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उत्पाद मैन्युअल
Disposable Baby Diaper Specification
IS 17509: 2021 के अनुसार

PRODUCTMANUAL
FOR Disposable Baby Diaper Specification
ACCORDINGTO IS 17509: 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 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानकसंख्या** **IS No.**	:	IS 17509: 2021
	शीर्षक **Title**	:	Disposable Baby Diaper Specification
	संशोधनोंकीसंख्या **No. of amendments**	:	03
2.	**नमूनादिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	Material shall conform to the requirements of Cl. 3 of IS 17509: 2021. Further, if applicable, the requirement of Biocompatibility Evaluation & Anti-Bacterial Activity Value as per Cl. 7.4 & 7.7 respectively (The Biocompatibility Evaluation and the Anti-bacterial activity value test shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product) Conformity of raw materials to the standard may be *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.* Further, manufacturer of Disposable Baby Diaper shall submit a declaration identifying the materials being used

			to make the product and stating that material used for manufacture of baby diaper does not have harmful effect during normal use, is comfortable for the baby, and is compliant to the requirements of the standard. 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)	**नमूनेकापरिमाण 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 परीक्षणकी स्कीम Scheme of Inspection and Testing**	:	Please refer to Annex-C
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**		
	Type and sizes, pH value, fastening and securing mechanism, workmanship and finish, Rate of Absorption, Rewet under Load and 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.	**लाइसेंसकादायरा/ScopeoftheLicence:**		
	"Licence is granted to use Standard Mark as per IS 17509: 2021 with the following scope:		
	Name of the product	Disposable Baby Diaper	
	Type and size	As per tables under 6.1 and 6.2 (in case non-standard weights and sizes are used, same to be declared and indicated accordingly)	
	Material	As declared	
	Optional requirements	1. With or without Biocompatibility Evaluation 2. With or without Biodegradability and Compostability 3. With or without Anti-Bacterial Activity	

ANNEX-A

GROUPING GUIDELINES

The following grouping guidelines shall apply for Grant of Licence (GoL)/Change in Scope of Licence (CSoL):

i. The manufacturer shall declare the types of materials being used to manufacture baby diapers as well as the types and sizes of the diapers being manufactured.

ii. Samples of baby diapers of each type of material and of any of the types/sizes of baby diapers being manufactured and intended to be covered in the scope of licence, shall be tested.

iii. In case optional requirements i.e. Biocompatibility Evaluation, Biodegradability and Compostability and/or Anti-Bacterial Activity are intended to be covered in the scope of licence, the samples shall also be tested for these optional requirements and shall found conforming to these requirements as per Cl. 7.4, 7.6 and 7.7 respectively.

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

v. 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

LISTOFTESTEQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Types and Sizes, Cl. 6	Weighing balance, Vernier calipers, scale/measuring tape
2	pH value, Cl. 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	Rate of Absorption, Rewet under Load and Minimum Absorption Capacity, Cl. 7.2	Weighing Balance, with resolution of ± 0.01 g, A rigid cover plate, with weight, total weight : 6 300 g (plate 605.3 g, weight 5 694.7 g) representing a pressure of 4.41 kPa (0.64 psi) for small, medium, large, X Large, XX Large and XXX Large sizes. The dimensions of the plate shall be around 200 mm × 70 mm and inner diameter of cylinder shall be 50 mm. A rigid cover plate, with weight, total weight : 2 500 g (plate 605.3 g, weight 1 894.7 g) representing a pressure of 1.75 kPa (0.25 psi) for premature and new born sizes . The dimensions of the plate shall be around 200 mm × 70 mm and inner diameter of cylinder shall be 40 mm. Food Tray, of approximately 500 × 300 mm to provide a flat surface under the diaper and capture any fluid that leaks through the back sheet. 0.9 percent NaCl solution, (22 – 24 °C) of pH 6.0 to 7.0 Food Coloring, such as indigo carmine or equivalent to color the saline solution. Graduated Cylinder, 100 ml with 1 ml graduation, Small Pipette of 5 to 10 ml volume to accurately adjust the volume of fluid for the test, Stopwatch (with an accuracy in 0.01s) 500 mm Ruler (with 1 mm graduation), Pen, filter paper, glass rod, beakers and other glassware, Conditioning chamber
4	Hygiene Testing Requirement, Cl 7.3	**<u>Bacterial and Fungal Bioburden</u>** **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,
		Test for Common Skin Pathogen— Staphylococcus Aureus **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
5	Biocompatibility Evaluation - Cytotoxicity, Irritation and Skin Sensitization (Optional), Cl. 7.4	**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(alternatively, in the absence of a suitable buffer in the cell culture medium, 7,5 % CO2/air may be used), Inverse phase contrast Microscope, Laboratory burner, centrifuge, laboratory balance, 96-well plate photometer(equipped with 540 nm filter), Laminar flow cabinet (Biological hazard standard), Shaker for microtitre plates, Cell counter or hemacytometer, 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 Chemicals, media and sera: 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, L-glutamine (200 mM) or glutamax, Newborn calf serum (NBCS), Trypsin/EDTA solution, 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(DMSO) analytical grade, Ethanol (ETOH) analytical grade, Glacial acetic acid analytical grade, Nutrient agar - Cell culture media - Penicillin/streptomycin solution. - Mouse fibroblasts - Agarose overlay - Neutral red, Distilled water. **Tests for Irritation and Skin Sensitization-**

		Test equipments and chemicals as mentioned in IS 17932(Part 6): 2023
6	**Phthalate 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 laboratoryglassware. • 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 extractionthimble. • Analytical balance, capable of measuring to an accuracy of 0,001 g. • Concentration apparatus, for example, a rotaryevaporator. 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 nominalcapacity. • Polytetrafluoroethylene (PTFE) membrane filter, of pore size 0,45 µm

7	Biodegradability and Compostability (Optional), Cl. 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 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
8	Anti Bacterial Activity (Optional), Cl. 7.6	Spectrophotometer, capable of measuring at a 620 nm to 660 nm wavelength, or McFarland's nephelometer. 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, for microbial test. 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, which can be read to the nearest 0.01 g. 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. Vials, 30 ml glass bottles, with screw openings, polytetrafluoroethylene or silicone packing and caps made of polypropylene, polycarbonate or another suitable material. 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 a diameter of 3,8 cm ± 0,1 cm. Disposable plastic bags, sterile bags suitable for containing food products, to be used for one of the shaking methods of the specimens Tweezers, made of a material which can be 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. Aluminium foil. Reciprocal incubation shaker. Autoclave, capable of sterilizing at 121 °C ± 2 °C and 103 kPa ± 5 kPa. Reagents used in tests shall be of analytical quality and/or suited for microbiological purposes

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 disposable baby diapers manufactured from the same consignment of raw material, of the same type and size, manufactured under similar conditions 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 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 pack of disposable baby diapers 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 additionalrequirement on each pack of disposable baby diapers:

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 (if applicable) – The baby diaper 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 17509.

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**		
Cl.	**Requirement**	**Test Methods**	**Clause Reference**		**No. of Sample**	**Frequency**	**Remarks**
3	Material						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.
3.1	Top cover or the top sheet	3.1	IS 17509	R	One	Each consignment	Visual and constructional requirements
3.2	Absorbent core;	3.2	IS 17509	R	One	Each consignment	Visual and constructional requirements
3.3	Outer protective barrier or back sheet	3.3	IS 17509	R	One	Each consignment	Visual and constructional requirements
7.4	Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)		IS/ISO 10993 Part 5, IS 17932 Part 6 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 or source of supply of raw material for manufacturing the product Note: IS 10993(Part 10) has been superseded by IS 17932(Part 6).		
4	Fastening and Securing mechanism	4	IS 17509	R	Manufacturer shall put in place adequate in process controls/inspections to		
					ensure conformity to the standard		
5	Manufacture, workmanship and finish	5	IS 17509	R	Manufacturer shall put in place adequate in process controls/inspections to ensure conformity to the standard		

6	Type and Size	6	IS 17509	R	Manufacturer shall put in place adequate in process controls/inspections to ensure conformity to the standard/prescribed requirements		
7	**Performance requirements**						
7.1	pH value		IS 1390	R	One	Each control unit	
7.2	Rate of Absorption, Rewet under Load and Minimum Absorption Capacity	Annex B	IS 17509	R	One	Each control unit	
7.3	Hygiene Testing Requirement						
7.3.1	Bacterial and Fungal Bioburden	7.3.1.1	IS 17509	S	The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is any change in the raw material, manufacturing premises and the raw material supplier		
7.3.2	Test for Common Skin Pathogen — Staphylococcus aureus	7.3.2.1	IS 17509	S			
7.5	Phthalate Test		IS 9873 (Part 6)	S	One	Once every 3 months	
7.6	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 source of supply of raw material for manufacturing the product (If applicable)		
7.7	Anti-Bacterial Activity Value (Optional)		IS/ISO 20743. (Absorption method)	S	The Anti-Bacterial Activity testing shall be carried out once for existing products and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product (If applicable)		