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उत्पाद मैन्युअल
DISPOSABLE ADULT INCONTINENCE DIAPER
IS 17508: 2020 केअनुसार

PRODUCT MANUAL
FOR DISPOSABLE ADULT
INCONTINENCE DIAPER ACCORDING TO
IS 17508: 2020

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने 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 लाइसेंस/प्रमाणपत्र 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 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.	मानकसंख्या **IS No.**	:	IS 17508: 2020
	शीर्षक **Title**	:	DISPOSABLE ADULT INCONTINENCE DIAPER
	संशोधनों की संख्या **No. of amendments**	:	01
2.	नमूनादिशानिर्देश **Sampling Guidelines**		
a)	कच्चामाल **Raw material**	:	The materials used for adult incontinence diapers shall conform to the requirements as per Cl. 3 and 5 of IS 17508: 2020 Biocompatibility evaluation, biodegradability and compostability, and Anti- Bacterial activity value are optional requirements for raw material. If the manufacturer intends to cover these in the scope of their licence, conformity of raw material to these requirements as per Clause 7.4, 7.5 & 7.6 of IS 17508:2020 is to 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 test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC17025 or in-house testing/combination thereof. 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**	:	Samples of any size intended to be covered in the scope of licence may be tested.
c)	**नमूने का परिमाण Sample Quantity**	:	30 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 ofLicence/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-A
4.	**निरीक्षणऔर परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer to Annex-B
5.	**एकदिन में संभावित परीक्षण Possible tests in a day**		
	I) Dimensions II) Manufacture, workmanship and finish III) pH Value IV) Rate of Absorption *V)* Rewet Under Load *VI)* Minimum Absorption Capacity 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 17508:2020 with the following scope:		
	Name of the product		Disposable Adult Incontinence Diaper
	Type/Size		Small, Medium, Large and/or X Large
	Optional requirement		(i) With/without biocompatibility evaluation (ii) With/without biodegradability and compostability and/or (iii) With/without Anti- Bacterial activity value

ANNEX–A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1.	Sizes (Clause 6 of IS 17508:2020)	Vernier caliperSteel scale
2.	pH Value (Clause 7.1 of IS 17508:2020) (IS 1390 (cold method)	Reagents: Distilled or deionized water, Potassium chloridesol. (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, Weighing Balance (accurate to 0.01g), Beakers(150ml), Volumetric flasks (1L), Stoppered glass or polypropylene flasks, Thermometer
3.	Rate of Absorption, Absorption time, Rewet under load (Clause 7.2 of IS 17508:2020) (Annex B)	Reagents: Distilled Water, Bromocresol purple (AR grade), Food colouring Apparatus: Flat Level Transparent Surface, StainlessDosing Ring Mechanical shaker, Standard weight (2.5 Kg) with 8 cm diameter. Weighing Balance (accurate to 0.01g), Graduated cylinder (500 ml, 1000 ml with min 5ml graduation. Small Pipette (5 ml, 10 ml) Pen Filter paper: of 110 mm diameter/Balloting Paper Separating Funnel (Flow rate of 7ml/Sec. or equivalent) Thermometer, Stop watch (LC 1 Sec.), AC for maintaining Temp. of 27°C ± 2°C Humidity Chamber for Maintaining humidity 65%± 2
4.	Bacterial and Fungal Bio burden (Clause 7.3.1 of IS 17508:2020)	Reagents: Plate count agar (PCA), Sabouraud chloramphenicol agar (SCA), Sodiumchloride (0.85%), Apparatus: Autoclave, Hot air oven, Incubator (30-350C), Incubator (20-250C) pHmeter, 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 of IS 17508:2020)	**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 of IS17508:2020) (IS/ISO 10993 Part 5 , IS/ISO 10993 Part10 and IS/ISO 10993 Part 12	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 hem cytometer.Weighing Balance, Air conditionerPetri dishes Pipetting aid. Pipettes (8-channel pipettes, dilution block) Cryotubes. Tissue culture flasks (80 cm2, 25 cm2)96-Well tissue culture micro titer plates.Culture medium to prevent absorption Cell lines Negative control material (High-density polyethylene) Positive control material. (Sodium LaurylSulphate (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+ andMg2 + (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 fibroblastsAgarose 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 evaporatorpH

		meter Pipetting aid Weighing BalanceShaker, Flasks Incubators Petri dishes Pipetting aid Air conditioner Pulverizing or grinder apparatus Extraction vial (borosilicate glass tubes withcaps) 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 dressingNon- 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 Dimethyl sulfoxide (DMSO)n- hexane Ethanol Hapten Lubricant Positive control (Sodium Lauryl Sulphate (SLS) Negative control (Non-irritant, Absorbent gauze)
7.	Biodegradability and Compost ability (Optional) (Clause 7.5 of IS 17508:2020) (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 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 vapors 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 chromatography) 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
8.	Anti-Bacterial Activity Value (Optional), Cl 7.6	Laboratory apparatus and, in particular, thefollowing • Spectrophotometer, capable of measuring at a 620 nm to 660 nmwavelength, or McFarland's nephelometer. • Incubator, capable of maintaining a constant temperature of 37 °C ± 2 °C • Water baths, one capable of maintaining ga 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 blowsper second to 8 blows per second, with the corresponding disposable containers • Clean bench, for microbial test • Washing machine, in accordance with the specifications of ISO 6330 • Humidity chamber, tropical chamber or other container capable of maintaining ahigh-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-measuringreagent • Printing apparatus, capable of applying a4 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 °C and another toa temperature below −20 °C • Balance, which can be read to thenearest 0, 01 g. • Filtering apparatus, consisting of anupper container equipped with a membrane filter and a lower container equipped with a suctionopening • 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 Vials, 30 ml glass bottles, with screwopenings, polytetrafluoroethylene or silicone packing and caps made of polypropylene, polycarbonate or another suitablematerial • Petri dishes, that have been sterilized,made of glass or plastic, in 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) with adiameter of 3,8 cm ± 0,1 cm • Disposable plastic bags, sterile bags suitable for containing food products, tobe used for one of the shaking methods of the specimens. • Tweezers, made of a material which canbe sterilized. • Stainless-steel cylinder, with a mass of 200 g ± 10 g and a diameter of 3,5 cm ±0,1 cm • Metal wire basket, for autoclaving. • Aluminum foil. • Reciprocal incubation shaker • Autoclave, capable of sterilizing at 121 °C ± 2 °C and 103 kPa ± 5 kPa. • Reagents and culture media as per Cl. 6 of IS/ISO 20743:2013

9.	Pthalate test, Cl. 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

ANNEX B

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 disposable adult incontinence diaper made from the same material, same type/size produced under similar conditions of manufacturing in a single run.

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 facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid 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 consumer pack of adult incontinence diaper 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 adult incontinence diaper:

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– 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 17508: 2020.

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 17508:2020	R	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.		
3.2	Absorbent Core	3.2					
3.3	Barrier or Back Sheet	3.3					
4	Fastening And Securing Mechanism.	4					
5	Manufacture, Workmanship And Finish	5					
6	Dimensions	6 (Table1)					
7	Performance Requirements						
7.1	pH Value	-	IS 1390	R	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.		
7.2	Rate of Absorption, Rewet Under Load and Minimum Absorption Capacity	- Annex- B	ISO 11948-1 IS 17508:2020				
7.3	Hygiene Testing Requirement						
7.3.1	Bacterial and Fungal Bio burden	7.3.1.1	IS 17508:2020	S	The manufacturer shall perform the hygiene testing for the final product once in 03 months 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	Staphylococcus Aureus	7.3.2.1	IS 17508:2020				

7.4	**Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization(Optional)**	**-**	**IS/ISO 10993 Part 5, IS/ISO 10993 Part 10 and ISO 10993 Part 12**		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	**Biodegradability and Compostability (Optional)**	**-**	**IS/ISO 17088**	**S**	The biodegradability and Compostability and 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 (If applicable)
7.6	**Anti-Bacterial Activity Value (Optional)**	**-**	**IS/ISO 20743**		
7.7	**Phthalate Test**	**7.7**	**IS 9873 Part 6**	**S**	Once in a year