



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

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

भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम 2018 की स्कीम-I के तहत यह उत्पाद मानुयल प्रमाणीकरणके प्रचलन में रीति और पारदर्शिता के सुसंगत 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 14625 :2015
	शीर्षक Title	:	प्लास्टिक की दूध पिलाने की बोतलें Plastics Feeding Bottles
	संशोधन संख्या No. of Amendments	:	04
2.	नमूनाकरण दिशा निर्देश 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.
b)	समूहिकरण दिशा निर्देश Grouping guidelines	: कृपया Annex-A देखें Please see Annex – A
c)	नमूनेका परिमाण Sample Size	: 60 bottles
3.	परीक्षण उपकरणों की सूची List of Test Equipment	: कृपया Annex-B देखें Please see Annex – B
4.	निरीक्षण व परीक्षण स्कीम Scheme of Inspection and Testing	: कृपया Annex-C देखें Please see 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)	
6.	लाइसेंस का कार्यक्षेत्र / Scope of the Licence:	
	IS 14625: 2015 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेंस निम्नलिखित कार्यक्षेत्रके लिए प्रदान किया जाता है Licence is granted to use Standard Mark as per IS 14625: 2015 with the following scope:	
	उत्पाद का नाम Name of the product	प्लास्टिक की दूध पिलाने की बोतलें Plastics Feeding Bottles
	Material	Polypropylene (PP) / Polyethersulfone (PES) / any other olefin-based polymer/ co-polymer or any other raw material (as per Annex –A of IS 14625:2015)

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ANNEX A
TO THE PRODUCT MANUAL FOR
PLASTICS FEEDING BOTTLES AS PER IS 14625:2015
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. In case it is also intended to cover ECO-Mark, the sample(s) shall conform to the additional requirements for ECO-Mark as given in Annex-G of IS 14625:2015.
6. 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
TO THE PRODUCT MANUAL FOR
PLASTICS FEEDING BOTTLES AS PER IS 14625:2015
List of test equipment

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(N₂), Sodium thiosulfate pentahydrate(Na₂ S₂O₃ · 5H₂O) 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 $60\pm1^{\circ}\text{C}$, Conditioning chamber capable of conditioning at least 15 containers at a temperature of $27\pm2^{\circ}\text{C}$ and $65\pm5\%$ 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 $40\pm2^{\circ}\text{C}$, 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 ($0-150^{\circ}\text{C}$, 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,

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

ANNEX- C
TO THE PRODUCT MANUAL FOR
PLASTICS FEEDING BOTTLES AS PER IS 14625:2015
Scheme of Inspection And Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare and implement a calibration plan for the test equipments.

2. TEST RECORDS – 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 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. Packing and Marking shall be done as per the provisions of the Indian Standard.

3.1 The information as mentioned under clause 7.2.1 of IS 14625:2015 shall be legibly and indelibly marked on each package. In addition, the following shall be incorporated on each bottle and each package:

a) BIS License Number CM/L—and

b) BIS website details i.e. — “ For details of BIS certification please visit www.bis.gov.in”. *

**In case of space constraints, (b) may be marked only on the package*

4. CONTROL UNIT – For the purpose of this scheme, 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.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. REJECTIONS – 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)

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	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	S	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 3
5.1.1	Description	5.1.1	-do-	R	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-	R	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	R	One	Each hour	
					1% of bottles in each consignment	Each consignment	
5.1.4.1	Brimful Capacity	5.1.4.1	IS 14625	R	One	Each hour	
					1% of bottles in each consignment	Each consignment	
5.1.4.2	Capacity Scale	5.1.4.2	IS 14625	R	One	Each hour	
					1% of bottles in each	Each consignment	

					consignment		
5.1.4.2	Permanency of pigment	Annex B	IS 14625	R	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)	S	One	Every 3 months	
ii)	Chromium		IS 3025 (Part 52 /IS 3025 (Part 2)	S	-do-	-do-	
iii)	Mercury		IS 3025 (Part 48 /IS 3025 (Part 2)	S	-do-	-do-	
iv)	Cadmium		IS 3025 (Part 4 /IS 3025 (Part 2)	S	-do-	-do-	
v)	Lead		IS 3025 (Part 4 /IS 3025 (Part 2)	S	-do-	-do-	
vi)	Barium		IS 1699/ IS 3025 (Part 2)	S	-do-	-do-	
vii)	Selenium		IS 15303/ IS 3025 (Part 56 /IS 3025 (Part 2)	S	-do-	-do-	
5.3	Performance Requirements						
5.3.1	Environmental Stress-Crack Resistance	Method 1	IS 8747	S	Five	Every 7 th control unit	
5.3.2	Transparency	Annex C	IS 14625	S	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-	R	Ten	Each control unit	
5.3.4	Drop Test	Annex D	-do-	R	Three	Each control unit	
5.3.5	Ageing Resistance	5.3.5	-do-	R	Three	Every third	

						control unit	
5.3.6	Compressive Deformation Resistance	Annex E	-do-	R	-do-	-do-	
5.3.7	Product Resistance of Printed Containers	14	IS 2798	R	-do-	-do-	
5.3.8	Migration Test		IS 9845	S	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)	S	One	Every 3 months	
ii)	Cobalt		IS 3025 (Part 2)	S	-do-	-do-	
iii)	Copper		IS 3025 (Part 2)	S	-do-	-do-	
iv)	Iron		IS 3025 (Part 2)	S	-do-	-do-	
v)	Lithium		IS 3025 (Part 2)	S	-do-	-do-	
vi)	Manganese		IS 3025 (Part 2)	S	-do-	-do-	
vii)	Zinc		IS 3025 (Part 2)	S	-do-	-do-	
viii)	Antimony		IS 3025 (Part 2)	S	-do-	-do-	
ix)	Phthalic Acid, bis (2-ethylexyl) ester (DEHP)		ISO 18856	S	-do-	-do-	

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 empaneled 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.

Note-3: 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.