PRODUCT MANUAL FOR SANITARY NAPKINS ACCORDING TO IS 5405:2019

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

1.	**Product**	:	**IS 5405:2019**
	Title	:	**Sanitary Napkins-Specification**
	No. of Amendments	:	**Nil**
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	**If cotton gauze is used, it shall conform to IS 758**
b)	**Grouping guidelines**	:	**Please refer Annex-A**
c)	**Sample Size**	:	**50 Nos.**
3.	**List of Test Equipment**	:	**Please refer Annex-B**
4.	**Scheme of Inspection and Testing**	:	**Please refer Annex-C**
5.	**Possible tests in a day :**		
	I) Type & shapes II) Size III) Manufacture, workmanship and finish IV) pH Value V) Ability to withstand pressure after absorption		
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 5405:2019 with the following scope:		
	Name of the product	**Sanitary Napkins**	
	Type	Thick / Thin Napkins	
	Any other aspect required as per the Standard	Wings / No wings, Tab / Tab-less	

Annex-A

Grouping Guidelines

1. According to IS 5405:2019 Sanitary Napkins are classified as follows:

Types:

- Thick Napkins
- Thin Napkins

Shapes/ design:

- Wings/ No wings
- Tab/ Tab-less
- Any other design

Recommended Sizes**:**

Size	Pad Length
Regular	≤ 210 mm
Large	211 to 240
Extra-Large	241 to 2800
XXL	≥ 281

2. Considering the above, Sanitary Napkins are categorized into following groups for the purpose of GoL/CSoL

No.	Group	Type	Sample to be drawn/ tested
1	Group 1	Thick Napkins	One sample of thick Napkins, any shape/design, any size
2	Group 2	Thin Napkins	One sample of thin Napkins, any shape/design, any size

3. Considering the above, one sample from each group shall be tested to cover all varieties of Sanitary Napkins of that group.

4. The Firm shall declare the varieties of Sanitary Napkins intended to be covered in the Licence. The Scope of Licence shall be restricted based on the Manufacturing & testing capabilities of the Manufacturer.

5. During the operation of the Licence, BO shall ensure that all type, shape, designs, size covered in the Licence is tested in rotation, to the extent possible

ANNEX-B

LIST OF TEST EQUIPMENTS

Major test equipments required to test as per the Indian Standard

Sr. No.	Tests used in with Clause Reference	Test Equipment/ Glassware/Chemicals
1.	**Sizes** (Clause 5 of IS 5405:2019)	- Vernier caliper - Steel scale
2.	**pH Value** (Clause 7.1 of IS 5405:2019) (IS 1390 (cold method)	**Reagents:** 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 0.1 pH units), Mechanical shaker, WeighingBalance (accurate to 0.01 g), Beakers (150ml), Volumetric flasks(1L), Stoppered glass or polypropylene flasks, Thermometer
3.	**Ability to Withstand Pressure after Absorption** (Clause 7.2 of IS 5405:2019) (Annex B)	**Reagents:** Coloured distilled Water, Bromocresol purple (AR grade), Distilled water, **Apparatus:** Flat Level Transparent Surface, Standard weight (1kg), WeighingBalance (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
5.	**Hygiene Testing Requirement** (Clause 7.3 of IS 5405:2019)	
5.1.	**Bacterial and Fungal Bioburden** (Clause 7.3.1 of IS 5405:2019)	**Reagents:** Plate count agar (PCA), Sabouraud chloramphenicol agar (SCA),

		Sodium chloride (0.85%), **Apparatus:** Autoclave, Hot air oven, Incubator (30-35^{0}C), Incubator (20-25^{0}C) pH meter, Water bath, Colony counter, Laminar Air Flow, Mechanical Shaker, Petri dishes, Flasks/bottles, Test tubes,
5.2.	**Test for Common Skin Pathogen— StaphylococcusAureus** (Clause 7.3.2 of IS 5405:2019)	**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^{0}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 and Skin Sensitization** (Clause 7.4 of IS 5405:2019) (IS/ISO 10993 Part 5 and IS/ISO 10993 Part 10	**<u>Cytotoxicity Test (IS/ISO 10993 Part-5)</u>** - Closed containers for extraction of sample - Extraction vehicle - pH meter - Water bath - Incubator (37±1°C) humidified 5% CO_2/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 cm^2, 25 cm^2) - 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 **<u>Tests for Irritation and Skin Sensitization (IS/ISO 10993 Part-10)</u>** - 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

		- Full-spectrum lighting source - Soft catheter or blunt-tipped cannula - Occlusive chamber containing a gauze pad. - Vernier caliper - Non-irritating dressing - Non-irritating tape - Gauze pad - Spectrophotometer - Bandage (semi-occlusive or occlusive) - Water or non-irritant solvent - Methanol - Acetone - Physiological saline -Vegetable oil - Ethylene oxide - Freund's complete adjuvant (FCA) - Cytotoxic marker chemicals (Sodium dodecyl sulphate) -Vital dyes - Tissue culture medium - Distilled or Deionized water - NaCl (0.9 %) - MTT Sol. (0.3 mg/ml to 1 mg/ml) - Isopropanol - Olive oil - Dimethylsulfoxide (DMSO) - *n*-hexane - Ethanol - Hapten - Lubricant - Positive control (Sodium Lauryl Sulphate (SLS) - Negative control (Non-irritant, Absorbent gauze)
7.	**Biodegradability and Compostability (Optional)** (Clause 7.5 of IS 5405:2019) (IS/ISO 17088)	- Composting facilities where typical conditions of composting can be consistently obtained (i.e. a long thermophilic phase, aerobic conditions, sufficient water content, suitable carbon/nitrogen ratio, etc.) - Fillers (Calcium carbonate, Titanium dioxide etc) - Catalysts (Metal carboxylates, Metal complexes etc) - Sieve (2.0mm,10 mm) - Positive-control reference material (Microcrystalline cellulose) - TLC (thin-layer chromatography) grade cellulose - Vermiculite - Composting vessels (Glass flasks or bottles) - Air-supply system - Apparatus for the determination of carbon dioxide - Gas-tight tubes - pH-meter. - Analytical equipmentfor determination of dry solids (at 105°C), volatile solids (at 550°C) and total organic carbon (TOC), for elemental analysis of the test material - Analytical equipmentfor the determination of oxygen in the air,

		moisture, volatile fatty acids and total nitrogen - Balance - Bioreactors for activation of the vermiculite -Incubation room with dark or diffused light, constant temperature of 58 °C ± 2 °C and free from vapours inhibitory to microorganisms - Inoculum - Soda lime (particle size 2-4 mm) - Anhydrous calcium chloride (particle size 2-3 mm) - Sodium hydroxide on a talc support (Soda talc) - Silica gel (with moisture indicator). particle size between 2-4 mm - Sea sand (particle size between 20-35 mesh) - TLC (Thin-layer ctlromatography) grade microcrystalline cellulose with a particle size of less than 20 um, - Thermostatic-control unit - Composting bin with air supply system, Drainage, Sample nets - Apparatus for temperature measurement - Apparatus for oxygen measurement - Biowaste, - Composting reactor - Synthetic solid waste - Distilled water - Hot air oven - Furnace

Note: The above list is indicative only and may not be treated as exhaustive.

ANNEX C

SCHEME OF INSPECTION AND TESTING

1. LABORATORY- A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipments.

2. TEST RECORDS– The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. PACKING AND MARKING –The Standard Mark, as given in the Schedule of the licence, shall be printed on each consumer pack of sanitary napkins, provided always that the sanitary napkins in each pack to which this mark is thus applied conforms to every requirement of the specification.

3.1 Packing and marking shall be done as per the provision of the IS 5405:2019. In addition, the following details shall be mentioned on each pack legibly and indelibly:

a) BIS Licence No. CM/L ……..…….

b) BIS website details i.e. –"For details of BIS certification please visit **www.bis.gov.in**"

4. CONTROL UNIT/LOT– For the purpose of this scheme, all the sanitary napkins of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a control unit/lot.

4.1 On the basis of the test results, decision regarding the conformity of the sanitary napkins with the requirement of the specification shall be taken in accordance with Table 1 below.

5. LEVELS OF CONTROL -The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with clause 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. 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 **Clause 7.3.3**, Annex C of IS 5405.

7. REJECTIONS – 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
LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Clause	**Requirements**	**Test Methods**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
3	**Materials**						
3.1	Cover / Top sheet	3.1	IS 5405:2019	R	One sample	Each consignment	
3.2	Absorbent Core	3.2	IS 5405:2019	R	One sample	Each consignment	
3.3	Barrier or Bottom Sheet	3.3	IS 5405:2019	R	One sample	Each consignment	
4	Type And Shapes Of Sanitary Napkins	4	IS 5405:2019	R	10 sample	Each control unit/lot	
5	Sizes	5	IS 5405:2019	R	10 sample	Each control unit/lot	
6	Manufacture, Workmanship And Finish	6	IS 5405:2019	R	See Note 3	Each control unit/lot	
7.1	pH Value	-	IS 1390(Cold method)	R	See Note 3	Each control unit/lot	
7.2	Ability to Withstand Pressure after Absorption	Annex- B	IS 5405:2019	R	See Note 3	Each control unit/lot	
7.3	**Hygiene Testing Requirement**				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.		
7.3.1	Bacterial and Fungal Bioburden	7.3.1.1	IS 5405:2019	S			
7.3.2	Test for Common Skin Pathogen - Staphylococcus Aureus	7.3.2.1	IS 5405:2019	S			
7.4	Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization		IS/ISO 10993 Part 5, IS/ISO 10993 Part 10 and ISO 10993 Part 12	S	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.		
7.5	Biodegradability and Compostability (Optional)		IS/ISO 17088	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.		

Note-1: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.

Note-2: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-3: The number of sanitary napkin to be selected from the control unit/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 of IS 5405. 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 of IS 5405. Otherwise, the lot shall be rejected. Out of the sample already found satisfactory according to the above, a sub-sample as per column 5 of Table 1 of IS 5405 shall be taken. This sub-sample shall be further tested for the remaining requirements. 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 is less than or equal to the acceptance number as given in column 6 of Table 1 of IS 5405.