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उत्पाद मैन्युअल

प्रयोज्य सेनेटरी नैपकिन/पैंटी लाइनर/मैटरनिटी पैड/पीरियड पैंटी — विशिष्टि

IS 5405: 2025 के अनुसार

PRODUCT MANUAL

Disposable Sanitary
Napkin/Panty Liner/Maternity Pad/Period Panty — Specification
ACCORDINGTO IS 5405: 2025

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 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 5405 : 2025
	शीर्षक **Title**	:	Disposable Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty — Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The materials of cover/top sheet, absorbent core and bottom sheet shall conform to the requirement of Cl. 3.1 to 3.3 of IS 5405: 2025. Biocompatibility evaluation and Anti-Bacterial activity value are optional requirements for raw material. If the manufacturer intends to cover the same in the scope of their licence, conformity of raw material to biocompatibility evaluation and Anti-Bacterial activity value requirement as per Clause 7.4 & 7.7 of IS 5405: 2025 respectively shall be established. 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 standard may be

			established through supplier's test certificate, test report of BIS recognized/empanelled lab or any other NABL accredited lab or through in house testing. 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).
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**		i. Product Type and size ii. Optional requirements Note: Apart from the above, any other requirements/parameters may also be declared as per the standard, as applicable.
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**		
	i. Type & shapes ii. Size iii. Manufacture, workmanship and finish iv. pH Value v. 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 5405: 2025 with the following scope:		
	Name of the product		Disposable Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty — Specification

	Product Type and size	1) Sanitary napkin a) Regular b) Large c) Extra large d) XXL 2) Panty liner a) Small b) Regular c) Large 3) Maternity pad 4) Period panty
	Optional requirement	i. With/without Biocompatibility ii. With/without Compostability iii. With/without Anti-Bacterial Activity Value

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MANAK BHAVAN,9, BAHADUR SHAH ZAFAR MARG,
NEW DELHI-110002

ANNEX-A

GROUPING GUIDELINES

1. The Standards covers the following 4 types of hygiene materials:
   i. Sanitary napkin
   ii. Panty liner
   iii. Maternity pad
   iv. Period panty

2. Further, following sizes have been defined in the standard for different type of hygiene materials:
   i. Sanitary napkin:
      a) Regular
      b) Large
      c) Extra Large
      d) XXL

   ii. Panty liner:
      a) Small
      b) Regular
      c) Large

   iii. Maternity pad
   iv. Period panty

3. Considering the above, following grouping guidelines have been prepared for GOL/CSOL:

   (i) Sample of each type of hygiene material (Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty) shall be drawn and tested to be covered in the scope of licence.

   (ii) Sample of any size of Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty may be drawn tested to cover all the sizes of particular type of hygiene material in the scope of licence.

   (iii) To cover optional requirements of Biocompatibility evaluation, Compostability and Anti-Bacterial activity value in the scope of licence, sample shall be tested for the optional requirements additionally.

   (iv) If product with optional requirements are tested, then the product without optional requirements may also be covered in the scope of licence.

   (v) If Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty having dimensions other than those specified in Table 1 (Size of Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty) of IS 5405: 2025 are intended to be covered in the scope of licence, the same shall be declared and a figure/schematic diagram for measurement of dimension of absorbent core length and width of the product may also be provided by the manufacturer.

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

   (vii) 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

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	**Tests Used In With Clause Reference**	**Test Equipment/Chemical**
Sr. No.	**Tests used in with Clause Reference**	**Test Equipment/ Glassware/Chemicals**
1.	**Sizes,** Clause 5	- Vernier caliper - Steel scale
2.	**pH Value,** Clause 7.1	**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 0.1pH units) - Mechanical shaker - Weighing Balance (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	**Reagents:** - 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
4.	**Bacterial and Fungal Bioburden**, Clause 7.3.1	**Reagents:** - Plate count agar (PCA) - Sabouraud chloramphenicol agar (SCA) - Sodium chloride (0.85%) **Apparatus:** - Autoclave - Hot air oven, - Incubator (30-350C) - Incubator (20-250C) - pH meter - Water bath - Colony counter - Laminar Air Flow - Mechanical Shaker - Petri dishes

		- Flasks/bottles - Test tubes
5.	**Test for Common Skin Pathogen— Staphylococcus Aureus,** Clause 7.3.2	**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 (370C) - 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 (optional),** Clause 7.4	**<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
7.	**Tests for Irritation and Skin Sensitization**	- 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)
8.	**Compostability (Optional),** Clause 7.6	- 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 equipment for 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 equipment for 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 - Bio-waste - Composting reactor - Synthetic solid waste - Distilled water - Hot air oven - Furnace

9.	Pthalate test, Clause. 7.5	**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) used for 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, 1000 mg 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
10.	Anti- Bacterial, Clause 7.7	- Spectrophotometer, capable of measuring at a 620 nm to 660 nm wavelength, - Incubator, capable of maintaining a constant temperature of 37 °C ± 2 °C, - Water baths, one capable of maintaining a constant temperature of 46 °C ± 2 °C and another capable of maintaining a temperature of 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, - Washing machine, in accordance with the specifications of ISO 6330, - Humidity chamber, tropical chamber or other container capable of maintaining a high-humidity more than 70 % RH atmospheric 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 s, - Refrigerator, capable of maintaining a temperature of between 2

		°C and 8 °C, - Freezers, one adjustable to a temperature below −70 °C and another to a temperature below −20 °C, - Balance, with the resolution of 0.01 g or better and 0.1 mg or better. - Filtering apparatus - Pipette, - Vials, 30 ml glass bottles, with screw openings, polytetrafluoroethylene or silicone packing and caps made of polypropylene, polycarbonate, - Petri dishes (diameter sizes of 90 mm to 100 mm or 55 mm to 60 mm), - Glass rod, with a diameter of approximately 18 mm. - Anti-bumping granules (glass beads), with a diameter of 3 mm to 4 mm. - Erlenmeyer flask, of capacity 100 ml. - Cutting template, made of a sterilizable material (stainless steel or glass) one with a diameter of 38 mm ± 1 mm and the other with the diameter 60 mm ± 1 mm. - Disposable plastic bags, sterile bags suitable for containing food products - Tweezers - Stainless-steel cylinder, with a mass of 200 g ± 10 g and a diameter of 35 mm ± 1 mm. - Metal wire basket, for autoclaving. - Aluminium foil. - Reciprocal incubation shaker. - Autoclave, capable of sterilizing at 121 °C ± 2 °C and 103 kPa ± 5 kPa. - pH meter, with a glass electrode detector.

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: All the hygiene material (Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty) with particular shape, size and optional requirements (Biocompatibility evaluation, Compostability, Anti-Bacterial activity value) produced under similar conditions of manufacture using same raw material in a day.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, 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 column 3 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/IEC 17025.

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 facilitiesor get testing done from BIS recognized/empanelled laboratory or any other laboratory having validNABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least withtest facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different testsgiven 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 laboratoryor 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 consumer pack of Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty, 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 consumer pack of Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty:

a) "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– Sanitary Napkin/Panty Liner/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 of IS 5405.

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**	**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	R	One sample	Each consignment	
3.2	Absorbent Core	3.2	IS 5405	R	One sample	Each consignment	
3.3	Barrier or Bottom Sheet	3.3	IS 5405	R	One sample	Each consignment	
4	Type And Shape	4	IS 5405	R	Firm to have adequate in-process controls to check compliance of this parameter as per the requirements specified in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.		
5	Sizes	5	IS 5405	R			
6	Manufacture, Workmanship And Finish	6	IS 5405	R			
7.1	pH Value	-	IS 1390	R	One sample	Each control unit / lot	
7.2	Ability to Withstand Pressure after Absorption	Annex-B	IS 5405	R	One sample	Each control unit / lot	
7.3	**Hygiene Testing Requirement**						
7.3.1	Bacterial and Fungal Bioburden	7.3.1.1	IS 5405	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 of the raw material.		
7.3.2	Test for Common Skin Pathogen – Staphylococcus Aureus	7.3.2.1					
7.4	Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization (optional)		IS/ISO 10993 (Part 5), IS 17932 (Part 7) and IS 17932 (Part 6)	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 (if applicable).		

7.5	Compostability (Optional)		IS/ISO 17088	S	The Compostability testing shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product (If applicable).
7.6	Pthalate test		IS 9873 (Part 6)	S	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.
7.7	Anti-Bacterial activity value (optional)		IS/ISO 20743	S	The Anti-Bacterial 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 (If applicable).