FDBTS XXX: 2022 IS 5405: 2019

BHUTAN STANDARD

Sanitary Napkins-Specification

ICS 59.080

BHUTAN STANDARDS BUREAU

The National Standards Body of Bhutan

THIMPHU 11001

…… 2022

Price group B

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NATIONAL FOREWORD

This Bhutan Standard which is identical with IS 5405: 2019 Sanitary Napkins- Specification issued by the Bureau of Indian Standards (IS) was adopted by Bhutan Standards Bureau by Pharmaceutical and Traditional Medicines Technical Committee (TC 05) and approved by the Bhutan Standards Bureau Board (BSB Board) on …… 2022.

The text of the IS Standard has been approved as suitable for publication as Bhutan Standard without deviation. Certain conventions are however, not identical to those used in Bhutan Standard.

Attention is particularly drawn to the following:

a) Where the words “IS Standard” appear referring to this standard, they should be read as “Bhutan Standard”.

b) Wherever page numbers are quoted, they are “IS (IS Standard)” page numbers.

भारतीय मानक
Indian Standard

IS 5405 : 2019

सैनिटरी नैपकिन — विशिष्टि

(दूसरा पुनरीक्षण)

Sanitary Napkins — Specification

(Second Revision)

ICS 59.080

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October 2019 **Price Group 4**

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

Sanitary napkin is an absorbent material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage.

This standard was originally published in 1969 and subsequently revised in 1980. The present revision has been made in the light of experience gained since its last revision and to incorporate the following major changes:

a) Material and sizes have been modified.
b) Types of sanitary napkin have been specified.
c) The procedure and requirement of ability to withstand pressure after absorption have been modified.
d) The optional requirement of disposability has been modified.
e) Hygiene testing requirement has been specified.
f) Good manufacturing practice guidelines for hygiene requirement has been specified.
g) Biocompatibility evaluation requirement has been specified.
h) Optional requirement of biodegradability and compostability have been specified.
j) Sampling and criteria for conformity has been specified.
k) Marking and packing clause has been modified.

This standard contains clause **5.1** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

The composition of the committee responsible for the formulation of this standard is given in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SANITARY NAPKINS — SPECIFICATION

(Second Revision)

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 subject 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. If cotton gauze is used, it shall conform to IS 758.

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	
Extra-large	241 to 280	
XXL	≥ 281	

6 MANUFACTURE, 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 adhesives 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 *p*H of the absorbent material shall be from 5.5 to 8.0 when tested by the method given in IS 1390 (cold method).

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 1 000 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; ISO 11737 (Part 1) shall be referred.

7.3.1.1 *Test method*

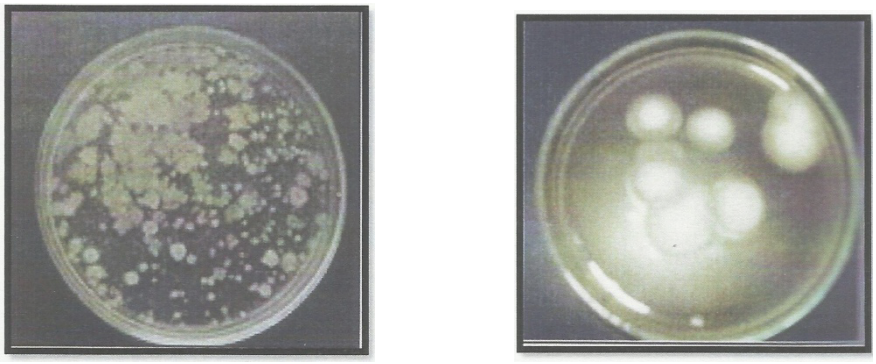
A sample of 5 gm cut from the centre portion of the napkin shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the napkin or the quantity in which the napkin completely 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, that is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30-35°C for 24 h and count colonies. Continue incubation upto 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°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.

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; IS 5887 (Part 2) shall be referred.

7.3.2.1 *Test method*

A sample of 5 gm 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°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.



(A) **(B)**

FIG. 1 TYPICAL COLONY CHARACTERISTICS OF BACTERIAL BIOBURDEN (A) AND FUNGAL BIOBURDEN (B)

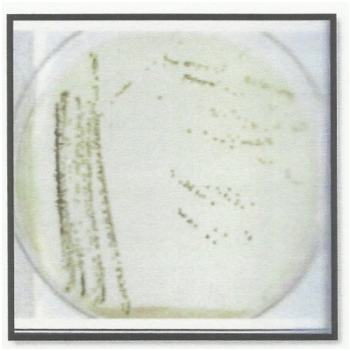


FIG. 2 TYPICAL COLONY CHARACTERISTICS OF *STAPHYLOCOCCUS AUREUS*

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

For cytotoxicity, the material shall show reactivity as 'None' when tested as per IS/ISO 10995 Part 5. Similarly, the material shall be 'Non-irritant and Non-sensitizer' when tested as per IS/ISO 10993 Part 10. For preparation of samples for these tests, 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 tested as per IS/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.

8.1.3 These sanitary napkin shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 1 Number of Sanitary Napkins to be Selected

(*Clause* 8.1.2)

Sl No.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of Napkins to be Selected	Acceptance Number	No. of Napkins to be Selected	Acceptance Number
	N	*n*	*a*	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13	1	5	0
ii)	281 - 500	13	1	5	0
iii)	501 - 1 200	20	1	5	0
iv)	1 201 - 3 200	32	2	8	0
v)	3 201 - 10 000	32	2	8	0
vi)	10 001 - 35 000	50	3	8	0
vii)	35 001 - 150 000	80	5	13	0
viii)	150 001 - 500 000	80	5	13	0
ix)	500 001 and over	125	7	13	0

NOTE — for hygiene testing, biocompatibility evaluation, biodegradability and compostability refer clause **8.2.4**, **8.2.5** and **8.2.6** respectively.

8.2 Number of Tests 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 defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 1. 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 specification, if the total number of defective sanitary napkin found in the sample (*see* **8.2.2**) is less than or equal 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 a change in the raw 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 in it, and size designation in addition to the following:

a) Directions of use;
b) Disposability instructions . The manufacturer 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 BIS 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 *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

10 PACKING

Sanitary napkins 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 STANDRDS

IS No./Other Publication	*Title*
758 : 1988	Specification for cotton gauze, absorbent, non-sterilized (*fourth revision*)
1390 : 2019	Textiles — Determination of *p*H of aqueous extracts (*second revision*)
4905 : 2015	Random sampling and randomization procedures (*first revision*)
5887 (Part 2) : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of *Staphylococcus aureus* and faecal *Streptococci* (*first revision*)
IS/ISO 10993 (Part 5) : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993 (Part 10) : 2010	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization
IS/ISO 17088 : 2012	Specifications for compostable plastics (*first revision*)
ISO 10993-12 : 2012	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

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 5 ml per minute, 30 ml of coloured distilled water maintained at temperature of 27°C ± 2°C on to the centre of the napkin from a height of 1-2 mm. After the napkin has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg 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 0.01 g colour of Bromocresol Purple (Grade – Chemical analytical grade or equivalent) in 1 000 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 consumers 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.

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

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

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

n) Hand hygiene shall be practised during manufacturing.

p) 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

(*Foreword*)

COMMITTEE COMPOSITION

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BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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