www.bis.gov.in

उत्पाद मैन्युअल

चिकित्सीय वस्त्रादि - अवशोषक कपास (विसंक्रमित तथा अविसंक्रमित) – विशिष्टि

IS 16468: 2016 के अनुसार

PRODUCT MANUAL
FOR
Medical Textiles-Absorbent Cotton (Sterile and Non Sterile)- Specification
ACCORDING TO IS 16468:2016

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 underScheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for variousproducts. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 16468:2016
	शीर्षक **Title**	:	**Medical Textiles-Absorbent Cotton (Sterile And Non Sterile)- Specification**
	संशोधनों की संख्या **No. of Amendments**	:	*NIL*
2.	**नमूना दिशानिर्देश** **Sampling Guidelines:**		
a)	**कच्चा माल** **Raw material**	:	No specific Requirements. 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**	:	Sample of Sterile and Non Sterile Absorbent Cotton to be tested separately to be covered in the scope of the licence.

c)	**नमूने का परिमाण** **Sample Quantity**	:	1 kg 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**		• Sterility 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 **ANNEX – A**
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – B**
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	All tests except Sterility 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 16468:2016”		
	Name of the Product	**MEDICAL TEXTILES-ABSORBENT COTTON**	
	Sterility	**Sterile/Non-Sterile**	

BUREAU OF INDIAN STANDARDS
Manak Bhawan, 9, Bahadur Shah
Zafar Marg, New Delhi – 110002

ANNEX – A
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment/Chemical
1.	Fibre Identification, clause 5	• Compound microscope (100 X to 500 X) • Dissecting needles • Glass slides • Cover Glasses • Cross sectioning device • Analytical Balance • Beaker • Graduated Cylinder • Dark Bottle • Distilled Water • Zinc Chloride Iodide • Filter Paper • Phloroglucinol • Alcohol • Hydrochloric Acid • Detex • Shirlastain A • Neocarmine W • Texchrome • Potassium Iodide • Cuprammonium Hydroxide Solution • Sulphuric Acid • Sodium Hydroxide
2.	Foreign Fibres, clause 5	• Compound microscope (100 X to 500 X) •
3.	Neps, clause 5	• Analytical balance • Glass transparent plates •
4.	Fluorescence, clause 5	• UV Chamber •
5.	Loss on drying, clause 5	• Analytical Balance • Hot air oven • Desiccator
6.	Absorbency, clause 5	• Conditioning Chamber • Cylindrical Copper wire basket • Analytical Balance • Beaker • Pipette • Stopwatch •

7.	pH of aqueous extract, clause 5	• pH meter • Mechanical shaker • Analytical Electronic Balance • Buffer solutions (pH around 4,7 or 9) • Potassium Chloride Solution • Paper Cutter/Scissor • Conditioning Chamber
8.	Extractable Colouring matter, clause 5	• Percolator • Analytical Balance • Beaker • Measuring Cylinder • Reference solution
9.	Water Soluble substance, clause 5	• Hot Plate • Analytical balance • Beaker • Stopwatch • Glass rod • Filter paper • Desiccator
10.	Ether Soluble substance, clause 5	• Soxhlet apparatus • Hot Plate • Analytical Balance • Stopwatch • Desiccator • Ether
11.	Sulphated Ash, clause 5	• Muffle Furnace • Crucible • Sulphuric Acid • Desiccator • Analytical balance • Ammonium carbonate • Stop watch
12.	Surface active Substances, clause 5	• Analytical Balance • Beaker • Stopwatch • Graduated Ground Glass Stoppered Cylinder with external diameter of 20mm & wall thickness greater than 1.5mm • Glass rod • Sulphuric Acid
13.	Sterility	• Autoclave • Hot air oven • Incubator • pH meter • Water bath • Colony counter • Laminar Air Flow • Mechanical Shaker • Petri dishes • Flasks/bottles • Test tubes

ANNEX B
SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence, manufacturers will implement a Quality Assurance Plan (QAP) 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 (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or subcontracting/sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: Each piece of absorbent cotton manufactured using same raw material under similar conditions of manufacturing 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. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

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.

2. **ENSURING COMPLIANCE THROUGH TESTING** - Manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i) Shared testing resources like common facility,

ii) Cluster based testing facility,

iii) Sub-contracting to outside laboratories which may either be:

a) BIS recognised/empanelled laboratories, or

b) Any accredited laboratory as per ISO/IEC 17025

2.1 **TEST RECORDS** - The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made 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 the label of each pack of absorbent cotton, 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 pack of **Absorbent Cotton**.

a) "For BIS certification details please visit www.bis.gov.in"

4. **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 to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1
(Recommended Levels of Control by BIS- For Guidance Only)

(1)				(2)		
Test details				**Levels Of Control**		
Clause	**Requirements**	**Test Method**		**No of Samples**	**Frequency**	**Remarks**
		Clause	**Ref.**			
5	Fibre identification	6	IS 667	One	Each Control Unit	-
-do-	Foreign Fibres	-	-	One	Each Control Unit	-
-do-	Neps	Annex B	IS 16468	One	Each Control unit	-
-do-	Fluorescence	-	-	One	Each Control Unit	-
-do-	Loss on drying	-	-	One	Each Control Unit	-
-do-	Absorbency a) Sinking Time b) Water Holding Capacity	6.11	IS 14944	One	Each Control Unit	-
-do-	pH of aqueous extract	8	IS 1390	One	Each Control Unit	-
-do-	Extractable colouring matter	Annex C	IS 16468	One	Each Control Unit	-
-do-	Water Soluble Substance	6.12	IS 14944	One	Each Control Unit	-
-do-	Ether Soluble Substance	6.13	IS 14944	One	Each Control Unit	-
do-	Sulphated ash	6.18	IS 14944	One	Each Control Unit	-
-do-	Surface Active Substances	Annex D	IS 16468	One	Each Control Unit	-
-do-	Sterility	--	IS 10150	One	The Sterility 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).	