

**BUREAU OF INDIAN STANDARDS**  
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*Draft Indian Standard*

**POLYALKYLENE TEREPHTHALATE (PET AND PBT), THEIR COPOLYMERS  
AND LIST OF CONSTITUENTS IN RAW MATERIALS AND END PRODUCTS FOR  
THEIR SAFE USE IN CONTACT WITH FOODSTUFFS AND PHARMACEUTICALS**  
(Second Revision of IS 12252)

(ICS No. 97.200.50)

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Plastics Sectional Committee,  
PCD 12

Last date for receipt of comment is  
**20 May 2022**

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**FOREWORD**

(Formal clause will be added later)

Plastics are being used on a large scale for packaging of foodstuffs and pharmaceuticals. Where direct contact occurs between the packed commodity and the plastics, the high-molecular mass polymer itself does not pose a toxic hazard being inert and essentially insoluble in food. There is, however, a likelihood that some transfer of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization solvents and of low molecular mass polymer fractions will occur from the plastics into the packaged material with consequent toxic hazard to the consumers. The occurrence of acute toxicity due to plastics materials in contact with food is most unlikely, since only trace quantities of potentially toxic materials are likely to migrate.

Polyalkylene terephthalates (saturated polyesters) are amongst the thermoplastic materials extensively used world over for packaging of foodstuffs and pharmaceuticals.

Acetaldehyde is generated in small amount as a by-product during condensation and subsequent processing of the polymer. This standard does not prescribe limits of acetaldehyde content. However, for mineral water and colabased drinks, it is reported to be affecting their taste mildly after long storage. For such uses, if required, the limit of acetaldehyde content and test method shall be mutually agreed to between the purchaser and the supplier.

This standard is intended to be used with the series of Indian Standards on plastics for food contact application which is given in Annex A. It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as the fabricators of thermoplastic packaging materials to derive maximum benefits. Besides, it may also

serve as basis for official agencies to frame suitable legislation to ensure effective safe-guards for the safety and health of consumers where thermoplastics for food contact applications are concerned.

The list of raw materials mentioned in this standard is based on commonly used materials used by Indian industry which may not be exhaustive. While preparing this standard, assistance has also been taken from US FDA regulations, 21CFR 177.1630.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## 1 SCOPE

**1.1** This standard prescribes the positive list of constituents of polyalkylene terephthalates (PET and PBT), namely the polymers and necessary additives, which will be regarded as safe for use in contact with foodstuffs and pharmaceuticals, when properly processed and when present in the prescribed limits of concentration. This standard also prescribes the limits of residual catalysts.

**1.2** This standard also specifies the requirements and methods of sampling and test for polyalkylene terephthalates (PET and PBT) for the manufacture of plastic items used in contact with foodstuffs and pharmaceuticals.

**1.3** This standard does not purport to establish the suitability of the ingredients and packaging media with particular foodstuffs or pharmaceutical from other than toxicological considerations a by-product during condensation and subsequent processing of the polymer.

## 2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revisions, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

<i>IS No.</i>	<i>Title</i>
4905 : 2015 / ISO 24153 : 2009	Random sampling and randomization procedures ( <i>first revision</i> )
9833 : 2014	List of pigments and colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water ( <i>first revision</i> )
9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis ( <i>second revision</i> )

10146 : 1982	Specification for polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
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### 3 TERMINOLOGY

For the purpose of this standard, the following definitions shall apply:

**3.1 PET (Polyethylene Terephthalate)** — The basic material produced by the catalytic condensation at high temperature and reduced pressure of dimethyl terephthalate (DMT), terephthalic acid (PTA) and, if required, relatively small amounts of dimethyl isophthalate (DMI), isophthalic acid (IPA) with monoethylene glycol.

**3.2 PBT (Polybutylene Terephthalate)** — The basic material produced by the catalytic condensation at high temperature and reduced pressure of DMT/PTA (and, if required, relatively small amounts of DMI/IPA) with 1, 4-butanediol.

### 4 REQUIREMENTS

#### 4.1 Basic Material

Thermoplastic (saturated) polyesters are condensation products of dimethylterephthalate (DMT)/terephthalic acid (PTA) and diols such as monoethylene glycol/ 1, 4-butanediol as prescribed in the positive list. To comply with this standard, the thermoplastic (saturated) polyester defined in **3.1** and **3.2** shall be made in such a way that they contain no ingredients or residues of ingredients other than those listed in **4.2** to **4.7**.

#### 4.2 Basic Raw Materials

The following basic raw materials may be used:

- a) Monoethylene glycol (MEG)
- b) 1, 4-Butanediol (BDO)
- c) Dimethyl terephthalate (DMT)
- d) Dimethyl isophthalate (DMI)
- e) Terephthalic acid (PTA)
- f) Isophthalic acid (IPA)

**4.2.1** The polymer shall contain at least 50 percent of units derived from PTA.

**4.2.2** To the thermoplastic polyesters made from the above raw materials, polyethylene up to 5 percent by mass conforming to IS 10146 may also be added. Ethylene terephthalate-isophthalate component of the thermoplastic polyesters shall not exceed 25 percent by mass.

#### 4.3 Crystallization Accelerators

The following crystallization accelerators may be present with maximum limits prescribed against each:

- a) Talc, free of asbestos: 0.25 percent by mass, *Max*
- b) Sodium benzoate: 0.25 percent by mass, *Max*
- c) Clay, calcined

#### 4.4 Auxiliary Items for Working

The following auxiliary items may be present with limits prescribed against each:

- a) Calcium stearate and Zinc stearate, together 0.5 percent by mass, *Max*
- b) Silica
- c) Paraffin wax
- d) Synthetic paraffin, 0.25 percent by mass, *Max*
- e) *iso*-butyl stearate, 0.2 percent by mass, *Max*
- f) Even numbered, saturated, aliphatic primary alcohols of the chain length C<sub>12</sub> to C<sub>20</sub>, 0.05 percent by mass, *Max*
- g) Low molecular polyolefins, 0.5 percent by weight, *Max* in combination with silicon oil 0.3 percent by mass, *Max* (mould release parting agent)
- h) Pentaerythrite ester of saturated even numbered aliphatic monocarbonic acids of the chain length C<sub>14</sub> to C<sub>22</sub>, 1.0 percent by mass, *Max*
- j) Pentaerythritol
- k) 1, 4-Cyclohexane dimethanol
- m) Phosphoric acid
- n) 2-Methyl-1,3-propanediol (MPdiol)
- p) Isosorbide
- q) Penta spiro glycol (PSG)
- r) Naphthalene dicarboxylic acid (NDA)
- s) Zinc orthophosphate (ZOP)
- t) Tricalcium phosphate (TCP)
- u) Nylon MXD-6 resin (MXD6)

NOTE — Amorphous Hydrogenated Carbon (AHC) is used for coating in PET/PBT containers either through dry or wet process to enhance barrier properties with maximum thickness of 0.15 µ.

#### 4.5 Residual Catalysts

Residues of oxides of antimony, calcium, gallium, germanium, cobalt, lithium, manganese, zinc and titanium may be present with limits as prescribed against each:

- a) Antimony : 300 mg/kg, *Max*
- b) Calcium : 100 mg/kg, *Max*
- c) Cobalt : 125 mg/kg, *Max*
- d) Gallium : 20 mg/kg, *Max*
- e) Germanium : 100 mg/kg, *Max*

- f) Lithium : 130 mg/kg, *Max*
- g) Manganese : 80 mg/kg, *Max*
- h) Tin : 30 mg/kg, *Max*
- j) Titanium : 120 mg/kg, *Max*
- k) Zinc : 80 mg/kg, *Max*

#### **4.6 Specific Migration Limits**

Polyalkylene terephthalates (PET and PBT) shall comply with Table 1 when tested as per Annex C.

#### **4.7 Pigments and Colorants**

In case, if coloured material is used, it shall comply with the list and limits of pigments and colourants prescribed in IS 9833.

#### **4.8 Overall Migration**

The material shall comply with the overall migration limits of 60 mg/l, *Max* of simulant and 10 mg/dm<sup>2</sup>, *Max* of the surface of the material or article when tested in accordance with IS 9845.

#### **4.9 Storage and Control**

##### **4.9.1 Storage**

Plastic materials intended for food contact use shall be stored separately from other materials in closed, properly identified containers.

##### **4.9.2 Control**

An authorized person shall supervise and control the issue of plastics material to the process or manufacturing area and shall maintain appropriate written records of the issue of such materials.

**4.9.3** Adequate standards of hygiene shall be maintained at all times and plant operators and storemen shall be trained in proper hygiene practices.

**Table 1 List of Authorized Monomers, other Starting Substances, Macromolecules Obtained from Microbial Fermentation, Additives and Polymer Production Aids**  
(Clause 3.6)

Sl No.	CAS No.	Substance Name	Use as Additive or Polymer Production Aid (yes/no)	Use as Monomer or Other Starting Substance or Macromolecule Obtained from Microbial Fermentation (yes/no)	Fat Reduction Factor (FRF) Applicable (yes/no)	Specific Migration Limit (SML) [mg/kg]	Restrictions and Specifications
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
i)	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	yes	no	no	0.05	
ii)	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	Yes	no	no	0.05	
iii)	0000088-68-6	2-aminobenzamide	Yes	no	No	0.05	Only for use in PET for water and beverages
iv)	0064365-11-3	charcoal, activated	Yes	no	no		Only for use at maximum 10 mg/kg of polymer.

							Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC with exception of ash content which can be up to 10 percent w/w).
v)	0132459-54-2	N,N'-bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-Naphthalene tetracarboxy diimide	no	Yes	no	0.05	Purity > 98.1 percent (w/w). Only to be used as co-monomer (Maximum 4 percent).
vi)	0143925-92-2	amines, bis (hydrogenated tallow alkyl) oxidized	Yes	no	no		Not to be used for articles in contact with fatty foods for which simulant D [Ethanol 50 percent (v/v)/Vegetable oil]. Only to be used at 0.25 percent (w/w) concentration.
vii)	—	titanium nitride, nanoparticles	yes	no	no		No migration of titanium nitride nanoparticles. Only to be used in PET

							bottles up to 20 mg/kg. In the PET, the agglomerates have a diameter of 100 – 500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.
viii)	0852282-89-4	N-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione	Yes	No	yes	0.05	
ix)	0124578-12-7	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	Yes	No	no		Only to be used up to 0.1 percent (w/w). Prepared by the reaction of poly(12-hydroxystearic acid) with polyethylenimine.



## 5 PACKING AND MARKING

### 5.1 Packing

The material shall be packed in gunny/paper bags with suitable liner, as agreed to between the purchaser and the supplier, in a manner so as to ensure that the items do not become contaminated during storage. It shall be securely sealed to prevent any ingress of moisture.

### 5.2 Marking

**5.2.1** Each package shall be clearly marked with the following information:

- a) Manufacturer's name and/or trademark, if any;
- b) Name and type of material;
- c) Month and year of manufacture;
- d) Net mass of the material;
- e) Lot and batch number; and
- f) Any other statutory requirement.

**5.2.2** The packages shall also carry the symbol as given in Fig. 1 clearly embossed/printed on it.



FIG. 1 SYMBOL

### 5.2.3 *BIS Certification Marking*

**5.2.3.1** The product may also be marked with the Standard Mark.

**5.2.3.2** The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards *Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

## 6 SAMPLING

### 6.1 Preparation of Test Samples

The method of drawing representative sample of the material and the criteria for conformity shall be as prescribed in Annex B.

**ANNEX A**  
(Foreword)  
(Informative)

**LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER**

<i>IS No.</i>	<i>Title</i>
9833 : 2018	List of pigments and colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water ( <i>first revision</i> )
9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis ( <i>second revision</i> )
10142 : 1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification ( <i>first revision</i> )
10146 : 1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10148 : 1982	Positive list of constituents of polyvinyl chloride and its copolymers for safe use in contact with foodstuffs, pharmaceuticals and drinking water
10149 : 1982	Positive list of constituent of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water
10151 : 2019	Polyvinyl Chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
10171 : 1999	Guide on suitability of plastics for food packaging ( <i>second revision</i> )
10910 : 1984	Specification for polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11434 : 1985	Specification for ionomer resins for its safe use in contact with foodstuffs, pharmaceutical and drinking water
11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11704 : 1986	Specification for Ethylene acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
11705 : 1986	Positive list of constituents of ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12247 : 1988	Specification for Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12248 : 1988	Positive list of constituents of Nylon- 6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
13449 : 1992	Positive list of constituents of ethylene vinyl acetate (EVA) copolymers in contact with foodstuffs, pharmaceuticals and drinking water
13576 : 1992	Ethylene methacrylic acid (EMAA) copolymers and terpolymers for their safe use contact with foodstuffs, pharmaceuticals and drinking water

13577 : 1992	Positive list of constituents of ethylene methacrylic acid (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water
13601 : 1993	Ethylene vinyl acetate (EVA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14971 : 2001	Polycarbonate resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water
14996 : 2001	Positive list of constituents of modified poly(phenylene oxide) (PPO) in contact with foodstuffs, pharmaceuticals and drinking water
14997 : 2001	Modified poly (phenylene oxide) (PPO) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
14998 : 2001	Positive list of constituents of melamine-formaldehyde resins in contact with foodstuffs, pharmaceuticals and drinking water
14999 : 2001	Melamine-formaldehyde resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
IS 16738 : 2018	Positive list of constituents for polypropylene, polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals

**ANNEX B**  
(Clause 6.1)

**SAMPLING OF POLYALKYLENE TEREPHTHALATES (PET AND PBT)**

**B-1 GENERAL**

**B-1.1** In drawing, preparing, storing and handling samples, the following precautions and directions shall be observed.

**B-1.2** Samples shall not be taken in an exposed place.

**B-1.3** The sampling instrument, where applicable shall be made of stainless steel or any other suitable material on which the material shall have no action. The instrument shall be clean and dry.

**B-1.4** Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

**B-1.5** The samples shall be placed in a suitable, clean, dry, air-tight metal or glass containers on which the material has no action. The sample containers shall be of such a size that they are almost completely filled by the sample.

**B-1.6** Each sample container shall be sealed air-tight with a stopper after filling and marked with full details of sampling, such as the date of sampling, the month and year of manufacture of the material etc.

**B-1.7** Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

## **B-2 SCALE OF SAMPLING**

### **B-2.1 Lot**

In a single consignment, all the packages of the same class, same type, same form and belonging to the same batch of manufacture shall be grouped together to constitute a lot. If a consignment is known to consist of packages belonging to different batches of manufacture of different forms, the packages belonging to the same batch of manufacture and same form shall be grouped together and each such group shall constitute a lot.

**B-2.1.1** The packages may consist of container of polyalkylene terephthalate (PET/PBT) chips and its roll, films or vials.

**B-2.2** For ascertaining the conformity of the material to the requirements of this standard, sample shall be tested from each lot separately. The number of packages to be sampled shall depend on the size of the lot and shall be in accordance with column 1 and 2 of Table 2.

**B-2.2.1** These packages shall be selected at random from the lot and in order to ensure the randomness of selection, procedures given in IS 4905 may be followed.

**Table 2 Scale of Sampling**  
(Clause B-2.2)

<b>Sl No.</b>	<b>No. of Packages in Lot</b>	<b>Sample Size</b>
(1)	(2)	(3)
i.	Up to 50	3
ii.	51 to 150	4
iii.	151 to 300	5
iv.	301 to 500	7
v.	501 and above	10

## **B-3 PREPARATION OF TEST SAMPLES**

**B-3.1** From each of the packages of material selected, small portions of material shall be drawn with the help of a suitable sampling instrument. The total quantity of material collected from each package shall be sufficient to test all the requirements given in 4.

**B-3.2** In the case of packages consisting of containers, vials, rolls, or films, the number of items to be selected from a package, for testing each of the requirements given in **4**, shall be one.

#### **B-4 NUMBER OF TESTS**

**B-4.1** Test for determining all the requirements given in **4** shall be carried out on the individual test samples.

#### **B-5 CRITERIA FOR CONFORMITY**

**B-5.1** From the individual test results, the average ( $\bar{x}$ ) and the range ( $R$ ) shall be calculated as follows:

$$\bar{x} = \frac{\text{sum of the test results}}{\text{Number of tests}}$$

$R$  = difference between the maximum and the minimum values of the test results.

The lot shall be declared as conforming to the requirement of various characteristics if:

$\bar{x} + KR \leq$  the maximum value specified; and where the value of  $K$  shall be chosen from as given below:

**Value of  $K$  for Various Sample Size and AQL**

Sample Size \ AQL	0.65	1.00	1.50	2.50	4.00
	3	—	—	—	0.587
4	—	0.651	0.598	0.525	0.450
5	0.663	0.614	0.565	0.498	0.431
7	0.613	0.596	0.525	0.465	0.405
10	0.755	0.703	0.650	0.579	0.507

#### **ANNEX C** (Clause 4.6)

#### **SPECIFIC MIGRATION ANALYSIS FOR POLYALKYLENE TEREPHTHALATE (PET & PBT)**

##### **C-1 GENERAL**

The specific migration is determined by exposing a food contact material or article to a chemical food simulant for a specified and appropriate length of time, after which the content of the specific substance in food or food simulant is determined by appropriate analytical methods.

## C-2 MIGRANTS

**C-2.1 Monomers** — PET polymer was made by the condensation reaction mechanism of ethylene glycol with either terephthalic acid, Isophthalic acid or dimethyl terephthalate (several researchers showed that these monomers may migrate into the food).

**C-2.2 Catalyst** — PET polymer synthesized using Antimony trioxide ( $Sb_2O_3$ ) catalyst is employed mainly due to its high efficiency, for minimal side reactions. Antimony trioxide also facilitates a role to impart clarity to PET articles. It is known that the residual antimony gets entrapped or bonded in the PET matrix and may leach into food simulants.

**C-2.3 Other Potential Specific Migrants** — Trace amounts of acetaldehyde, and other aldehydes, are unavoidable by-products in the production of PET bottles. Modern manufacturing practices in the PET industry are used to minimize the formation of aldehydes. In addition, Phthalate esters were also found leaching from PET polymer shown in some literature. For examples phthalate esters such as dibutyl phthalate (DBP), diethyl phthalate (DEP) and di(2-ethylhexyl) phthalate (DEHP), have been detected in PET bottled water.

**Table 3 List of specific migrants from PET polymer**

<i>Substance</i>	<i>Function</i>	<i>Analytical Instruments</i>
Mono- and diethylene glycol (including the ester of stearic acid with ethylene glycol)	Monomer	GC, GC-MS, HPLC, LC/MS
Terephthalic acid	Monomer	GC, GC-MS, HPLC, LC/MS
Isophthalic acid	Monomer	GC, GC-MS, HPLC, LC/MS
Antimony trioxide	Catalyst	ICP-OES, ICP-MS
2-Aminobenzamide (anthranilamide)	Acetaldehyde scavenger	GC, GC-MS, HPLC, LC/MS
Acetaldehyde	Upon heat exposure	GC, GC-MS, HPLC, LC/MS
Formaldehyde	Upon heat exposure	GC, GC-MS, HPLC, LC/MS
Barium	Other Heavy metal contaminants	ICP-OES, ICP-MS
Cobalt	Other Heavy metal contaminants	ICP-OES, ICP-MS
Copper	Other Heavy metal contaminants	ICP-OES, ICP-MS
Iron	Other Heavy metal contaminants	ICP-OES, ICP-MS
Lithium	Other Heavy metal contaminants	ICP-OES, ICP-MS

Manganese	Other Heavy metal contaminants	ICP-OES, ICP-MS
Zinc	Other Heavy metal contaminants	ICP-OES, ICP-MS

NOTE — The heavy metals that are prescribed as per Food Safety and Standards (Packaging) Regulation, 2018.

**Table 4 Food simulants**

<i>Food simulant</i>	<i>Code</i>	<i>Type of food</i>
Ethanol 10 percent (v/v)	Food simulant A	Aqueous, non-acidic foods (pH > 5) without fat
Acetic acid 3 percent (w/v)	Food simulant B	Aqueous, acidic foods (pH < 5) without fat
Ethanol 20 percent (v/v)	Food simulant C	Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 percent and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.
Ethanol 50 percent (v/v)	Food simulant D1	Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 percent and for oil in water emulsions.
n-Heptane	Food simulant D2	Oils, fats and processed dry foods with surface fat or volatile oil
poly (2,6-diphenyl-p-phenyleneoxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E	Specific migration for Dry foods

**Table 5 Experimental Conditions**

<i>Type Food (simulant)</i>	<i>Ethanol 10 percent (v/v)</i>	<i>Acetic acid 3 percent (w/v)</i>	<i>Ethanol 20 percent (v/v)</i>	<i>Ethanol 50 percent (v/v)</i>	<i>n-Heptane</i>
Room temperature filled and stored also in refrigerated and frozen conditions	40°C / 10 days	40°C / 10 days	40°C / 10 days	40°C / 10 days	38°C/ for 30 minutes
Hot filled or pasteurized Below 66°C	60°C / 10 days	60°C / 10 days	60°C / 10 days	60°C / 10 days	38°C/ for 30 minutes

## **C-3 METHOD FOR DETERMINATION OF SPECIFIC MIGRATION**

### **C-3.1 Sampling**

Finished articles of each lot or subplot which is to be examined shall be sampled separately. Triplicate samples representing from lot or batch have to be selected for analysis.

### **C-3.2 Apparatus**

**C-3.2.1 Electrical hot-air oven**, equipped with thermostat with an accuracy of  $\pm 1$  °C.

**C-3.2.2 Electric hot plate**, with temperature control.

**C-3.2.3 Weighing balance**, accuracy 0.1 mg.

**C-3.2.4 Analytical equipment's**: GC, GC/MS, HPLC, LC/MS or UPLC, ICP and ICP-MS (for metals).

**C-3.2.5 Glass beakers**, 1000ml volume approximately.

**C-3.2.6 Micro pipets**, to prepare standard solutions.

**C-3.2.7** Instrument detection limit should be 0.001mg/kg.

### **C-3.3 Preparation of Test Specimen**

The PET bottles/containers/pouches used shall be carefully rinsed with water to remove inessential materials prior to the actual migration test.

### **C-3.4 Sample Exposure to Food Simulants**

The sample used for analysis should be measured to the nearest surface area of 1000 cm<sup>2</sup> and the simulant quantity should be 1 ml/cm<sup>2</sup>.

### **C-3.5 Determination amount of specific migrants**

#### **C-3.5.1 *Exposure of food simulants***

The rinsed test sample should be used to expose with food simulant (as per the food applications used for) at a particular time and temperature accordingly mentioned in Table 5. After exposure to food simulant at different storage conditions, the samples must be removed and the simulant should be used for extracting specific migrants.

#### **C-3.5.2 *Analysis of specific migrants***

The exposed food simulant shall be used to extract specific migrants for the analysis. For this, a known volume of exposed food simulant shall be taken into a beaker and can be treated with a suitable solvent for the extraction of specific migrants. The extracted specific migrants should be analysed with a suitable analytical instrument. The analytical method should be validated by considering parameters such as system suitability, linearity, and recovery. Further, the limit of Detection (LOD) and limit of quantification (LOQ) for the analytical method should be mentioned



clearly. The results will be calculated and the amount of extractives will be mentioned in mg/kg or mg/l or ppm of the PET articles concerning the simulant quantity should be 1 ml/cm<sup>2</sup>.

### **C-3.5.3** *Colour migration*

In the case of coloured plastic materials, if the colour migrated is visible, such materials are not suitable for food contact applications, even though the extractive value is within the limit (*see IS 9833*).

## **C-4 EVALUATION OF RESULTS**

The PET bottle/containers/films used in the migration tests for each simulant used, the average of at least three results does not exceed the value of specific migration limit specified in the SML limits in Table 1.