



उत्पाद मैनुअल

पोलीविनाईल क्लोराइड (पीवीसी) होमोपॉलिमर

17658:2021 के अनुसार

**PRODUCT MANUAL FOR
POLYVINYL CHLORIDE (PVC) HOMOPOLYMERS- SPECIFICATION
ACCORDING TO IS 17658:2021**

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	उत्पाद Product	:	IS 17658:2021
	शीर्षक Title	:	POLYVINYL CHLORIDE (PVC) HOMOPOLYMERS - SPECIFICATION
	संशोधनों की संख्या No. of Amendments	:	Nil
2	नमूना दिशानिर्देश Sampling Guidelines:		
A	कच्चा माल Raw material	:	No specific requirement
B	समूहिकरण दिशा निर्देश Grouping guidelines	:	कृपया Annex-A देखें Please refer ANNEX-A
C	नमूने का परिमाण Sample Size	:	1.For Factory sample: Approximately 1 kg (or higher quantity required for testing) of sample collected from 3 or more sealed bag/package to be collected into a clean plastic bag, or other appropriate clean sealed container, to have ~ 3 kg composite sample. Proper mixing to be done for homogenization of composite sample before

			testing.(See Annex-A2 of IS 17658) 2. For Market sample: Minimum 3 kg of sample
3	परीक्षण उपकरणों की सूची List of Test Equipment	:	कृपया Annex-B देखें Please refer ANNEX-B
4	निरीक्षण व परीक्षण स्कीम Scheme of Inspection and Testing	:	कृपया Annex-C देखें Please refer ANNEX-C
5	एक दिन में संभावित परीक्षण Possible tests in a day:	:	All tests
6	लाइसेन्स का दायरा / Scope of the Licence:		
	Licence is granted to use standard Mark as per IS 17658:2021 with the following scope:		
	उत्पाद का नाम Name of the product		Polyvinyl Chloride (PVC) Homopolymers
	Varieties/Type/Grades		Designation of PVC-SR / PVC-PR / PVC-SR (mass/bulk) as per Cl. 4 of IS 17658:2021 e.g. – IS 17658-S-5
	Optional requirements		Polymer Used for Moulding or Extrusion Articles in Contact with Food Stuffs, Pharmaceutical and Drinking Water

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

ANNEX-A
GROUPING GUIDELINES

1. The manufacturer shall declare, in their application for considering grant of licence and/or change in scope of licence, types, grades each designation code which they intend to cover in their scope of the licence.
2. For considering grant of licence and/or change in scope of licence, the following grouping shall be considered:

Data Block	Details of Data Block	Sample to be drawn/tested pertaining to each data block
Data Block 1	For Indian Standard	For information purpose only and has no bearing on the testing
Data Block 2	Identification of the type of material	a) Manufacturer shall declare the type of material intended to be covered in the scope of licence as per code-letters in Cl. 4.2.2 b) One sample of each type of material (PVC-PR, PVC-SR, PVC-SR (Mass/Bulk)) shall be tested.
Data Block 3	K - value	One sample for each grade (i.e. Grade 1 to 7 as per table 1 for PVC-SR and Grade 1 to 8 as per table 2 for PVC-PR) shall be tested.

3. Scope of licence shall be restricted based on the manufacturing and testing facilities available.
4. During the operation of the Licence, BO shall ensure that all the varieties covered in the Licence are tested in rotation, to the extent possible.

ANNEX – B
List of test equipment
(For Guidance Purpose Only)

Sl. No	Tests used in with Clause Reference	Test Equipment
1	Residual Vinyl Chloride Monomer (RVCM) Content Cl.3.2	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 Phials or Flasks Fitted with Silicon or Butyl Rubber Septa, Micro-syringes, Gas-Tight Syringes for Manual Headspace Sampling, Analytical Balance (LC= 0.1 mg)
2	K-Value, Cl. 3.3, Table 1 and 2	Cyclohexanone, Viscometer, Graduated flask, Filter funnel, Mechanical agitator equipped with a heating device, Analytical balance, Temperature-regulated bath, Thermometer, Time-measuring device
3	Sieve Analysis, Cl. 3.3, Table 1	Sieves, Vibrating device, Analytical balance, Carbon Black, Bottles, Funnel OR Sieves, Air-jet sieve apparatus, Timer (e.g. stopwatch), Balance
4	Apparent Density, Cl. 3.3, Table 1	Measuring cylinder, Funnel, Analytical balance
5	Plasticizer Absorption, Cl. 3.3, Table 1	Burette, Glass or Glazed Porcelain Tile, Mould (Aluminium or brass), Stainless Steel Spatula, Plasticizer (Di-2-ethyl-n-hexyl-phthalate (DOP) OR Analytical balance, Burette, Centrifuge, Centrifuge Tubes, Sheaths, Cotton wool, Bis-(2-ethylhexyl) phthalate (DOP)
6	Dry Flow of 140 g, Cl. 3.3, Table 1	Funnel, Funnel support, to hold the axis of the funnel vertically, Stopwatch, Analytical balance
7	Conductivity, Cl. 3.3, Table 1	AC Wheatstone bridge, Conductivity Cell, Wide-mouthed Flat-Bottomed Flask with Ground-Glass Stopper, Analytical balance, Measuring Cylinder, High purity Water, Methanol
8	Volatile Matter, Cl. 3.3, Table 1 and 2	Analytical balance, Weighing bottle, Air circulating oven, Desiccator
9	Inherent Viscosity, Cl. 3.3, Table 2	Volumetric flask-Class A, Ubbelohde viscometer No.75 weighing balance, Cyclohexanone AR grade, Water Bath, Thermometer
10	Apparent Viscosity at low shear rates using rotational viscometer at 23°C with 60	Brookfield-type viscometer (type A, B or C), Thermostatic liquid bath, Support, Beaker, Thermometer

	phr plasticizer and 2 h ageing, Cl. 3.3, Table 2	
11	Pigments and colourants, Cl. 5	<u>For determination of Lead, Arsenic, Mercury, Cadmium, Zinc, Barium, Chromium, Antimony as per Cl. 15 of IS 1699</u> Kjeldahl Flasks, Atomic Absorption Spectrophotometer, hydride generation vessel accessory, Standard solutions of copper, zinc, chromium, antimony, lead, barium, arsenic, cadmium. Nitric acid - sp gr 1.42, Perchloric acid, Sulphuric acid-98%, Hydrochloric acid - sp gr 1.16 to 1.18, Hydrochloric acid - 5 N solution prepared by dilution with metal-free distilled water, Sodium sulphate, Sodium borohydride pellets, Potassium Chloride, Water – metal free. <u>For determination of Selenium as per IS 3025 (Part 56)</u> <u>Spectrophotometric Method (Diamino naphthalene Method) -</u> Spectrophotometer (480nm, light path of 1 cm), Volumetric Glasswares, Separating Funnel, Fluorocarbon Stopcock, Water Bath – Thermostatically Controlled, pH Meter, Centrifuge, Centrifuge Bottles with Fluorocarbon Screw Cap Stock Selenium Solution, Hydrochloric Acid, Ammonium Hydroxide, 2,3 – Diaminonaphthalene (DAN), Hydroxylamine Hydrochloride, Sodium Salt of EDTA, Amberlite XAD -8 or Equivalent Resin, Conc Hydrochloric Acid, Potassium Hydroxide <u>Atomic Absorption Spectrometric Method (Hydride Technique)–</u> Atomic Absorption Spectrometer (196.0 nm) Fitted with Hydride System and Hollow Cathode Lamp/Electrodeless Discharge Lamp, Gas (Argon or Nitrogen), Glasswares Decomposition Apparatus (Round Bottom Flask, Reflux Condenser, Condensate Reservoir) Nitric Acid, Sulphuric Acid, Hydrochloric Acid, Hydrogen Peroxide, Sodium Hydroxide, Sodium Tetrahydro borate, Selenium Stock Solution (1mg/ml). <u>For determination of primary aromatic amines and sulphonated aromatic amine (as per Annex B of IS 9833)</u> Weighing balance nearest to 0.0001 g, Ultrasonic bath, Centrifuge capable of 3000 rpm, HPLC system (equipped with gradient elution, DAD detector and pump), pH strips, Hydrochloric Acid, Sodium Hydroxide, Methanol HPLC grade, Analytical Reference Standards, Phosphoric acid, Diammonium Hydrogen Phosphate, Distilled water <u>For determination of Polychlorinated biphenyl as per</u>

		<u>Annex C of IS 9833</u> LRGC HRMS with EI Mode, Rotary Evaporator, Weighing Balance nearest to 0.0001 g, Micropipette with Disposable Pipette Tips, Surgical Hand Gloves, Glass Column, Magnetic Stirrer and Magnetic Bar, Ground Joint Conical Flask— 500 ml, Conditioning/Test chamber for maintaining temperature condition $22 \pm 2^{\circ}\text{C}$. Dust free environment with positive pressure inside the laboratory by air handling unit. Concentrated Sulphuric Acid (Analytical Reagent Grade), n-Hexane (Analytical Reagent Grade), Dichloro Methane (Analytical Reagent Grade), Silica Gel - Equivalent to ICN/MP - Silica 63-200-60A or Other Suitable, PCB Standard Solution (EC 4058 - Cambridge) or Equivalent, n-Nonane, Celite-545, Cesium Hydroxide, Silver Nitrate, Alumina (MP - Alumina B Super -1) or Alternate, Sodium Sulphate Anhydrous, Toluene-Analytical Reagent Grade, Ethanol - Analytical Reagent Grade <u>For determination of Carcinogenic amine as per IS 14816</u> Suitable Reaction Vessel, Hot Cabinet with Sand Bath or water bath with thermostat, Thermometer — 0.1°C accuracy at 70°C, Volumetric Flasks, Polypropylene or Glass Column, Polypropylene or Polyethylene Syringe — 2 ml, Vacuum Rotary Evaporator, Pipettes— 10ml, 5ml, 2ml, 1 ml, Ultrasonic Bath with Thermostat, Round-bottom Flask with Standard-Ground Joint -100 ml, Analytical Instruments - Automatic applicator for HPLC or DC, Densitometer, Capillary electrophoresis with DAD, Capillary GC, split/splitless injector, preferably with MS/MSD, HPLC with gradient Controller preferably with DAD or HPLC-MS. Methanol, t-Butyl Methyl Ether, Sodium Dithionite — minimum 87 percent purity, Aqueous Sodium Dithionite Solution, n-Hexane, Amines (highest available purity standard), Stock-Solution of the Amines, Citrate Buffer Solution, 20 percent Methanolic Sodium Hydroxide. For Carbon Black : Determination of Toluene Extract Spectrophotometer, Absorption Cells, Analytical Balance (Sensitivity 0.01 mg), Oven, Filter Paper — Whatman No. 41 or equivalent, Mechanical Shaker, Mortar and Pestle, Glass Filtering Funnel, Beaker, Erlenmeyer Flask, Toluene-Analytical grade. DETERMINATION OF 3-4 BENZOPYRENE BY GC/MS GC/MS Equipped with auto sampler and a 30 m, 0.25 ID DB-5 MS fused silica capillary column, Rotary evaporator, Helium Gas, Dichloromethane, PAH Standard, Internal Standard
12	Migration of RVCM into Foodstuffs, Cl. 5	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)
13	Overall migration, Cl. 5	Simulating solvents as per Cl. 4 of IS 9845 Electric oven/water bath/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 100 ml capacity, stainless steel tongs, glass rod, plate glass, cylindrical glass jar, glass/stainless steel pins as per IS 9845.

ANNEX C

SCHEME OF INSPECTION AND TESTING

For the purpose of this scheme, there shall be two types of units

a) Manufacturing units:

Manufacturing units are those units which produce the POLYVINYL CHLORIDE (PVC) HOMOPOLYMERS material.

b) Repacking units:

Repacking units are those units which procure ISI Marked PVC HOMOPOLYMERS material as per IS 17658 from a manufacturing unit holding a BIS licence for this product, repack it and dispatch it to the customer(s).

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturing units 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 manufacturing units 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. They 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 manufacturing units, the recommended definition of control unit is the entire quantity of material of same designation (and same additional properties) extruded continuously in a line over a period of one day or part thereof shall constitute a control unit.

1.3.2 For the guidance of manufacturing units 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 manufacturing units shall ensure compliance of their products to all the requirements of the Indian Standard.

1.5 For repacking units, since the product is inert and its properties are not affected in the process of transportation and repacking, the repacking units shall not be required to test the product again, i.e. the levels of control as per Table 1 shall not be applicable, however, repacking units shall maintain the records of repacking in such a way as to ensure traceability

of the repacked material to the product manufactured by the manufacturing unit. (see Table 2). Copies of test certificates issued by the manufacturing units shall be maintained.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturing units (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 manufacturing units, 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 manufacturing units, 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 manufacturing units **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 manufacturing units 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 manufacturing units 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. Repacking units shall maintain the records of repacking in such a way as to ensure traceability of the repacked material to the product manufactured by the manufacturing unit (see Table 2). Copies of test certificates issued by the manufacturing units shall be maintained by repacking units.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each package of PVC provided always that the material so marked conforms to each requirement of the specification.

3.1 The material shall be packed in suitable form of packing as agreed to between the purchaser and supplier.

3.2 Manufacturing units shall mark each bag and/or unit package whichever is smallest in size that is being delivered to the customer and the test certificate (as given in annexure-1) with the following

- a) Name and type of the material,
- b) Designation Code,
- c) Net Mass of the material
- d) Batch Number/Lot Number
- e) Month and year of manufacture of the material and
- f) Name of the manufacturer and trade mark; if any
- g) BIS Licence Number CM/L—and

3.3 Repacking units shall mark each bag and/or unit package whichever is smallest in size that is being delivered to the customer with the following

- i) Name and type of the material,
- j) Designation Code,
- k) Net Mass of the material
- l) Batch Number/Lot Number
- m) Month and year of manufacture and month and year of repackaging of the material
- n) Manufactured by: Name, trade mark (if any) and BIS Licence Number CM/L—of the manufacturing unit
- o) Packaged by: Own Name, trade mark (if any) and BIS licence number (i.e. of the repackaging unit)

3.4 Additional Marking requirements: The material shall also be marked with the following additional requirement on each bag and/or unit package:

- 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 so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1 (LEVELS OF CONTROL)
(Para 5 of Scheme of Inspection and Testing)

SI No.	(1)				(2)	(3)		
	Test Details				Test equipment requirement R: required (or) S: Subcontracting permitted	Levels of Control		
	Cl.	Requirement	Test method			No. of Sample	Frequency	Remarks
			Clause	Reference				
i)	3.2	Residual Vinyl Chloride Monomer (RVCM) Content	4.4.1	IS 10151/ISO 24538	R	One	Each Control Unit	
ii)	Cl. 3.3, Table 1 and 2	K-Value	--	IS 4669 / ISO 1628-2	R	One	-do-	
iii)	Cl. 3.3, Table 1	Sieve Analysis	6 of IS 4669	IS 4669 / ISO 4610	R	One	-do-	
iv)	Cl. 3.3, Table 1	Apparent Density	7 of IS 4669	IS 4669 / ISO 60	R	One	-do-	
v)	Cl. 3.3, Table 1	Plasticizer Absorption	10 of IS 4669	IS 4669 / Method A of ISO 4608	R	One	-do-	
vi)	Cl. 3.3, Table 1	Dry Flow of 140 g	7.2	Method A of ISO 6186	R	One	-do-	

vii)	Cl. 3.3, Table 1	Conductivity	9 of IS 4669	IS 4669	R	One	-do-	
viii)	Cl. 3.3, Table 1 and 2	Volatile Matter	5 of IS 4669	IS 4669/ ISO 1269	R	One	-do-	
ix)	Cl. 3.3, Table 2	Inherent Viscosity, Cl. 3.3, Table 1 and 2	--	ASTM D1243	R	One	-do-	
x)	Cl. 3.3, Table 2	Apparent Viscosity at low shear rates using rotational viscometer at 23°C with 60 phr plasticizer and 2 h ageing	--	ISO 2555	R	One	-do-	
xi)	5	Pigments and colourants	4.3	IS 10151	S	One	Once in 6 months	For food contact materials
xii)	5	Migration of RVCM into Foodstuffs Annex B	4.4.2	IS 10151	S	One	Once in 6 months	For food contact materials
xiii)	5	Overall migration	4.5	IS 10151	S	One	Once in 6 months	For food contact materials

ANNEXURE-I
TEST CERTIFICATE
TO BE ISSUED BY MANUFACTURING UNITS
ONLY

ABC LIMITED
(REGISTERED OFFICE ADDRESS AND WORKS
ADDRESS)CM/L-

TEST CERTIFICATE FOR POLYVINYL CHLORIDE HOMOPOLYMERS

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 17658:2021. Properties of the product as tested in accordance with Scheme of Inspection and Testing contained in the BIS Certification Marks Licence CM/LNo. _____are as indicated below against each order (PLEASE REFER TO IS 17658:2021 FOR DETAILS OF SPECIFICATION REQUIREMENTS)TEST RESULTS

Name and Type of material	Designation code	Net mass	Batch No./Lot No. and Month and year of manufacture	RVCM Content	K-Value	Sieve analysis	Apparent Density	Plasticizer Absorption	Dry flow of 140 g	Conductivity	Volatile matter	Inherent Viscosity	Pigments & Colourants(optional)	Migration of RVCM into foodstuffs(optional)	Overall Migration	Remarks

WAGON NO./TRUCK NO.

For ABC Company

TABLE 2
**RECORD OF REPACKING OF POLYETHYLENE
MATERIAL**

Sl. No.	Name of the manufacturing unit with licence no.	Particulars of test certificates received with C.U/Batch no.	Date of manufacture	Quantity received	Date of receipt	Date of repacking	Batch no.	Details of repacking		Total quantity repacked	Details of dispatch (date and customer details)
								Size of Packi ng	No.		
1	2	3	4	5	6	7	8	9	10	11	12