000 mL beaker in an excess of the water and leave the tampon in the water for at least 5 min. Remove the tampon with the tongs and gently squeeze to remove excess water and repeat the test as above.

Record the average of 6-9 readings as the mean pull strength (force) of the cord.

Water repellency: Cut a section of the cord approximately 75 mm long and gently place them on the top of a beaker containing 500ml water. Observe at the end of 5h to see if the cord samples are floating on the water surface or have sunk completely beneath the surface. If the repellency of the cord is such that it does not sink in a prescribed time, the cord is determined to have satisfactory water repellency. Do five samples parallel.

Glossary

Pledget: is a compress or pad used to apply medication to or absorb discharges

TCF: Total chlorine free

Definitions

Unit pack: The pack enclosing a single tampon with or without the applicator.

Primary pack: The pack containing one or more unit packs. This is form that the users/customers see when procured.