www.bis.gov.in

उत्पाद मैन्युअल

पुन: प्रयोज्य सैनिटरी पैड / सैनिटरी नैपकिन / पीरियड पैंटीज –विशिष्टि

IS 17514:2021 के अनुसार

PRODUCT MANUAL FOR
Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification
ACCORDING TO IS 17514:2021

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment)Regulations,2018 forvarious products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	**मानक संख्या** **IS No.**	:	IS 17514:2021
	शीर्षक **Title**	:	Reusable Sanitary Pad / Sanitary Napkin / Period Panties — Specification
	संशोधनों की संख्या **No. of amendments**	:	04
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	The materials used for making Reusable Sanitary Pad / Sanitary Napkin / Period Panties shall be as per the requirements at Cl. 3 and Cl. 4 of IS 17514:2021. The raw material/fabric used for manufacturing the product shall meet the Colour fastness and Dimensional Stability Requirement of Raw Material/Fabric as per Table 1 of IS 17514:2021 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 (Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)) If agreed between the buyer and the seller, the raw

			material/fabric used for reusable sanitary pad/sanitary napkin/period panties shall have anti-bacterial activity value (initially and after declared cycle washes) greater than or equal to 2 (Anti-Bacterial Activity Value (Optional)) 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 Conformity of raw materials to the requirements may be established through supplier test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC17025 or inhouse testing/combination thereof, as applicable*)* Note: This section indicates the requirements for raw material(if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance
b)	**समूहीकरण दिशानिर्देश Grouping Guidelines**	:	Please refer to Annex-A
c)	**नमूने का परिमाण Sample Quantity**	:	*50 Nos.* Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (in case of market surveillance, effort may be made to procure the required quantity of product sample, as far as possible since raw material sample may not be available in market)
3.	**परीक्षण उपकरणों की सूची List of Test Equipment**	:	Please refer to Annex-B
4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer to Annex-C
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**		
	1. Manufacture, Workmanship And Finish 2. Fastening Mechanism 3. Sizes 4. Washing, Drying And Handling Instruction 5. pH Value 6. Ability To Withstand Pressure After Absorption Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies(OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by The officer/auditor.		
6.	**लाइसेंस का दायरा/Scope of the Licence:**		

	"Licence is granted to use Standard Mark as per IS 17514:2021 with the following scope: IS 17514:2021 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है	
	Name of the product **उत्पाद का नाम**	Reusable Sanitary Pad / Sanitary Napkin / Period Panties
	Size Class	Small/Medium/Large/Extra Large
	Optional requirements	1. With/Without Biocompatibility Evaluation 2. With./Without Anti Bacterial Activity Value Note: if with Anti Bacterial Activity Value, the declared value (initially and after declared cycle washes) shall be specified.

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9, BAHADUR SHAH ZAFAR
MARG, NEW DELHI-110002

ANNEX-A

GROUPING GUIDELINES

For Grant of Licence/Change in Scope of licence, the following grouping guidelines shall apply

Group	Product type	Samples to be tested	Remarks
Group I	Reusable Sanitary Pad / Sanitary Napkin	One sample of any product type and of any size shall be tested to cover all types and size classes intended to be covered in the scope	If sizes other than the recommended sizes as per IS 17514 are to be covered, manufacturer shall declare the applicable sizes for each size class
Group II	Period Panties	One sample of any size shall be tested	

In case it is intended to cover optional requirements i.e. Biocompatibility Evaluation and Anti Bacterial Activity Value, the sample(s) shall also be tested for the applicable optional requirements.(in case these optional requirements are not intended to be covered in the scope, samples may not be tested for these requirements, in that case scope of licence may state “Without Biocompatibility Evaluation and/or Without Anti Bacterial Activity Value”).

Scope of licence shall be restricted based on the manufacturing and testing facilities available.

During operation of licence, samples of each variety covered in the scope of licence, shall be tested in rotation, to the extent possible.

ANNEX–B

LIST OF TEST EQUIPMENTS

(INDICATIVELIST, FOR GUIDANCE ONLY)

S. No.	Tests used in with Clause Reference	Test Equipment
1	Sizes (Clause 6 of IS17514:2021)	Vernier caliper Steel scale
2	pH Value (Clause 9.1 of IS17514:2021) IS 1390	Distilled or deionized water, Potassium chloride sol. (0.1mol/l), Buffer solutions (Having pH around 4, 7 or 9), Apparatus: pH- meter (with glass electrode, capable of measuring to at least 0.1pH units), Mechanical shaker, Weighing Balance (accurate to 0.01 g),Beakers (150ml), Volumetric flasks(1L), Stoppered glass or polypropylene flasks, Thermometer
2	Ability to Withstand Pressure after Absorption(Clause 9.2 of IS 17514:2021) (Annex B)	Coloured distilled Water, Bromocresol purple (AR grade),Distilled water, **Apparatus:** Flat Level Transparent Surface, Standard weight (1kg), Weighing Balance (accurate to 0.01 g), Thermometer, Auto Burette Unit (Flow rate 5ml per minute)Stop watch (LC 1Sec), AC for maintaining Temp. of 27°C ± 2°C.
3	**Hygiene Testing Requirement (Clause 9.3 of IS 17514:2021)**	
4	Bacterial and Fungal Bioburden (Clause 9.3.1 of IS 17514:2021) ISO 11737(PART 1)	**Reagents:** Plate count agar (PCA), Sabouraud chloramphenicol agar (SCA), Sodium chloride (0.85%), **Apparatus:** Autoclave, Hot air oven, Incubator (30-35°C), Incubator (20-25°C) pH meter, Water bath, Colony counter, Laminar Air Flow, Mechanical Shaker,Petri dishes, Flasks/bottles, Test tubes,

5	Test for Common Skin Pathogen—StaphylococcusAureus (Clause 9.3.2 of IS 17514:2021) IS 5887 (PART2)	**Reagents:** Cooked salt medium, Baird Parker medium, Blood agar, Citrated Rabbit plasma, Nutrient agar, Normal saline water, Gram's Stain kit, **Apparatus**: Autoclave, Hot air oven, Incubator (37°C), pH meter, Water bath, Laminar Air Flow, Microscope Mechanical shaker, Petri dishes, Glass Slide, Test Tubes (Narrow), Straight nichrome wire
6.	Biocompatibility Evaluation - Cytotoxicity, Irritation andSkin Sensitization (Clause 9.4 of IS 17514:2019) (IS/ISO 10993 Part 5 and IS/ISO 10993 Part 10)	**Cytotoxicity Test (IS/ISO 10993 Part-5)** Closed containers for extraction of sample Extraction vehicle pH meter Water bath Incubator (37±1°C) humidified 5% CO2/air. Microscope Laminar flow cabinet (Biological hazard standard). Shaker for microstate plates. Cell counter or hemacytometer. Weighing Balance, Air conditioner Petri dishes Pipetting aid. Pipettes (8-channel pipettes, dilution block) Cryotubes. Tissue culture flasks (80 cm2, 25 cm2) 96-Well tissue culture microtitre plates. Culture medium to prevent absorption Cell lines Negative control material (High-density polyethylene) Positive control material. (Sodium Lauryl Sulphate (SLS) Reference materials Dulbecco's Modification of Eagle's Medium (DMEM), without L-glutamine Newborn calf serum (NBCS). Phosphate-buffered saline (PBS), without Ca2+ and Mg2+ (for trypsinization). Phosphate-buffered saline (PBS), with Ca2+ and Mg2+ (for rinsing). HEPES(4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid) Dimethyl sulfoxide (AR Grade). L-glutamine (200 mM), Trypsin/EDTA solution. Nutrient agar

		Cell culture media Penicillin/streptomycin solution. Mouse fibroblasts Agarose overlay Neutral red, Ethanol (AR Grade). Glacial acetic acid (AR Grade). Distilled water **Tests for Irritation and Skin Sensitization (IS/ISO 10993 Part-10)** Rotary evaporator pH meter Pipetting aid Weighing Balance Shaker, Flasks Incubators Petri dishes Pipetting aid Air conditioner Pulverizing or grinder apparatus Extraction vial (borosilicate glass tubes with caps) Absorbent gauze patch (non-occlusive dressing) Marker with permanent ink. Extract vehicle
7.	Anti-Bacterial Activity Value (Optional) Cl.10 of IS 17514:2021 IS/ISO 20743	Spectrophotometer, 620 nm to 660 nm wavelength, or McFarland's nephelometer, Incubator, 37 °C ± 2 °C, Water baths 46 °C ± 2 °C and another 70 °C to 90 °C, Mixer, producing a vortex shaking action. Stomacher, capable of speeds of 6 blows per second to 8 blows per second, with the corresponding disposable containers. Clean bench, for microbial test. Washing machine, (ISO 6330. IS/ISO 20743 : 2013) Humidity chamber, tropical chamber or other container capable of maintaining a high-humidity more than 70 %RHatmospheric condition. Luminescence photometer, capable of measuring ATP of 10−12 mol/l to 10−7 mol/l at 300 nm to 650 nm with a luminescence- measuring reagent. Printing apparatus, capable of applying a 4 N load to a test specimen and rotating the specimen 180° in one direction for a period of 3,0 s. Refrigerator, capable of maintaining a temperature of between 2 °C and 8 °C. Freezers, one adjustable to a temperature below −70 °Cand another to a temperature below −20 °C. Balance, which can be read to the nearest 0,01 g.

8.	Pthalate test, Cl. 9.5	**Reagents:** Dichloromethane, CAS No. 75-09- 2, analytical grade or higher, free of phthalate esters. Phthalate reference substances, DBP, BBP, DEHP, DNOP, DINP, and DIDP (see Annex A), minimum of 95 % purity. Stock solution, 100 mg/l of DBP, BBP, DEHP, DNOP each, and 500 mg/l of DINP, DIDP each in dichloromethane External Standard (ES) calibration solutions. Internal Standard (IS) calibration solutions. **Apparatus:** Normal laboratory glassware. Gas chromatography-mass spectrometer (GC-MS), with a capillary column coupled to amass Spectrometric detector (electron ionization, EI) usedfor the analysis. See7.4.1. Soxhlet extractor, see FigureB.1. Solvent extractor, see FigureB.2. Extraction thimble, cellulose. Cotton wool, for extraction thimble. Analytical balance, capable of measuring to an accuracy of 0,001 g. Concentration apparatus, for example, a rotary evaporator. Solid phase extraction(SPE) cartridge, 1000mg silica gel/6 ml tubes, or equivalent. Volumetric flasks, of 5 ml, 10 ml, 25 ml, 50 ml, and 100 ml nominal capacity. Pipettes, of 0,5 ml, 1 ml, 2 ml, 5 ml, and 10 ml nominal capacity. Polytetrafluoroethylene (PTFE) membrane filter, of pore size 0,45 µm Filtering apparatus, consisting of an upper container equipped with a membrane filter and a lower container equipped with a suction opening. Pipette, having the most suitable volume for each use, with a tip made of glass or plastic, and with a tolerance of 0.5 % or less.

ANNEX C

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers(licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: entire quantity of sanitary napkins/sanitary pads or period panties of the same material and dimensions and produced under similar conditions of manufacturer in a day.

1.3.2 FortheguidanceofmanufacturersinpreparingtheQualityAssurancePlan, recommended levels of control are given in **Table 1**.

1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING It is expected that manufacturers(licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as“R”or other tests which can be subcontracted as “S”. Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as “R” in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empanelled laboratory or any other laboratory having NABL accreditation as per IS/ISO/IEC 17025.

2.3 Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1), where different tests given in the specification shall be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 TEST RECORDS- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each package of Reusable Sanitary Pad / Sanitary Napkin / Period Panties provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per the Indian Standard.

3.2 **Additional Marking requirements:** The material shall also be marked with the following additional requirement on each package of Reusable Sanitary Pad / Sanitary Napkin / Period Panties:

a) The product is made from biocompatible material and/or antibacterial material with its Antibacterial value.(if applicable)

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 regulations published from time to time.

b) "For BIS certification details please visit www.bis.gov.in"

Note: In case a manufacturer with same brand name is holding BIS licences at multiple premises (units) under same ownership and opts for marking multiple licence numbers on the unified label, the same may be considered, provided the identification and traceability of the product, is established as envisaged.

4. **HYGIENIC CONDITIONS–** 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 of IS 17514.

5. **REJECTION-** All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016

TABLE 1
(ONLY FOR GUIDANCE PURPOSE)

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Recommended Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
3	Materials	3					
3.1	Cover / Top sheet	3.1	IS 17514: 2021	R	One	Each consignment	
3.2	Absorbent Core	3.2					
3.3	Bottom Layer	3.3					
4	Manufacture, Workmanship And Finish	4				Each control unit/lot	
5	Fastening Mechanism	5					
6	Sizes	6					
7	Washing, DryingAnd Handling Instruction	7					
8	**GENERAL REQUIREMENTS**						
8 and 11.2.4	Table 1 Colour fastness and Dimensional Stability Requirement of Raw Material/Fabric						

i)	Colour fastness to rubbing	--	IS/ISO 105-X12	S	One	Each consignment	Conformity of raw materials to the requirements may be established through *supplier test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC17025 or inhouse testing/combination thereof, as applicable)*
ii)	Colour fastness to perspiration (acidic and alkaline)	--	IS/ISO 105-E04				
iii)	Colour fastness to washing	--	IS/ISO 105-C06				
iv)	Dimensional stability to washing, percentage	--	Annex C of IS 16394				
9	**PERFORMANCE REQUIREMENTS**						
9.1	pH Value	--	IS 1390	R	One	Each control unit/lot	
9.2	Ability to Withstand Pressure after Absorption	9.2	Annex B of IS 17514 : 2021				
9.3	**Hygiene Testing Requirement**						
9.3.1	Bacterial and Fungal Bioburden	9.3.1	9.3.1.1 (IS 17514 : 2021) &ISO 11737(Part1)	S	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 ofthe raw material.		
9.3.2	Test for Common Skin Pathogen — Staphylococcus Aureus	9.3.2	9.3.2.1 (IS 17514 : 2021) & 5887 (Part 2)				

9.4	Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization (Optional)	--	IS/ISO 10993 Part 5, IS/ISO 10993 Part 10 and ISO 10993 Part 12	S	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 or whenever required by purchaser Conformity to the requirements may be established through *supplier test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC 17025 or inhouse testing/combination thereof, as applicable)*
10	Antibacterial Activity Value (Optional)	--	IS/ISO 20743		The Antibacterial Activity Value testing shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product or whenever required by purchaser Conformity to the requirements may be established through *supplier test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC17025 or inhouse testing/combination thereof, as applicable)*
9.5	Pthalate test	--	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.