



उत्पाद मैनुयल

**POLYVINYL CHLORIDE (PVC) AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH
FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION
IS 10151:2019 के अनुसार**

**PRODUCT MANUAL FOR
POLYVINYL CHLORIDE (PVC) AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH
FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER — SPECIFICATION ACCORDING TO
IS 10151:2019**

भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम 2018 की स्कीम-I के तहत यह उत्पाद मानुयल प्रमाणीकरणके प्रचलन में रीति और पारदर्शिता के सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों एवं लाइसेन्स धारियों द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस लाइसेन्स/प्रमाण पत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग 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.	उत्पाद Product	:	IS 10151:2019
	शीर्षक Title	:	Polyvinyl Chloride (PVC) And Its Copolymers for Its Safe Use In Contact With Foodstuffs, Pharmaceuticals And Drinking Water — Specification
	सांशोधन सांख्या No. of amendments	:	01
2.	नमूनाकरण दिशा निर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	i) Basic Resin - Manufacturer needs to submit declaration/ undertaking/test certificate in compliance to the requirements of Cl.4.1 of IS 10151:2019 ii) Material - Manufacturer may submit declaration/ undertaking in compliance to the requirements of Cl. 4.2 of IS 10151:2019 iii) In case auxiliary items are used, they shall comply with the requirements of Cl. 4.3 of IS 10151:2019 iv) In case coloured material is to be covered in the

		scope of licence, sample shall be tested for conformity to requirement for pigments and colourants as per Cl. 4.4 of IS 10151:2019
b)	समूहिकरण दिशा निर्देश Grouping Guidelines	: Not applicable
c)	नमूने का आकार Sample Size	: For factory sample: Sample shall be drawn from three or more sealed bags/package in a manner to have composite sample of 3 kg, approximately (Cl 6.1, Annex D of IS 10151). For market sample: Minimum 3 kg
3	परीक्षण उपकरणों की सूची List of Test Equipment	: कृपया Annex-A देखें Please refer Annex-A
4	निरीक्षण व परीक्षण स्कीम Scheme of Inspection and Testing	: कृपया Annex-B देखें Please refer Annex-B
5.	एक दिन में संभावित परीक्षण Possible tests in a day	
	Residual Vinyl Chloride Monomer (RVCM) Content, Cl 4.5.1 and 4.5.2	
6	लाइसेंस का दायरा /Scope of the Licence:	
	Licence is granted to use Standard Mark as per IS 10151:2019 with the following scope:	
	Name of the product	Polyvinyl Chloride (PVC) And Its Copolymers For Its Safe Use In Contact With Foodstuffs, Pharmaceuticals And Drinking Water
	Optional requirements	Coloured material/Uncoloured material

**BUREAU OF INDIAN STANDARDS
MANAK BHAVAN,
9, BAHADUR SHAH ZAFAR MARG,
NEW DELHI-110002**

ANNEX – A

LIST OF TEST EQUIPMENTS FOR POLYVINYL CHLORIDE (PVC) AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER ACCORDING TO IS 10151:2019

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Limits of pigments and colourants, Cl. 4.4	<u>For determination of Lead, Arsenic, Mercury, Cadmium, Zinc, Barium, Chromium, Antimony as per Cl. 15 of IS 1699:1995</u> Kjeldahl Flasks, Atomic Absorption Spectrophotometer, hydride generation vessel accessory, Standard solution of copper, zinc, antimony, lead, barium, arsenic, cadmium and other reagents <u>For determination of primary aromatic amines and sulphonated aromatic amine (as per Annex B of IS 9833:2014)</u> Weighing balance, ultrasonic bath, Centrifuge capable of 3000 rpm, HPLC system (equipped with gradient elution, DAD detector and pump), Column: (Nucleodur 100-5 C18 ec (Machery Nagel); 250 mm × 4 mm, 5 µm or Equivalent) pH strips, Hydrochloric Acid, Sodium Hydroxide, Methanol HPLC grade, Analytical Reference Standards, phosphoric acid, Diammonium Hydrogen Phosphate <u>For determination of Polychlorinated biphenyl as per Annex C of IS 9833:2014</u> LRGC HRMS with EI Mode, Rotary Evaporator, and Weighing Balance nearest to 0.0001 g, Micropipette with Disposable Pipette Tip, Surgical Hand Gloves, Glass Column, Magnetic Stirrer and Magnetic Bar, Ground Joint Conical Flask— 500 ml, Conditioning/Test chamber for maintaining temperature condition 22 ± 2°C. Dust free environment with positive pressure inside the laboratory by air handling unit and laboratory reagents.
2	Residual Vinyl Chloride Monomer (RVCM) Content, Cl. 4.5.1 and 4.5.2	Vinyl Chloride (VC), N, N-dimethylacetamide (DMA), Diethyl Ether or cis-2-butene, Gas Chromatograph fitted with Headspace Autosampler, Flame Ionization Detector or Other Detectors, Gas Chromatographic Column, Sample Vials or Flasks Fitted with Silicon or Butyl Rubber Septa, Micro-syringes, Gas-Tight Syringes for Manual Headspace Sampling, Analytical Balance (LC= 0.1 mg)

3	Migration of RVCM into Foodstuffs, Cl. 4.5.3	Vinyl Chloride (VC), N, N-dimethylacetamide (DMA), Diethyl Ether or cis-2-butene, Distilled Water or Demineralized Water, Gas Chromatograph fitted with Headspace Autosampler, Flame ionization detector or other detectors, Gas Chromatographic Column, Sample Phials or Flasks Fitted with Silicon or Butyl Rubber Septa, Micro-syringes, Analytical Balance (LC= 0.1 mg)
4	Overall migration, Cl. 4.6	Simulating solvents as per Cl. 4 of IS 9845 Electric oven/water bath/, pressure cooker electric hot plate with temperature control regulator, analytical balance sensitive upto 0.1 mg, heat resistant glass beakers of 1000 ml capacity, stainless steel evaporating dish of 100ml capacity, stainless steel tongs, glass rod, plate glass, cylindrical glass jar, glass/stainless steel pins as per IS 9845:1998

This is an indicative list and may not be taken as being exhaustive

ANNEX B

SCHEME OF INSPECTION AND TESTING FOR POLYVINYL CHLORIDE (PVC) AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER ACCORDING TO IS 10151:2019

1. **LABORATORY-** A laboratory shall be maintained, which shall be suitably equipped (as given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the method given in the specification.
 - 1.1 The manufacturer shall prepare and implement a calibration plan for the test equipment.
2. **TEST RECORD-** 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 incorporated legibly and indelibly on each package containing the material provided always that the material so marked conforms to each requirement of the specification. Marking to be done on smallest bag and/or unit package that is being sent to customer.
 - 3.1 The information as mentioned under clause 5.2 of IS 10151:2019 shall be legibly and indelibly marked on each bag and/or unit package. In addition, the following shall be incorporated on each bag and/or unit package:
 - (i) BIS License Number CM/L—and
 - (ii) BIS website details i.e. —” For details of BIS certification please visit www.bis.gov.in”
4. **CONTROL UNIT-** For the purpose of this scheme, the entire quantity of material manufactured under similar conditions in a day shall be taken as one control unit.
5. **TEST CERTIFICATE** - For each consignment of BIS Certified material conforming to IS 10151:2019 there shall be a test certificate which shall contain the Lot/Batch/Control Unit number and the corresponding test results (an indicative format is given in Annexure-I enclosed).
6. **LEVELS OF CONTROL** :- The tests as indicate in Table 1 and at the levels of controls in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and records maintained in accordance with paragraph 2 above.
 - 6.1 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.
7. **STORAGE, AND HYGIENIC CONDITIONS:** Plastics materials intended for food contact use shall be stored separately from other materials in closed, properly identified containers. Adequate standards of hygiene shall be maintained at all times and plant operators and storemen shall be trained in proper hygienic practices.
8. **REJECTION** - 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.

TABLE1
LEVELS OF CONTROL
(Para 6 of Scheme of Inspection and Testing)

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S:Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Methods			No. of Sample	Frequency	Remarks
		Clause	Reference				
4.4	Pigments and colourants		IS 9833	S	One	Once in 6 months	For coloured materials only
4.5.1 and 4.5.2	Residual Vinyl Chloride Monomer (RVCM) Content	Annex A	IS 10151	R	One	Each control unit	
4.5.3	Migration of RVCM into Foodstuffs	Annex B	IS 10151	S	One	Once in 6 months	
4.6	Overall migration		IS 9845	S	One	Once in 6 months	

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 empanelled 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 by BO Head.

ANNEXURE-I
(Indicative format of TEST CERTIFICATE)
(PARA 6 OF SCHEME OF INSPECTION AND TESTING)
ABC LIMITED
(REGISTERED OFFICE ADDRESS AND WORKS ADDRESS)
CM/L-

**TEST CERTIFICATE FOR POLYVINYL CHLORIDE (PVC) AND ITS COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS,
PHARMACEUTICALS AND DRINKING WATER**

TEST CERTIFICATE NO. DATE:.....

TO M/s(NAME AND ADDRESS OF CONSIGNEE)

We certify that the material described below fully conforms to the requirement of IS 10151:2019

Properties of the product as tested in accordance with Scheme of Inspection and Testing contained in the BIS Certification Marks Licence CM/L
Noare as indicated below against each order
(PLEASE REFER TO IS 10151:2019 FOR DETAILS OF SPECIFICATION REQUIREMENTS)

TEST RESULTS

Name of product		
Batch Number/ Lot No. and Month/ Year of Manufacture		
Basic Resin		
Properties	Unit	Values
Residual Vinyl Chloride Monomer (RVCM) Content		
Migration of RVCM into Foodstuffs		
Overall migration		
Pigments and colourants (<i>optional</i>)		

REMARKS
WAGON NO./TRUCK NO.

(for BIS certification details www.bis.gov.in)

For ABC Company