नेपाल सरकार
उद्योग, वाणिज्य तथा आपूर्ति मन्त्रालय
नेपाल गुणस्तर तथा नापतौल विभाग

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नेपाल गुणस्तर
NEPAL STANDARD

SANITARY NAPKINS-SPECIFICATION

नेपाल सरकार
उद्योग, वाणिज्य तथा आपूर्ति मन्त्रालय
नेपाल गुणस्तर तथा नापतौल विभाग

Government of Nepal
Ministry of Industry, Commerce and Supplies
Nepal Bureau of Standards and Metrology (NBSM)
Kathmandu, Nepal
www.nbsm.gov.np

Table of Contents

1 Scope

This standard covers the requirements for disposable (non-reusable) sanitary napkins for external use.

2 References

The standards given in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subjected to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

3 Materials

All types of sanitary napkins basically consist of three major components:
a) Cover or the top sheet;
b) Absorbent core, and
c) The barrier or bottom sheet.

3.1 Cover/Top Sheet

The cover/top sheet is the material which comes under contact with skin during use. The cover of sanitary napkin shall be of good quality cotton, rayon knitted sleeve or gauze, non-woven fabric or any other materials with sufficient porosity to permit the assembled pad to meet the absorbency requirements.

3.2 Absorbent Core

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material.

3.3 Barrier or Bottom Sheet

The barrier shall be made of suitable leak proof material so that it meets the requirement specified in 7.2

4 Type and Shapes of Sanitary Napkins

4.1 The sanitary napkin shall be of following types:

a) Thick napkins and
b) Thin napkins

NOTE: - The thin napkins contain a compressed sheet of absorbent material in the core, whereas thick napkins are referred as fluff pulp napkins.

4.2 Sanitary napkins can be of various shapes and design such as wings/no wings, tab/tab-less etc. or as per purchaser's needs.

NOTE – Sanitary napkins with wings provide better grip on the undergarments so that napkin remains in its position under dynamic conditions. Some napkins can also be folded to be carried in a small pouch.

5 Sizes

Size of sanitary napkins shall be as agreed to between the purchaser and the supplier. Sizes of sanitary napkins shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows:

Size	Pad length (mm) (Absorbent Core Only)	Pad width (mm) (Absorbent Core Only)
Regular	≤ 210	Min 55
Large	211 to 240	Min 55
Extra-Large	241 to 280	Min 55
XXL	≥ 281	Min 55

6 Manufacturers, Workmanship and Finish

6.1 The wood pulp or other absorbent filler shall be arranged and neatly cut to the required size and shape of the napkin without any wrinkles and distortion. The absorbent material is deposited on to a pre-glued cover in such a way that it does not cause lump formation with the effect of sudden pressure. The covering fabric should cover the filler completely and shall extend beyond the width for wing formation or beyond the length of the filler to form tabs or loops at each end. The absorbent along with the cover is then fed to the embossing unit, if any pattern is required to be embossed. Finally, a pre-glued barrier is applied on to other side of absorbent filler, forming a complete napkin structure. A napkin is then sealed using heat and pressure along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less napkins, an adhesive system or other suitable method may be introduced for holding the napkin securely in position. The barrier is applied with release paper to fix the napkin to the undergarment, for the tab-less napkins.

6.2 The sanitary napkins shall have a soft feel and when worn shall not chafe or give any uncomfortable feeling. They shall be free from all sorts of foreign matter.

7 Requirements

7.1 *p*H Value

The pH of the absorbent material shall be from 5.5 to 8.0 when tested by the method given in NS/ISO 3071:2020

7.2 Ability to Withstand Pressure after Absorption

The sanitary napkin shall absorb 30 ml of coloured distilled water and it shall not show leakage at the bottom or sides of the sanitary napkin, when tested according to method given in Annex B.

7.3 Hygiene Testing Requirement

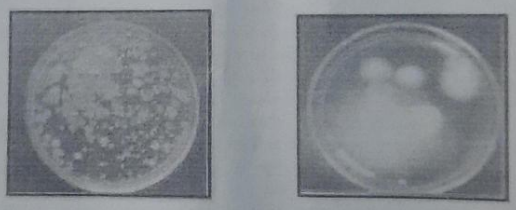
Total viable count (total number of bacteria and fungi) shall not be more than 1000 cfu/gm and *staphylococcus aureus* shall be absent.

7.3.1 Bacterial and Fungal Bioburden

The napkin shall be tested for bacterial and fungal bioburden in accordance with method given in **7.3.1.1**. For selecting sample item portion (SIP), appropriate eluent and methods of extraction: NS/ISO 11737 (Part 1) shall be referred.

7.3.1.1 Test Method

A sample of 5gm cut from the centre portion of the napkin shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the napkin or the quantity in which the napkin completely immerse. The napkin shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, this is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30-35^{0}C for 24 h and count colonies. Continue incubation up to 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20-25^{0}C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig.1.



(A) (B)

Fig.1 Typical Colony Characteristics of Bacterial Bioburden (A) and Fungal Bioburden (B)

7.3.2 Test for Common Skin Pathogen – *Staphylococcus aureus*

The napkin shall be tested for the presence of *Staphylococcus aureus* in accordance with method given in **7.3.2.1**. For the preparation of medium such as cooked salt medium, baird-parker medium and method for coagulase test: Annex D shall be referred.

7.3.2.1 Test Method

A sample of 5gm cut from the centre portion of the napkin shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37^{0}C for 24 h. Report the quantity of the medium used for enrichment in the test report. The incubated sample shall be shaken vigorously in the medium and the liquid shall be extracted from the

napkin. The extract shall be streaked onto a *Staphylococcal* isolation medium, such as Baird-Parker medium or equivalent and incubated at 37°C for 24-48 h and examine for growth. The result is considered positive if black colonies with a narrow white margin, surrounded by a zone of clearance are seen. Suspect colonies must show coagulase activity to confirm presence of *Staphylococcus aureus*. The typical colony characteristic is shown in Fig. 2.

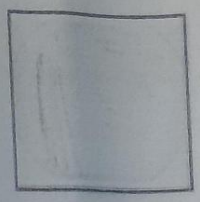


Fig.2 Typical Colony Characteristics of *Staphylococcus Aureus*

7.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement

The sanitary napkin shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C.

7.4 Biocompatibility Evaluation – Cytotoxicity, Irritation and skin Sensitization

The manufacture shall ensure raw material used for manufacturing the final product are safe for user based on its known toxicological characteristic at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per NS/ISO 10993 part 5 and NS/ISO 10993 part 10 respectively.

For cytotoxicity, the material shall show reactivity as 'None' when tested as per NS/ISO 10993 part 5. Similarly, the material shall be 'Non-irritant and Non-sensitizer' when tested as per NS/ISO 10993 part 10. For preparation of samples for these tests, NS/ISO 10993 part 12 shall be referred.

7.5 Biodegradability and compostability (optional)

The manufacturer who are claiming their product as biodegradable or compostable shall perform the above testing for the final product. The product shall be biodegradable or compostable when test as per NS/ISO 17088. The information whether the product is biodegradable, compostable or oxy-degradable shall be marked on every packet of sanitary napkin.

8 Sampling and criteria for conformity

8.1 Lot

All the sanitary napkin of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

8.1.2 The number of sanitary napkin to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of table 1.

Table 1 Number of sanitary napkins to selected (Clause 8.1.2)

S.N.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of Napkins to be Selected	Acceptance Number	No. of Napkins to be Selected	Acceptance Number
1	Up to 280	13	1	5	0
2	281-500	13	1	5	0
3	501-1200	20	1	5	0
4	1201-3200	32	2	8	0
5	3201-10000	32	2	8	0
6	10001-35000	50	3	8	0
7	35001-150000	80	5	13	0
8	150001-500000	80	5	13	0
9	500001 and over	125	7	13	0

Note: for hygiene testing, biocompatibility evaluation, biodegradabillty and compostabillity refer clause **8.2.4**, **8.2.5** and **8.2.6** respectively.

8.1.3 These sanitary napkin shall be selected at random from the lot. For this purpose, reference may be made to NS 145:2044.

8.2 Number of Test and Criteria for Conformity

8.2.1 All sanitary napkins to be selected as per column 3 of Table 1 shall be examined for workmanship and finish.

8.2.1.1 Any sanitary napkin failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements. If the total number of defective found in the sample is less than or equal to the acceptance number given in column 4 of Table1. Otherwise, the lot shall be rejected.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 5 of Table 1 shall be taken. This sub-sample shall be further tested for the remaining requirements.

8.2.3 The lot shall be considered as conforming to the requirements of the specifications, if the total number of defective sanitary napkin found in the sample (see 8.2.2) is less than or to the acceptance number as given in column 6 of Table 1.

8.2.4 The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.

8.2.5 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material for manufacturing the product.

8.2.6 The biodegradability and compostability testing shall be carried out once for existing products and whenever there is change in the raw material for manufacturing the product.

8.2.6 The biodegradability and compost ability testing shall be carried out once for existing products and whenever there is change in the row material for manufacturing the product

9 Marking

9.1 Each consumer pack shall be legibly and indelibly marked with the manufacturer's name or trademark, number of sanitary napkins contained it, and size designation in addition to the following:

a) Direction of use:

b) Disposability instruction: The manufacture shall provide the instruction to users for safe disposal of the product as per *Solid Waste Management Rules*, 2016 or any other rules and regulation published from time to time:

c) Batch/Lot No. and Date of Manufacturing: and

d) Any other information required by law in force or agreed between the buyer and the seller.

9.2 NS certification marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Nepal Standard (Certification Mark) Act, 2037 and the Rules and Regulations framed thereunder, and the products may be marked with the standard mark.

10 Packing

Sanitary napkin shall be packed in rigid or flexible packages that protect the product from contaminants during shipment and storage. This package could be constructed of materials such as carton board, polyethylene, polypropylene, polyester or other safe materials that provide sufficient protection to the product. The package should be free of any torn or damaged areas.

ANNEX A
(Clause 2)

List of Referred Standards

NS 145: 2044 Random Sampling Method

NS/ISO 3071: 2020
Textiles- Determination of pH of aqueous extract

NS/ISO 10993 (Part 5): 2009
Biological evaluation of medical devices: Part 5 Tests for in-vitro cytotoxicity

NS/ISO 10993 (Part 10): 2010
Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization

NS/ISO 17088: 2012
Specifications for compostable plastics

NS/ISO 10993 (Part 12): 2012
Biological evaluation of medical devices (Part 12) Sample preparation and references materials

NS/ISO 11737 (Part1): 2018
Sterilization of medical devices - Microbiological methods - Part1: Determination of a population of microorganisms on products

NS 587:2077

ANNEX B
(*Clause 7.2*)

Method for Determination of Ability to Withstand Pressure after Absorption

B-1 Test Procedure

Lay the sanitary napkin on a flat level transparent surface, so that underside of sanitary napkin can be observed. Drip at the rate of 5ml per minute, 30ml of coloured distilled water maintained at temperature of $27^0C \pm 2^0C$ on to the centre of the napkin from a height of 1-2mm. After the napkin has absorbed full amount of coloured distilled water, keep a standard weight of 1kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and sides of sanitary napkin for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

B-2 Add 0.01gm colour of Bromocresol Purple (Grade – Chemical analytical grade or equivalent) in 1000 ml of distilled water and stir evenly to get uniform coloured solution.

ANNEX C
(*Clause 7.3.3*)

Good Manufacturing Practice for Hygiene Requirement

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumer use. Following are recommended guidelines for ensuring hygiene at facilities:

a) Location should be free from objectionable odours, smoke dust and other contaminants.

b) Separate areas shall be demarcated for storing raw materials, production and final product storage.

c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.

d) Toilet and hand washing station shall be provisioned away from storage/production area.

e) Provision of 70 percent isopropyl alcohol (IPA) solution for hand sanitization inside the production facility.

f) Appropriate lighting and proper ventilation of the facility shall be ensured.

g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors, and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.

h) Regular pest control measures shall be put in place.

i) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.

j) Poster sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc., shall be displayed.

k) Pre-packed finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.

l) Hand hygiene shall be practiced during manufacturing.

m) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning disinfection of the equipment.

ANNEX D

D-1 MEDIA

D-1-1 Nutrient broth – mix and dissolve by heating 10 g peptone. 10 g meat extract, and 5 g sodium chloride in 1000 ml water. When cool adjust pH to 7.5 to7.6. Remove precipitate by filtration through filter paper. Sterilize by autoclaving at 120^{0}c for 15 minutes.

D-1-2 Nutrient agar – To the medium as in D-1-1, add agar in such a concentration as will solidify and produce a sufficiently firm surface when poured in sterile petri dishes. The concentration of agar to be added varies from batch to batch and should be adjusted accordingly. Usual concentrations required vary from 1.5 to 3 percent. Dissolve the agar in the nutrient broth and sterilize by autoclaving at 120^{0}c for 15 minutes. Plates and slopes are prepared from sterile nutrient agar.

D-1-3 Blood agar – Melt sterile nutrient agar as prepared in D-1-2 and hold between 50 to 55^{0}C in water–bath. Add sterile blood free from preservatives to give a concentration of 10 percent. Mix well and pour plates. Horse blood is commonly used but when not available, that of sheep, human or rabbit may be used.

D-2 salt Medium

D-2-1 Cooked meat medium – Mix 500 g fresh beef heart and place in 500 ml of alkaline boiling water containing 1.5 ml of 1N sodium hydroxide solution. Simmer for 20 minutes. Drain off the liquid through muslim filter while still hot and partially dry the meat in cloth or on filter papers. To 500 ml of liquid filtered from the cooked meat add 2.5 g, peptone and 1.25 g sodium chloride. Steam at 100^{0}C for 20 minutes and add 1ml concentrated hydrochloric acid and filter. Bring the reaction of the filtrate to pH 8.2 and steam again at 100^{0}C for 30 minutes; adjust PH to 7.8. Place meat in test–tubes or in about 30 ml screw-capped bottles to a depth of about 2.5 cm and cover with 10 ml of the broth obtained. Autoclave at 120^{0}C for 20 minutes. A layer of sterile paraffin may be added to cover the surface.

D-2-1-1 For salt medium – Add further 10 percent sodium chloride to the broth (D-2-1) adjust the PH to 7.8 and proceed as in D-2-1

D-3 Baird –Parker medium – Dissolve by boiling in 950 ml of water. 10 g tryptone, 5 g meat extract. 1 g yeast extract, 12g sodium pyruvate, 12 g glycine, 5g lithium chloride and 15 to 30 g agar. Distribute in 95 ml amounts into sterilized flasks (or screw-capped bottles) and sterilize at 120^{0}C for 15 minutes. The final PH should be 6.8 to 7.2.

To 95 ml of the molten medium D-3 kept at 45^{0}C to 50^{0}C. Add 5 ml of Bacto–EY tellurite enrichment which has been pre-warmed to 45^{0}C to 50^{0}C. Mix well and pour on to sterilized petri dishes. The plates should be made freshly before use and should not be stored longer than 48 hours before use. The plates, before use, should be well-dried by keeping in an incubator at 50^{0}C for about 30 minutes, with the lid removed and agar surface downward.

D-4 coagulase Test

This test may be carried out by the following. The tube method shall be preferred:

a) Slide method – Emulsify a portion of the suspect colony in normal saline or water. Mix this with a straight wire dipped in human or rabbit plasma. Coagulase-positive staphylococci produce visible clumping immediately.

b) Tube method – Emulsify a single suspect colony from a 24 hour growth of blood agar medium (D-1-3) in 1 ml titrated rabbit plasma diluted 1 in 5 in 0.8.5 percent saline. The test is usually carried

Out in narrow tubes placed in an incubator preferably saline. The test is easily carried out in narrow tubes. Place in an incubator preferably in water-bath at 37^0C. Observe every hour to note clotting of plasma. Reading should be carried out for as long as possible, preferably avoiding overnight incubation. Positive control with a known coagulase-positive strain of staphylococcus and a control of the diluted plasma without inoculums should be included in the test.

Note1- If the slide method gives a negative results, the tube method shall be carried out.

Note2- False positive result may occur on the slide test. A small number of the strains give a positive slide test with a negative tube test due to the production of 'bound' coagulase alone.

	Document To Submitted for NS Applicant	YES	NO	REMARK
~~i~~	NS को निवेदन			
i	कम्पनी दर्ताको प्रमाण पत्र जारी गर्ने कार्यालय : कम्पनी रजिस्ट्रारको कार्यालय			
ii	स्थायी लेखा नम्बर दर्ता प्रमाण पत्र जारी गर्ने विभाग : आन्तरिक राजश्व विभाग			
iii	ट्रेडमार्क दर्ता प्रमाण पत्र जारी गर्ने विभाग : उद्योग विभाग			
iv	उद्योग दर्ता प्रमाण पत्र जारी गर्ने विभाग : उद्योग विभाग			
v	कर चुक्ता प्रमाण पत्र जारी गर्ने कार्यालय : आन्तरिक राजश्व कार्यालय			
vi	आवेदन शुल्क बुझाएको रसिद (रू २,०००/-)			
~~vii~~	Quality Manual			

4.Topic covered in Quality Manual [where applicable]	YES	NO	REMARK
Quality Manual Submitted			
1. Company/Industry Profile			
2.Organization Chart/Structure			
3. Job Description/Role and Responsibility			
4. Process flow chart with description			
5. Process description with control points			
6. Description of process from raw materials to finished product stage ready for dispatch with control points			
7. Quality Assurance Plan i. Quality Plan of Incoming Raw Materials ii. Quality Plan of In-process iii. Quality Plan of Finished Goods			
8. List of Machineries			
9. List of Testing Equipments and their calibration plan (both internal and external)			
10. List of consumables (chemicals)			
11. Environmental condition of Testing Laboratory			
12. Format of test report issued by Testing Laboratory			
13. List of Technical manpower with competency requirements (Name, Designation, Qualification, Experience and Training)			
14. Information concerning all outsourced processes used by client that will affect conformity to requirements			
15. Product identification and traceability (labelling and marking system)			