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BUREAU OF INDIAN STANDARDS

*Draft for comments only*

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**व्यापक परिचालन मसौदा**

**पुनः प्रयोज्य सेनेटरी पैड/सेनेटरी नैपकिन/पीरियड पैंटीज — विशिष्टि (पहला पुनरीक्षण)**

(IS 17514 का पहला पुनरीक्षण)

*Wide Circulation Draft*

Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification (*first revision of IS 17514*)

ICS 59.080

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Technical Textiles for Medtech Applications  
Sectional Committee, TXD 36

last date for receipt of comments is  
11 Dec 2024

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FOREWORD

(Formal clause will be added later)

Reusable sanitary pad/sanitary napkin/period panties are hygiene products that are worn by menstruators (children and adults) to absorb blood and other fluids during menstrual periods.

This standard was originally published in 2021. The first revision has been made to incorporate the following major changes: -

- a) All amendments have been incorporated.
- b) Material and sizes have been updated.
- c) The procedure and requirement of ability to withstand pressure after absorption have been modified.
- d) pH and hygiene testing requirement have been updated.
- e) Sampling and criteria for conformity has been modified.

- f) Marking clause has been modified.
- g) References to Indian Standard have been updated.

This standard contains clause **6** which calls for an agreement between the purchaser and the supplier regarding dimensions. However, recommended dimensions have been specified.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (second revision)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

**IS 17514 : 2024 REUSABLE SANITARY PAD / SANITARY NAPKIN /  
PERIOD PANTIES — SPECIFICATION**

**1 SCOPE**

This standard covers the requirements for reusable (multiple use) sanitary pad/sanitary napkin/period panties for external use.

**2 REFERENCES**

The standards given in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

**3 MATERIALS**

The reusable sanitary pad/sanitary napkin/period panties generally consist of following major components:

- a) cover or the top sheet;
- b) absorbent core; and
- c) bottom layer.

**3.1 Cover/Top Sheet**

The cover/top sheet is the material which comes under contact with skin during use. The material used for the top layer/cover shall be safe, soft to the touch and should not shed any fibers when rubbed dry or wet.

The cover of reusable sanitary pad/sanitary napkin/period panties shall be of good quality cotton, polyester, polyester/cotton blended fabric, viscose, polyester/viscose blended fabric, rayon knitted sleeve or gauze, non-woven fabric, or any other suitable materials as agreed mutually between the buyer and seller.

**3.2 Absorbent Core**

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cotton, viscose, polyester, micro terry, viscose/polyester, cellulose pulp, cellulose wadding, tissue, nonwoven materials, a combination of these materials or any other suitable absorbent materials as agreed mutually between the buyer and seller. The absorbent materials must be free from lumps, oil spots, dirt or foreign material. The absorbent material shall not form lumps with the effect of sudden pressure.

### **3.3 Bottom Layer**

The bottom layer of reusable sanitary pad/sanitary napkin/period panties shall be made of suitable material(s) that prevents the leakage when used.

‘NOTE — The requirements given in 3.1 to 3.3 are for guidance of the manufacturer. The material and design may vary between different types and sizes of the reusable sanitary pad/sanitary napkin/period panties or as per the agreement between buyer and seller.’

## **4 MANUFACTURE, WORKMANSHIP AND FINISH**

The material used for reusable sanitary pad/sanitary napkin/period panties shall be smooth, safe for skin contact, and shall not leach dyes or bleed colour. When visually examined, the reusable sanitary pad/sanitary napkin/period panties shall be free from defects or lumps. There shall be no loose stitching, or visible defects on the material. The materials shall be free from odour, smooth to the touch and when worn, shall not chafe or be uncomfortable for the user. They shall be free from all sorts of foreign matter.

## **5 FASTENING MECHANISM**

If the style/design of the reusable sanitary pad/sanitary napkin/period panties requires a fastening mechanism, there shall be a suitable device for fastening the reusable sanitary pad/sanitary napkin/period panties for secure use for example, buttons, clasps, elastic, string, velcro or any other suitable material. The material used for the fastening mechanisms shall not cause harm to skin and shall not be abrasive when the product is used. The fastening mechanism shall be durable and free from rusting until the life cycle of the product as declared by the manufacturer.

## **6 SIZES**

Size of reusable sanitary pad/sanitary napkin/period panties shall be as agreed to between the buyer and the seller. Sizes of reusable sanitary pad/sanitary napkin/period panties may be variable depending on the absorbent capacity or as per buyer requirement. The recommended sizes of reusable sanitary pad/sanitary napkin are classified as follows in table 1:

**Table 1 Size of Reusable Sanitary Pad/Sanitary Napkin/Period Panties**

(for reference and guidance only)

SI No	Name of product	Size Class	Length (mm) (Absorbent core only)	Width (mm) (Absorbent core only)
(1)	(2)	(3)	(4)	(5)
i)	Sanitary Pad/Sanitary Napkin	Small	≤ 240	Min 60
		Medium	241 to 260	
		Large	261 to 280	
		Extra Large	≥ 281	
ii)	Period Panty	-	230-300	80-140

\*NOTES —

- 1) The actual dimension of absorbent core may differ as per the product design of manufacturer. If required, the manufacturer may also provide the figure/schematic diagram for measurement of dimension of absorbent core length and width of the product.
- 2) The recommended dimension (for reference and guidance only) of absorbent core length and width for other size class/type of reusable sanitary pad/sanitary napkin/period panties not covered in Table 1 shall be declared by the manufacture.\*

## 7 WASHING, DRYING AND HANDLING INSTRUCTION

The manufacturer shall provide the washing, drying, handling and storage instruction on every packet of reusable sanitary pad/sanitary napkin/period panties to ensure proper use and care by the consumer.

## 8 GENERAL REQUIREMENTS

The raw material/fabric used for manufacturing the product shall meet the following requirements (initially and after declared cycle washes) as specified in Table 2.

**Table 2 Colourfastness and Dimensional Stability Requirement of Raw Material/Fabric**  
(Clauses 8 and 11.2.4)

SI No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Colour fastness to rubbing		IS/ISO 105-X12
	a) Dry b) Wet	4 or better 3 or better	

ii)	Colour fastness to perspiration (acidic and alkaline) a) Colour change b) Staining	4 or better 4 or better	IS/ISO 105-E04
iii)	Colour fastness to washing a) Colour change b) Staining	4 or better 4 or better	IS/ISO 105-C06
iv)	Dimensional stability to washing, percentage, <i>Max</i> Length and width	$\pm 5$	Annex C of IS 16394

## 9 PERFORMANCE REQUIREMENTS

The reusable sanitary pad/sanitary napkin/period panties shall meet the requirements (initially and after declared cycle washes) as specified in 9.1 to 9.3.

### 9.1 pH Value

The pH of reusable sanitary pad/sanitary napkin/period panties (top and absorbent core) shall be from 3.5 to 7.5 when tested by the method given in IS 1390.

\*NOTE — If the required weight of the test specimen is not sufficient in one sample, then more no. of samples of the same lot may be taken for testing of the product.

### 9.2 Ability to Withstand Pressure after Absorption

The reusable sanitary pad/sanitary napkin/period panties shall absorb 10 ml (for small/medium size pad/napkin and period panties) and 30 ml (for large/extra-large size pad/napkin) of coloured distilled water and it shall not show leakage at the bottom or side edges of the reusable sanitary pad/sanitary napkin/period panties, when tested according to method given in Annex B.

### 9.3 Hygiene Testing Requirement

Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm and *Staphylococcus aureus* shall be absent.

#### 9.3.1 Bacterial and Fungal Bioburden

The reusable sanitary pad/sanitary napkin/period panties shall be tested for bacterial and fungal bioburden in accordance with method given in 9.3.1.1. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; IS/ISO 11737 (Part 1) shall be referred.

### 9.3.1.1 Test method

A sample of 5 gm cut from the centre portion of the reusable sanitary pad/sanitary napkin/period panties shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit. Add eluent either ten times the absorbent quantity of the pad/napkin/panty or the quantity in which the pad/napkin/panty completely immerse. The pad/napkin/panty shall be shaken vigorously in the eluent and the liquid shall be extracted from it. Report the quantity of the eluent used for extraction, time and frequency of shaking in the test report. The extract shall be serially diluted and plated out on respective mediums, that is, plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30 – 35 °C for 24 h and count colonies. Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20 – 25 °C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth. The typical colony characteristics are shown in Fig.1.

### 9.3.2 Test for Common Skin Pathogen — *Staphylococcus Aureus*

The reusable sanitary pad/sanitary napkin/period panties shall be tested for the presence of *Staphylococcus aureus* in accordance with method given in 9.3.2.1. For the preparation of medium, such as cooked salt medium, baird-parker medium and method for coagulase test; IS 5887 (Part 2) shall be referred.

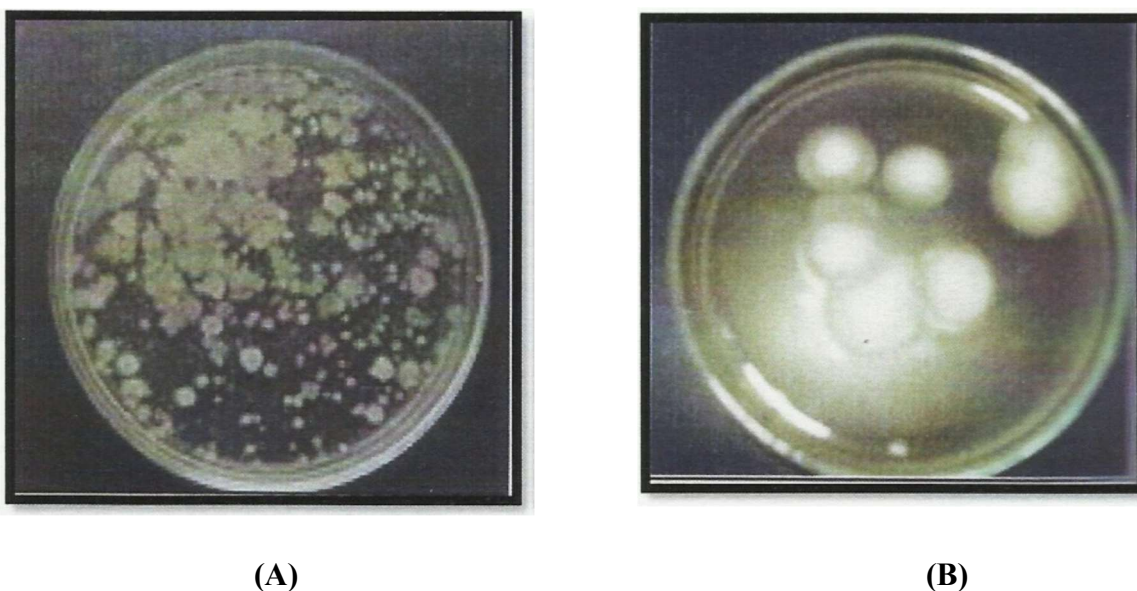


Fig 1 Typical Colony Characteristics of Bacterial Bioburden (A) and Fungal Bioburden (B)

### 9.3.2.1 Test method

A sample of 5 gm cut from the centre portion of the reusable sanitary pad/sanitary napkin/period panties shall be completely immersed in appropriate volume of enrichment medium like cooked salt medium or equivalent medium. Incubate for enrichment purpose at 37 °C for 24 h. Report the quantity of the medium used for enrichment in the test report. The incubated sample shall be shaken vigorously in the medium and the liquid shall be extracted from the pad/napkin/panty. The extract shall be streaked onto a Staphylococcal isolation medium, such as Baird-Parker medium or equivalent and incubated at 37 °C for 24-48 h and examine for growth. The result is considered positive if black colonies with a narrow white margin, surrounded by a zone of clearance are seen. Suspect colonies must show coagulase activity to confirm presence of *Staphylococcus aureus*. The typical colony characteristic is shown in Fig. 2.



Fig. 2 Typical Colony Characteristics of *Staphylococcus Aureus*

‘NOTE — If the required weight of the test specimen under clause 9.3.1.1 and 9.3.2.1 is not sufficient in one sample, then more no. of samples of the same lot may be taken for preparation of test specimen.’

### 9.3.3 Good Manufacturing Practice Guideline for Hygiene Requirement

The reusable sanitary pad/sanitary napkin/period panties 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.

### 9.4 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)



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. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 Part 5, IS 17932 (Part 7) and IS 17932 (Part 6) respectively.

For cytotoxicity, the material shall show reactivity as “non-cytotoxic” when tested as per IS/ISO 10995 (Part 5). Similarly, the material shall be ‘Non-irritant and Non-sensitizer’ when tested as per IS 17932 (Part 7) and IS 17932 (Part 6) respectively. For preparation of samples for these tests, IS/ISO 10993 Part 12 shall be referred.

### **9.5 Phthalate Test**

The amount of phthalate present in reusable sanitary pad/sanitary napkin/period panties shall be < 0.1 percent (individual or in combination) when tested as per the method given in 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.

## **10 ANTI-BACTERIAL ACTIVITY VALUE (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 when tested by the absorption method prescribed in IS/ISO 20743. The fabric shall be washed as per the procedure specified in **D-5.1** of IS 16394.

## **11 SAMPLING AND CRITERIA FOR CONFORMITY**

### **11.1 Lot**

All the reusable sanitary pad/sanitary napkin/period panties of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

**11.1.1** Each lot shall be tested separately for ascertaining the conformity of the lot.

**11.1.2** The number of reusable sanitary pad/sanitary napkin/period panties to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 3.

**11.1.3** These reusable sanitary pad/sanitary napkin/ period panties shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

**Table 3 Number of Reusable Sanitary Pad/Sanitary Napkin/Period Panties to be Selected**  
(Clauses 11.1.2, 11.2.1, 11.2.1.1 11.2.2 and 11.2.3)

Sl No.	Lot size	Non-destructive Testing		Destructive Testing	
		No. of Pad/Napkin/Panty to be Selected <b>n</b>	Acceptance Number <b>a</b>	No. of Pad/Napkin/Panty to be Selected <b>n<sub>1</sub></b>	Acceptance Number <b>a<sub>1</sub></b>
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13	1	5	0
ii)	281 – 500	13	1	5	0
iii)	501 – 1 200	20	1	5	0
iv)	1 201 – 3 200	32	2	8	0
v)	3 201 – 10 000	32	2	8	0
vi)	10 001 – 35 000	50	3	8	0
vii)	35 001 – 150 000	80	5	13	0
viii)	150 001 – 500 000	80	5	13	0
ix)	500 001 and over	125	7	13	0

NOTES —  
 1) for colour fastness and dimensional stability, hygiene testing, biocompatibility evaluation, anti-bacterial activity refer clauses **11.2.4**, **11.2.5**, **11.2.6** and **11.2.7** respectively  
 2) The sampling plan given in table 3 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

## 11.2 Number of Tests and Criteria for Conformity

**11.2.1** All reusable sanitary pad/sanitary napkin/period panties to be selected as per column 3 of Table 3 shall be examined for workmanship and finish.

**11.2.1.1** Any reusable sanitary pad/sanitary napkin/ period panties 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 3. Otherwise, the lot shall be rejected.

**11.2.2** Out of the sample already found satisfactory according to **11.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

**11.2.3** The lot shall be considered as conforming to the requirements of the specification, if the total number of defective sanitary pad/sanitary napkin/period panties found in the sample (*see 11.2.2*) is less than or equal to the acceptance number as given in column 6 of Table 3.

**11.2.4** The conformance for colourfastness and dimensional stability as given in Table 2 may be accepted at fabric stage for a product if agreed between buyer and manufacturer. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

**11.2.5** 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.

**11.2.6** 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.

**11.2.7** 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.

## **12 MARKING**

**12.1** Each consumer pack shall be legibly and indelibly marked with the manufacturer's name or trademark, number of reusable sanitary pad/sanitary napkin/period panties contained in it and total absorption capacity in addition to the following:

- a) Use and care instructions;
- b) Storage instructions;
- c) Batch/Lot no. and date of manufacturing;
- d) Declared life cycle/wash cycle or best before (years.);
- e) Country of origin;
- f) Size class and pad length for reusable sanitary pad/sanitary napkin or length for period panty.
- g) 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.

- h) The information whether the material of the product is biocompatible that is meets the requirement of the standard for biocompatibility evaluation — cytotoxicity, irritation and skin sensitization (if applicable).
- i) Additional features of antibacterial (if required); and
- j) Any other information required by law in force or agreed between the buyer and the seller.

## 12.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

## 13 PACKING

The reusable sanitary pad/sanitary napkin/period panties shall be supplied in rigid or flexible packages made of suitable materials which are sealed so as to protect the product from moisture, soiling and contamination during storage and transportation. The package should be free of any torn or damaged areas.

### ANNEX A

(Clause 2)

#### LIST OF REFERRED STANDARDS

<i>IS No.</i>	<i>Title</i>
IS 1390 : 2022/ISO 3071 : 2020	Textiles — Determination of pH of aqueous extract ( <i>third revision</i> )
IS 4905 : 2015 ISO 24153 : 2009	Random sampling and randomization procedures ( <i>first revision</i> )
IS 5887 (Part 2) : 1976	Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of staphylococcus aureus and faecal streptococci ( <i>first revision</i> )
9873 (Part 6) : 2021/ ISO 8124-6 : 2018	Safety of toys Part 6 Determination of certain phthalate esters in toys and children's products ( <i>first revision</i> )
IS 16394 : 2015	Textiles — Woven shirting made of cotton, man-made fibres/ filaments and their blend — Specification
17932 (Part 6) : 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7) : 2024	Biological evaluation of medical devices Part 7 Tests for irritation

IS/ISO 105-C06 : 2010	Textiles — Tests for colour fastness: Part C06 Colour fastness to domestic and commercial laundering ( <i>first revision</i> )
IS/ISO 105-E04 : 2013	Textiles — Tests for colour fastness: Part E04 Colour fastness to perspiration ( <i>first revision</i> )
IS/ISO 105-X12 : 2016	Textiles — Tests for colour fastness: Part X12 Colour fastness to rubbing ( <i>first revision</i> )
IS/ISO 10993 (Part 5) : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 20743 : 2021	Textiles — Determination of antibacterial activity of textile products ( <i>first revision</i> )
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 10993-12 : 2012	Biological evaluation of medical devices: Part 12 Sample preparation and reference materials

**ANNEX B**  
(*Clause 9.2*)

**METHOD FOR DETERMINATION OF ABILITY TO WITHSTAND  
PRESSURE AFTER ABSORPTION**

**B-1 TEST PROCEDURE**

Thoroughly wash the reusable sanitary pad/sanitary napkin/period panty as per the wash care instruction with suitable detergent to ensure removal of any finishing treatment given to fabric for aesthetic purposes. Lay the reusable sanitary pad/sanitary napkin/period panties on a flat level transparent surface, so that underside of pad/ napkin/panty can be observed.

Drip at the rate of X ml ( $X = 50$  percent of absorbency/min) with 1 min interval for total volume of 2 X ml of coloured distilled water maintained at temperature of  $27\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$  on to the centre of the pad/napkin/panty from a height of 5 to 7 mm.

*For example:*

For small/medium size pad/napkin and period panties : 5 mL per min for total volume of 10 mL  
For large/extra-large size pad/napkin: 15 mL per min for total volume of 30 mL

After the pad/napkin/panty has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed.

Observe the bottom and side edge of pad/napkin/panty for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

‘NOTES —

- 1) The dimension of 1 kg weight should have length and width of 150 mm x 50 mm with a tolerance of  $\pm 1$  mm.
- 2) For period panty, cut along the lateral seam on both the sides (left and right) and then lay the period panty flat for absorbency testing.’

**B-2** Add 0.01 g colour of bromocresol purple (grade – chemical analytical grade or equivalent) in 1 000 ml of distilled water and stir evenly to get uniform coloured solution.

### ANNEX C (Clause 9.3.3)

#### GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

- a) Location should be free from objectionable odours, smoke, dust and other contaminants.
- b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
- c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
- d) Toilet and hand-washing station shall be positioned away from storage/production area.
- e) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production facility.
- f) Appropriate lighting and proper ventilation of the facility shall be ensured.
- g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
- h) Regular pest control measures shall be put in place.
- j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
- k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed.
- m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.

- n) Hand hygiene shall be practised during manufacturing.
- p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/ disinfection of the equipment.