

**केंद्रीय मुहर विभाग-2**

संदर्भ : कें.मु.वि-2/16: 5405

13 12 2019

**विषय: IS 5405:2019 (सैनिटरी नैपकिन ) का संशोधित Scheme of Inspection and Testing (SIT )**

- 1) यह उपरोक्त के संदर्भ में है।
- 2) IS 5405:2019 का अनुमोदित संशोधित Scheme of Inspection and Testing (SIT ) अनुपालन हेतु संलग्न है। SIT को IS 5405:2019 में दिये गए Sampling and Criteria for Conformity के साथ संरक्षित किया गया है।
- 3) सभी शाखा कार्यालयों से अनुरोध है की SIT को अनुज्ञप्तिधारकों को 7 दिन के भीतर भेजें एवं अनुपालन सुनिश्चित करें।

(आदित्य दास)  
वैज्ञानिक सी (कें.मु.वि.-2)

**प्रमुख, (कें.मु.वि.-2)**  
**उपमहानिदेशक (प्रमाणन)**  
**क्षेत्रीय/शाखा कार्यालयों को intranet माध्यम से परिचालित**

**प्रतिलिपि: ITS - इंटरनेट पर अपलोड करने के लिए**

**CENTRAL MARKS DEPARTMENT-2**

Our Ref: CMD-2/ 16: 5405

13 12 2019

**Subject: Revised Scheme of Inspection and Testing (SIT) for Sanitary Napkins According to IS 5405:2019**

1. This has reference to the subject mentioned above.
2. The approved revised SIT for IS 5405:2019 is enclosed for implementation. The SIT has been aligned with the Sampling and Criteria for Conformity given in revised IS 5405:2019.
3. BOs are advised to send this SIT to all Licensees within 7 days and ensure its implementation.

**Aditya Das**  
**Sc. C**

**Head (CMD 2)**

**DDG (Certification)**

**Circulated to: All ROs/BOs through BIS intranet**

**Copy to: ITS for hosting on Intranet**

**SCHEME OF INSPECTION AND TESTING  
FOR SANITARY NAPKINS ACCORDING TO IS 5405:2019**

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

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

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

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

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

a) BIS Licence No. CM/L \_\_\_\_\_.

b) BIS website details i.e –“For details of BIS certification please visit [www.bis.gov.in](http://www.bis.gov.in)”.

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

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

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

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

**6. HYGIENIC CONDITIONS** - The sanitary napkin shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C of IS 5405.

**7. REJECTIONS**–Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

**TABLE 1**  
**LEVELS OF CONTROL**

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

			10993 Part 12		
7.5	Biodegradability and Compostability (Optional)		IS/ISO 17088	S	The biodegradability and compostability testing shall be carried out once for existing products and whenever there is a change in the raw material for manufacturing the product.

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval to BO head.

Note-3: The number of sanitary napkin to be selected from the control unit/lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 1 of IS 5405. Any sanitary napkin failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 1 of IS 5405. Otherwise, the lot shall be rejected.

Out of the sample already found satisfactory according to the above, a sub-sample as per column 5 of Table 1 of IS 5405 shall be taken. This sub-sample shall be further tested for the remaining requirements. The lot shall be considered as conforming to the requirements of the specification, if the total number of defective sanitary napkin found in the sample is less than or equal to the acceptance number as given in column 6 of Table 1 of IS 5405.