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Draft Indian Standard

**IS 5405 : 2024 Disposable Sanitary Napkin/ Pantyliner/ Maternity Pad/Period Panty —
Specification (*third revision*)**

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FOREWORD

(Formal clause will be added later)

Sanitary napkin/panty liner/maternity pad/period panty is an absorbent hygiene 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. Panty liners are a thinner, smaller version of a sanitary napkin. They are made of similar absorbent material for daily use to absorb light vaginal discharge, minor menstrual flow, or spotting. Maternity pads are generally thicker and can be longer version of a sanitary napkin used to absorb postpartum bleeding that happens for weeks after childbirth. Period panties are wearable form of sanitary napkin and made of absorbent material used to absorb fluid discharged during menstruation. Period panties are also referred as period underwear or period underpants. Sanitary napkins are also referred as sanitary pads or menstrual pads.

This standard was originally published in 1969; and subsequently revised in 1980 and 2019. The third revision has been made to incorporate the following major changes:-

- a) All amendments have been incorporated.
- b) Title and scope of the standard has been updated.
- c) Material and sizes have been modified.
- d) Requirement of pantyliner, maternity pad and period panty have been specified.
- e) Manufacture, workmanship and finish have been modified.
- f) The procedure and requirement of ability to withstand pressure after absorption have been modified.
- g) pH and hygiene testing requirement have been updated.
- h) The requirement of compostability has been updated.

- i) Optional requirement of anti-bacterial activity test has been specified.
- j) Sampling and criteria for conformity has been modified.
- k) Marking clause has been modified.
- l) References to Indian Standard have been updated.

This standard contains clause **5** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

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 : 2022 'Rules for rounding off numerical values (second revision)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard

**IS 5405 : 2024 DISPOSABLE SANITARY NAPKIN/ PANTYLINER/
MATERNITY PAD/PERIOD PANTY — SPECIFICATION**
(*Third Revision*)

1 SCOPE

This standard covers the requirements for disposable (non-reusable) sanitary napkin/pantyliner/maternity pad/period panty 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 napkin/pantyliner/maternity pad/period panty 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/pantyliner/maternity pad/period panty 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 product 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 (unintended), oil

spots, dirt or foreign material (unintended foreign matter that can cause injury or discomfort) when examined visually.

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.

‘NOTE — The requirements given in 3.1 to 3.3 are for guidance of the manufacturer. The material and design may vary between different types and sizes of the sanitary napkin/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller.’

4 TYPE AND SHAPES OF SANITARY NAPKIN/PANTYLINER/MATERNITY PAD/PERIOD PANTY

4.1 The sanitary napkin/pantyliner/maternity pad/period panty shall be of following types:

- a) Sanitary napkin
- b) Pantyliner
- c) Maternity pad; and
- d) Period panty

4.2 Sanitary napkin/pantyliner/maternity pad/period panty can be of various shapes and design such as wings/no wings, tab/tab-less etc. or as per purchaser’s needs.

NOTES —

- 1) Sanitary napkin/pantyliner/maternity pad/period panty with wings provide better grip on the undergarments so that product remains in its position under dynamic conditions. Some products can also be folded to be carried in a small pouch.
- 2) The requirements given in 4.1 to 4.2 are for guidance of the manufacturer. The type and shape may vary between different design of the sanitary napkin/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or manufacturers product design.

5 SIZES

Size of sanitary napkin/pantyliner/maternity pad/period panty shall be as agreed to between the purchaser and the supplier. Sizes of sanitary napkin/pantyliner/maternity pad/period panty shall be variable depending on the absorbent capacity, purchaser’s needs and wing features. The recommended sizes are classified as follows in table 1:

Table 1 Size of Sanitary Napkin/Pantyliner/Maternity Pad/Period Panty
(for reference and guidance only)

(Clause 5)

SI No	Name of product	Size class	Length (mm) (absorbent core only)	Width (mm) (absorbent core only)
(1)	(2)	(3)	(4)	(5)
i)	Sanitary napkin	Regular	≤ 210	Min 55
		Large	211 to 240	

		Extra large	- 241 to 280	
		XXL	≥ 281	
ii)	Pantyliner	Small	≤ 135	<i>Min 30</i>
		Regular	136 to 179	
		Large	≥ 180	
iii)	Maternity pad	-	≥ 281	<i>Min 80</i>
iv)	Period panty	-	> 230	<i>Min 55</i>

‘NOTE —

- 1) The actual dimension of absorbent core may differ as per the product design of manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of absorbent core length and width of the product.
- 2) The recommended dimension (for reference and guidance only) of absorbent core length and width for other size class/type of sanitary napkin/pantyliner/maternity pad/period panty not covered in Table 1 shall be declared by the manufacture.’

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 sanitary napkin/pantyliner/maternity pad/period panty without any wrinkles and distortion. The absorbent material is deposited on to a pre-glued or without glue 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 of the filler 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 sanitary napkin/pantyliner/maternity pad/period panty structure. A sanitary napkin/pantyliner/maternity pad/period panty is then sealed using heat and pressure or other methods along the periphery or alternatively, it can be stitched or glued, depending upon the type of material used. In case of tab-less sanitary napkin/pantyliner/maternity pad/period panty, an adhesive system or other suitable method may be introduced for holding the sanitary napkin/pantyliner/maternity pad/period panty securely in position. The barrier is applied with adhesives with release paper to fix the sanitary napkin/pantyliner/maternity pad/period panty to the undergarment, for the tab-less sanitary napkin/pantyliner/maternity pad/period panty.

‘NOTE — The requirements given in 6.1 are for guidance of the manufacturer. The manufacture, workmanship and finish may vary between different design, types, and sizes of the sanitary napkin/pantyliner/maternity pad/period panty or as per the agreement between buyer and seller or as per manufacturers design. The manufacture should use elemental or total chlorine free bleached wood pulp in the absorbent core of the product.’

6.2 The sanitary napkin/pantyliner/maternity pad/period panty 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 (unintended foreign matter that can cause injury or discomfort).

7 REQUIREMENTS

7.1 pH Value

The pH of sanitary napkin/pantyliner/maternity pad/period panty (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.

‘NOTE — If the required weight of the test specimen is not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product .

7.2 Ability to Withstand Pressure after Absorption

The sanitary napkin/pantyliner/maternity pad/period panty shall absorb coloured distilled water as given in table 2 and it shall not show leakage at the bottom or side edges of the product, when tested according to method given in Annex B.

Table 2 Ability to Withstand Pressure after Absorption for Sanitary Napkin/Pantyliner/Maternity Pad/Period Panty

(Clause 7.2, Annex B)

SI No	Name of product	Liquid Absorption (ml), Min
(1)	(2)	(3)
i)	Sanitary napkin	30
ii)	Pantyliner	1
iii)	Maternity pad	50
iv)	Period panty	30

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 sanitary napkin/pantyliner/maternity pad/period panty 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; IS/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 sanitary napkin/pantyliner/maternity pad/period panty 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

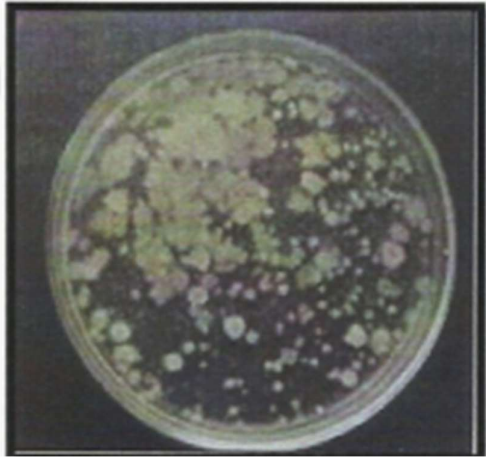
absorbent quantity of the sanitary napkin/pantyliner/maternity pad/period panty or the quantity in which the sanitary napkin/pantyliner/maternity pad/period panty completely immerse. The sanitary napkin/pantyliner/maternity pad/period panty shall be shaken vigorously in the eluent and the liquid shall 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 sanitary napkin/pantyliner/maternity pad/period panty 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 sanitary napkin/pantyliner/maternity pad/period panty 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 sanitary napkin/pantyliner/maternity pad/period panty. 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*

‘NOTE — If the required weight of the test specimen under clause 7.3.1.1 and 7.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.’

7.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement

The sanitary napkin/pantyliner/maternity pad/period panty 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 (Optional)

If required by the buyer, the manufacturer 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, IS 17932 (Part 7) and IS 17932 (Part 6) respectively.

For cytotoxicity, the material shall show reactivity as 'non-cytotoxic' when tested as per IS/ISO 10995 Part 5.

Similarly, the material shall be 'Non-irritant and Non-sensitizer' when tested as per IS 17932 (Part 7) and IS 17932 (Part 6) respectively. For preparation of samples for these tests, IS/ISO 10993 Part 12 shall be referred.

7.5 Phthalate Test

The amount of phthalate present in sanitary napkin/pantyliner/maternity pad/period panty shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6). The phthalate test shall be done at raw material stage once for existing raw material and whenever there is a change in the raw material for manufacturing the product. The manufacturer of final product shall also do the phthalate test once in a year.

7.6 Compostability (Optional)

The manufacturer who are claiming their product as compostable shall pass the test on the final product as per IS/ISO 17088.

7.7 Anti-Bacterial Activity Value (Optional)

If claimed by the manufacturer, the raw material used for the product or final product shall have antibacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the sanitary napkin/pantyliner/maternity pad/period panty 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/pantyliner/maternity pad/period panty 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 3.

8.1.3 These sanitary napkin/pantyliner/maternity pad/period panty shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 3 Number of Sanitary Napkin/Pantyliner/Maternity Pad/Period Panty to be Selected
(Clause 8.1.2)

SI No.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of Products to be Selected	Acceptance Number	No. of Products to be Selected	Acceptance Number
		N	n	a	n_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

NOTES —

- 1) For hygiene testing, biocompatibility evaluation, compostability, anti-bacterial activity test refer clause **8.2.4, 8.2.5, 8.2.6** and **8.2.7** respectively.
- 2) The sampling plan given in table 3 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

8.2 Number of Tests and Criteria for Conformity

8.2.1 All sanitary napkin/pantyliner/maternity pad/period panty to be selected as per column 3 of Table 3 shall be examined for workmanship and finish.

8.2.1.1 Any sanitary napkin/pantyliner/maternity pad/period panty 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 3. 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 3 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/pantyliner/maternity pad/period panty found in the sample (*see 8.2.2*) is less than or equal to the acceptance number as given in column 6 of Table 3.

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

8.2.7 The anti-bacterial activity testing shall be carried out once for existing raw material or final product and whenever there is a change in the raw material or source of supply of 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 trade mark, size, type and number of sanitary napkin/pantyliner/maternity pad/period panty contained in the pack 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;
- d) The information whether the product is compostable (if applicable).
- e) The information whether the material of the product is biocompatible that is, meets the requirement of the standard for biocompatibility evaluation – cytotoxicity, irritation and skin sensitization (if applicable);
- f) Additional feature of antibacterial (if applicable) ; and
- g) 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 napkin/pantyliner/maternity pad/period panty 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

<i>IS No./Other Publication</i>	<i>Title</i>
758 : 2023	Specification for cotton gauze, absorbent, non-sterilized (<i>fourth revision</i>)
1390 : 2022/ ISO 3071 : 2020	Textiles — Determination of <i>pH</i> of aqueous extract (<i>third revision</i>)
4905 : 2015	Random sampling and randomization procedures (<i>first revision</i>)
5887 (Part 2) : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of <i>Staphylococcus aureus</i> and faecal <i>Streptococci</i> (<i>first revision</i>)
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products (<i>first revision</i>)
17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

IS/ISO 17088 : 2021	Compostable plastics — Specification (<i>second revision</i>)
IS/ISO 20743 : 2021	Textiles — Determination of antibacterial activity of textile products (<i>first revision</i>)

ANNEX B

(*Clause 7.2*)

METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND PRESSURE AFTER ABSORPTION

B-1 TEST PROCEDURE

Lay the sanitary napkin/pantyliner/maternity pad/period panty on a flat level transparent surface, so that underside of sanitary napkin/pantyliner/maternity pad/period panty can be observed. Drip at the rate of 1 ml (pantyliner)/5 ml (other product) per min, coloured distilled water as given in table 2 maintained at temperature of $27^{\circ}\text{C} \pm 2^{\circ}\text{C}$ on to the centre of the sanitary napkin/pantyliner/maternity pad/period panty from a height of 5-7 mm. After the sanitary napkin/pantyliner/maternity pad/period panty 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 side edges of sanitary napkin/pantyliner/maternity pad/period panty for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

‘NOTES —

- 1) The dimension of 1 kg weight should have length and width of 150 mm x 50 mm with a tolerance of ± 1 mm.
- 2) For period panty, cut along the lateral seam on both the sides (left and right) and then lay the period panty flat for absorbency testing.’

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 positioned 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.