उत्पाद मानुयल
प्लास्टिक की द्रुध पिलाने की बोतलें
IS 14625: 2015 के अनुसार

Product Manual for
PLASTICS FEEDING BOTTLES
ACCORDING TO IS 14625:2015

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 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.	मानक संख्या **IS No.**	:	IS 14625 :2015
	शीर्षक **Title**	:	PLASTICS FEEDING BOTTLES — Specification
	संशोधनों की संख्या **No. of amendments**	:	05
2.	नमूना दिशानिर्देश **Sampling Guidelines**		
a)	कच्चा माल **Raw material**	:	a) For material used for plastics feeding bottles excluding teats, each consignment to be accompanied with test certificates as per Cl. 4.1 and 4.2 b) In case the applicant uses/intends to use ISI Marked teats as per IS 3565, the manufacturer may submit a consent letter from the BIS licensed manufacturer, that he has agreed to supply ISI Marked teats to the applicant firm. In that case test reports from third party labs need not be submitted. The letter from BIS licensed manufacturer shall not be older than 90 days on the date of submission of application. However, if the teats are not ISI-marked, each consignment of teats, to be accompanied with test certificates conforming to IS 3565 or third-party lab test report conforming to IS 3565. c) For printing inks, each consignment to be accompanied with

			declaration/undertaking from the supplier in compliance to IS 15495. 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**	:	Please see Annex – A
c)	**नमूने का परिमाण** **Sample Quantity**	:	60 bottles 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**	:	Material 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 –B
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer Annex - C
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	a) Wall thickness (Cl. 5.1.3) b) Capacity (Cl. 5.1.4) c) Transparency (Cl. 5.3.2) d) Leakage Test (Cl. 5.3.3) e) Drop Test (Cl. 5.3.4) f) Compressive Deformation Resistance (Cl. 5.3.6) 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 14625 : 2015 with the following scope:		
	Name of the product	Plastics Feeding Bottles	
	Material	Polypropyelene (PP) / Polyethersulfone (PES) / any other olefin-based polymer/ co-polymer or any other raw material (*as per Annex –A of IS 14625:2015*)	

ANNEX A

GROUPING GUIDELINES

1. The manufacturer shall declare the type of material of Plastics Feeding Bottles which they intend to cover in the scope of licence as per provisions of Cl. 4.1 of IS 14625:2015. The sample of each type to be drawn and shall be subjected to testing for considering grant of licence/inclusion of that type.

2. The manufacturer shall submit the drawing of all the sizes of Plastic Feeding Bottles and declare the minimum wall thickness for sizes to be included in the scope of licence.

3. Sample (of requisite quantity) of plastic feeding bottles made from each type of material (PP/PES any other olefin-based polymer/ co-polymer or any other raw material as per Annex –A of IS 14625:2015), shall be drawn and subjected to testing for considering grant of licence/inclusion of that type of material.

4. It shall be ensured that the firm is having all the necessary manufacturing and testing facilities for the types to be included in the licence.

5. During the operation of licence, BO shall ensure that all the types of Plastics Feeding Bottles covered in the scope of license are drawn for independent testing on rotation basis over a period of time.

ANNEX – B
LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr. No.	Tests used in with Clause Reference	Test equipment
1.	Bisphenol A (BPA) (Cl. 4.4)	Water (grade 1), Acid (hydrochloric acid or sulfuric acid), Acetone, 4-(1,1,3,3-Tetramethylbutyl)phenol, 4-(1,1,3,3-Tetramethylbutyl)phenol monoethoxylate, 4-(1,1,3,3-Tetramethylbutyl)phenol diethoxylate, 4-(3,6-Dimethyl-3-heptyl)phenol, 4-(3,6-Dimethyl-3-heptyl) phenol monoethoxylate, 4-(3,6-Dimethyl-3-heptyl) phenol diethoxylate, Bisphenol-A, 2,2,2-Trifluoro-N-methyl-N-(trimethylsilyl)acetamide (MSTFA), Solid-phase material, on styrene-divinylbenzene polymer basis, Sand(e.g. sea sand, acid washed and calcinated for analysis, particle size 0.1 mm to 0.3 mm), Nitrogen(N_2), Sodium thiosulfate pentahydrate($Na_2S_2O_3 \cdot 5H_2O$) Narrow-neck flat bottomed glass bottles, Solid-phase extraction cartridges, of inert non-leaching plastic, Vacuum or pressure assembly, ne-mark volumetric flasks, Quartz wool, Pear-shaped flask, Evaporation assembly, Vials, brown glass with PTFE-lined septa, capacity e.g. 1.5 ml, according to the autosampler. Stainless steel cocks, with stainless steel cone. Gas chromatograph
2.	Wall Thickness (Cl. 5.1.3)	Micrometer/screw gauge, fitted with ball point tips or dial caliper gauge fitted with spherical anvils giving an accuracy of measurement of 0.02 mm Cutting Tools
3.	Capacity (Cl. 5.1.4)	Beakers and Measuring Cylinders
4.	Permanency of Pigment [Cl. 5.1.4.2 a)]	Sodium Bicarbonate, Conc. Sulphuric Acid, Analytical Balance and Glass ware
5.	Migration of Certain Elements (Cl. 5.2.1)	**Apparatus/Reagents for Migration of elements** • Water bath, able to maintain the temperature of the test mixture at 37 ± 2 oC and having the means to agitate the test mixture. • pH meter, with an accuracy of ±0.2 pH units • Membrane filter, with a pore size of 0.45 µm • Centrifuge, capable of centrifuging at 5 000 ± 500 rpm. • Analytical Balance • Hydrochloric acid and other chemicals and laboratory reagents

		Apparatus/Reagents for determination of quantity of migrated elements Inductively coupled plasma optical emission Spectrophotometer (ICP-OES) along with necessary laboratory apparatus and reagents as per IS 3025 (Part 2):2019 OR, Atomic Absorption Spectrophotometer and associated apparatus and reagents as per IS 15303 (Antimony and Selenium), IS 3025 (Part 37) – (Arsenic), IS 3025 (Part 48) – Mercury, IS 3025 (Part 41)- (Cadmium), IS 3025 (Part 47) – (Lead), and IS 1699 – (Barium)
6.	Environmental Stress-Crack Resistance (Cl. 5.3.1)	Circulating Air Oven capable of housing at least 15 containers and providing temperature of at least 60±1°C, Conditioning chamber capable of conditioning at least 15 containers at a temperature of 27±2°C and 65±5% RH, Any environmental stress cracking reagent, Heat sealing equipment, closures, Plastic bags, rubber band/seal/tape etc
7.	Transparency (Cl. 5.3.2)	Integration ball type light transmittance measurement apparatus as per Annex C or Apparatus as per ASTM 1003
8.	Leakage Test (Cl 5.3.3)	Blotting paper, Closures
9.	Drop Test (Cl 5.3.4)	Flat horizontal surface of steel or smooth concrete
10.	Ageing Resistance (Cl. 5.3.5)	Boiling water and ice water arrangement
11.	Compressive Deformation Resistance (Cl.5.3.6)	Compression Jig with 2 kgf load Room Thermometer with LC 1°C
12.	Product Resistance of Printed Containers (Cl 5.3.7)	Simulant: Distilled water (to simulate the product) Arrangement to heat the samples to 40±2°C , thermometer Cold Water/Hard tissue paper
13.	Migration Test (Cl.5.3.8)	Simulants: n-heptane and distilled water, Oven/water bath/ pressure cooker/autoclave, Electric hot plate with temperature control regulator, Water Bath/Electrical Oven with digital Temp controller (0-150 °C, LC 0.1 °C), Stainless steel evaporating dish of 100 ml capacity, stainless steel tongs(SS pins), Dessicators, Analytical Balance (LC 0.1 mg), Pyrex Beakers and other laboratory glassware and reagents
14.	Specific Migration (Cl. 5.3.9)	Water, complying with grade 1, Nitric acid, Hydrogen peroxide, Sulfuric acid, Hydrochloric acid, Ammonium sulfate, Element stock solutions of Ba, Co, Cu, Fe, Li, Mn, Sb, Radiofrequency generator, Mass-flow controller, Nebulizer, Ultrasonic nebulizer, Inductively coupled plasma optical emission spectrometer, Argon gas supply, General labware, Storage bottles, Acid dispensers, Filtration equipment,

ANNEX- C

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: Plastic feeding bottles of same nominal capacity and of same material manufactured from the same consignment of raw material in a day/shift (if production is in more than one shift in a day) shall constitute one control unit.

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 each plastics feeding bottle and its packaging along with the other marking details as required by the standard, 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**: Additionally, the following shall also be marked on product or package:

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

4. REJECTION - 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

(*Recommended Levels of Control by BIS- for Guidance Only*))

(1)				(2)		
Test Details				**Levels of Control**		
Cl.	**Requirement**	**Test Method**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
4.3 and 4.4	Bisphenol A (BPA)		ISO 18857-2 or EN 13130-13	One	Once in every six months or whenever there is change in raw material, whichever is earlier	
5	**REQUIREMENTS**					
5.1	**Physical Requirements**					See Note 1
5.1.1	Description	5.1.1	-do-	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
5.1.2	Manufacture, Workmanship, Finish and Appearance	5.1.2	-do-	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
5.1.3	Wall Thickness	4.5	IS 2798	One	Each hour	
				1% of bottles in each consignment	Each consignment	
5.1.4.1	Brimful Capacity	5.1.4.1	IS 14625	One	Each hour	
				1% of bottles in each consignment	Each consignment	
5.1.4.2	Capacity Scale	5.1.4.2	IS 14625	One	Each hour	
				1% of bottles in each consignment	Each consignment	

5.1.4.2	Permanency of pigment	Annex B	IS 14625	Three	Every seventh control unit	For bottles with printed scale/ graduations
5.2	**Chemical Requirements**					
5.2.1	Migration of Certain Elements	5.2.1	IS 14625			
i)	Arsenic		IS 3025 (Part 37 /IS 3025 (Part 2)	One	Every 3 months	
ii)	Chromium		IS 3025 (Part 52 IS 3025 (Part 2)	-do-	-do-	
iii)	Mercury		IS 3025 (Part 48 IS 3025 (Part 2)	-do-	-do-	
iv)	Cadmium		IS 3025 (Part 4 IS 3025 (Part 2)	-do-	-do-	
v)	Lead		IS 3025 (Part 4 IS 3025 (Part 2)	-do-	-do-	
vi)	Barium		IS 1699/ IS 3025 (Part 2)	-do-	-do-	
vii)	Selenium		IS 15303/ IS 3025 (Part 56 IS 3025 (Part 2)	-do-	-do-	
5.3	**Performance Requirements**					
5.3.1	Environmental Stress-Crack Resistance	Method 1	IS 8747	Five	Every 7th control unit	
5.3.2	Transparency	Annex C	IS 14625	Three	Once in two months for each type of material (PP/PES etc.)or for each consignment whichever is earlier	
5.3.3	Leakage Test	5.3.3	-do-	Ten	Each control unit	
5.3.4	Drop Test	Annex D	-do-	Three	Each control unit	
5.3.5	Ageing Resistance	5.3.5	-do-	Three	Every third control unit	

5.3.6	Compressive Deformation Resistance	Annex E	-do-	-do-	-do-	
5.3.7	Product Resistance of Printed Containers	14	IS 2798	-do-	-do-	
5.3.8	Migration Test		IS 9845	One	Every third control unit with nheptane as stimulants	
				One	Once in a fortnight with Distilled water as stimulant	
5.3.9	Determination of Specific Migration	5.3.9	IS 14625			
i)	Barium		IS 3025 (Part 2)	One	Every 3 months	
ii)	Cobalt		IS 3025 (Part 2)	-do-	-do-	
iii)	Copper		IS 3025 (Part 2)	-do-	-do-	
iv)	Iron		IS 3025 (Part 2)	-do-	-do-	
v)	Lithium		IS 3025 (Part 2)	-do-	-do-	
vi)	Manganese		IS 3025 (Part 2)	-do-	-do-	
vii)	Zinc		IS 3025 (Part 2)	-do-	-do-	
viii)	Antimony		IS 3025 (Part 2)	-do-	-do-	
ix)	Phthalic Acid, bis (2-ethylexyl) ester (DEHP)		ISO 18856	-do-	-do-	

Note-1: Physical requirements shall be checked either hourly or consignment wise or control unit wise against a drawing incorporating material, design, wall thickness, shape and capacity for each capacity which shall be prepared & endorsed by both purchaser and manufacturer.