



उत्पाद मैनुअल
खाद्य पदार्थों, फर्मास्यूटिकलस और पेय जल के संपर्क में निरापद उपयोग के लिए पॉलीप्रोपाइलीन और
इसके कोपोलिमर के लिए विशिष्टि
IS 10910: 1984 के अनुसार

PRODUCT MANUAL FOR
SPECIFICATION FOR POLYPROPYLENE AND ITS COPOLYMERS FOR ITS SAFE USE IN
CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER
ACCORDING TO IS 10910: 1984

भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम 2018 की स्कीम-I के तहत यह उत्पाद मानुअल प्रमाणीकरण के प्रचलन में रीति और पारदर्शिता के सुसंगत सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों एवं लाइसेंस धारियों द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस लाइसेंस/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 10910 : 1984
	शीर्षक Title	:	Specification for Polypropylene and its Copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water - Specification
	संशोधनों की संख्या 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.3.1 of IS 10910:1984 ii) Material - Manufacturer may submit declaration/undertaking in compliance to the requirements of Cl. 3.2 of IS 10910:1984 ii) 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. 3.3 of IS 10910: 1984.

b)	समूहिकरण दिशा निर्देश Grouping Guidelines	:	Not applicable
c)	नमूने का आकार Sample Size	:	Approx 500 gm
3.	परीक्षण उपकरणों की सूची List of Test Equipment	:	Please refer Annex-A
4.	निरीक्षण व परीक्षण स्कीम Scheme of Inspection and Testing	:	Please refer Annex-B
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	Pigments and colourants (<i>if the manufacturer have in-house test facilities</i>)		
6.	लाइसेंस का दायरा /Scope of the Licence:		
	Licence is granted to use Standard Mark as per IS 10910 : 1984 with the following Scope :		
	Name of the product	Polypropylene 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
SPECIFICATION FOR POLYPROPYLENE AND ITS COPOLYMERS FOR ITS SAFE USE
IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER
ACCORDING TO IS 10910 : 1984

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. 4.3	<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 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
2	Overall migration, Cl. 4.4	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.

The list above is indicative only and may not be considered as exhaustive

ANNEX B
**SCHEME OF INSPECTION AND TESTING FOR
SPECIFICATION FOR POLYPROPYLENE AND ITS COPOLYMERS FOR ITS SAFE USE
IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER
ACCORDING TO IS 10910 : 1984**

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.

3.1 Packing and Marking shall be done as per the provisions of the Indian Standard. In addition, the following details shall be marked on each container/package :-

- a) BIS Licence No. CM/L -----.
- b) 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 10910:1984 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.

TABLE 1: 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 Clause Reference			No. of Sample	Frequency	Remarks
3.3	Pigments and colourants	-	IS 9833	S	01	Once in 6 months	For coloured materials only
3.4	Overall migration	-	IS 9845	S	01	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 POLYPROPYLENE 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 10910:1984

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 10910:1984 FOR DETAILS OF SPECIFICATION REQUIREMENTS)

TEST RESULTS

Name of product		
Batch Number/Lot Number and Month/year of manufacture		
Basic Resin		
Properties	Unit	Values
Overall migration		
Pigments and colourants (<i>optional</i>)		

REMARKS

WAGON NO./TRUCK NO.

For ABC Company

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