



उत्पाद मानुयल
बोटल से दूध पिलाने के लिए निपल – विशिष्ट
IS 3565 : 2018 के अनुसार

**Product Manual For
Teats for Feeding Bottles - Specification
According to IS 3565 : 2018**

भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम की स्कीम-I के तहत यह उत्पाद मानुयल प्रमाणीकरण के 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 3565 : 2018
	शीर्षक Title	:	बोटल से दूध पिलाने के लिए निपल - विशिष्ट Teats for Feeding Bottles - Specification
	संशोधनों की संख्या No. of Amendments	:	एक 01
2.	नमूनाकरण दिशा निर्देश Sampling Guidelines:		
a)	कच्चा माल Raw material	:	कृपया Annex-A देखें Please refer ANNEX –A

b)	समूहीकरण दिशानिर्देश Grouping guidelines	:	Teats for feeding bottles of each type i.e. Type 1 (made out of Natural rubber) and Type 2 (made out of Silicone rubber) shall be subjected to testing for considering grant of licence/inclusion of teats of that type.
c)	नमूने का परिमाण Sample Size	:	<u>50 nos</u>
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:		
	Workmanship and finish- Clause 5.2.1		
	Shape and Size- Clause 5.2.2		
	Resistance to autoclaving- Clause 5.2.3		
	Water Extract (pH, Colour, Turbidity and odour)- Clause 5.3.1 and Table 1		
	Ash Content- Clause 5.3.1 and Table 1		
6.	लाइसेन्स का कार्यक्षेत्र / Scope of the Licence:		
	IS 3565 : 2018 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है Licence is granted to use Standard Mark as per IS 3565 : 2018 with the following scope:		
	Name of the product	:	Teats for feeding bottles
	Grade Designation	:	Type 1 (Teats made out of natural rubber) and/or Type 2 (Teats made out of silicone rubber)

ANNEX A

Raw Materials

1. The teats shall be made out of natural rubber or silicone rubber, together with necessary compounding and vulcanizing ingredients. In case of natural rubber, solid rubber or latex may be used.
2. Teats shall be free from grits, reclaimed rubber or vulcanized waste. The rubber/silicone mix shall not include any ingredient known to be injurious or poisonous to human beings.
3. All ingredients used in the manufacture of teats shall be free from harmful substances liable to extraction by contact with milk/liquid food or which may cause development of undesirable odour, taste or discolouration. Softeners, organic accelerators, vulcanizing agents and antioxidants, if incorporated shall not impart any undesirable odour or taste to the finished teats.

ANNEX-B
List of Test Equipments
For Teats for Feeding Bottles- Specification
According to IS 3565 : 2018

Major test equipment required to test as per the Indian Standard

Sl. No.	Test Equipment	Tests used in with Clause Reference
1	- Autoclave, capable of being maintained at $121 \pm 2^\circ\text{C}$ and at 0.1 MPa. - Hot Air Oven, capable of being maintained at $105 \pm 2^\circ\text{C}$.	Resistance to autoclaving, clause 5.2.3
2	- Buffer solution, pH 7.0 - Beaker 500ml - Beaker 100ml - Watch Glass, of suitable diameter to cover the 500 ml beaker - Separating funnel, 500ml - Distilled water - pH meter, equipped with glass electrode and calomel electrode capable of directly reading pH, with an accuracy of ± 0.05 pH	Water extract, Clause 5.3.1, Table 1, Sl. No. (i)
3	Acetone Extractable Matter - - Weighing balance, to weigh accurately to 0.1 mg - Soxhlet Extraction Assembly, attached round bottom flask shall be of capacity about 50 cm³ above that of the extraction cup. Typically, extraction cup maybe 50 cm³ and round bottom flask be 100 cm³ in capacity. - Water Bath, with temperature control of $\pm 2^\circ\text{C}$. - Hot Air Oven, capable of being maintained at $70 \pm 5^\circ\text{C}$. - Desicator, capacity suitable for keeping the round bottom flask of soxhlet extraction assembly Free Sulphur From Acetone Extractable Matter in Rubber teats- - Bromine Water — Saturated aqueous solution. - Nitric Acid — Specific gravity 1.50. - Zinc Oxide-Nitric Acid Solution - Potassium Chlorate, Crystals. - Picric Acid — Saturated aqueous solution. - Barium Chloride, aqueous solution, 100 g/litre. - Hydrochloric Acid, specific gravity 1.18. - Silver Nitrate — 1 percent aqueous solution. - Water Bath - Hot Plate - Silica Crucible, with lid, capacity 80 ml.	Acetone Extract, Clause 5.3.1, Table 1, Sl. No. (ii)

	• Muffle Furnace, capable of heating up to 1 000°C, having temperature sensing device accurate to 25°C. • Desiccator • Watch Glass • Whatman No.1 filter paper • Whatman No. 42 or 542 filter paper	
4	• Platinum or Silica Dish, having a capacity of 100 ml. • Muffle Furnace, capable of heating upto 1 000 °C and having temperature sensing device accurate to ± 25 °C. • Bunsen Burner • Desiccator • Weighing scale • Watch Glass	Ash Content, Clause 5.3.1, Table 1, Sl. No. (iii)
5	• Weighing Balance, with accuracy of 1 mg • Hot Air Oven, which can be heated to at least 110 °C and having an accuracy of ± 2 °C. • Desiccator • Suitable dish to hold sample	Volatile components, Clause 5.3.1, Table 1, Sl. No. (iv)
6	• Standard Laboratory Glasswares • Centrifuge, with 15ml capacity tubes and minimum speed of 3000 rpm. • Centrifuge, with 50ml capacity tubes and minimum speed of 3000 rpm. • Vortex Mixture • Spectrophotometer, for measurement of colour at 750 nm. • Weighing scale • Whatman no 1 (or equivalent) filter paper Reagents: • Trichloro Acetic Acid — 35 percent w/v aqueous solution. • Phospho Tungstic Acid — 40 percent w/v aqueous solution. • Sodium Hydroxide, 0.1 M. • Sodium Hydroxide, 0.25 M. • Reagent A, 6 percent sodium carbonate in 0.2M sodium hydroxide. • Reagent B, 1.5 percent copper sulphate in 3 percent sodium citrate. • Reagent C, 50 ml reagent A mixed with 1 ml reagent B. • Folin Reagent — 3 Parts of phenol folin and 1 part of water. • Bovine Serum Albumin • Distilled water	Extractable Protein content, Clause 5.3.1, Table 1, Sl. No. (v)

7	Antimony – Chemicals and equipments as per IS 15303 Arsenic - Chemicals and equipments as per IS 3025 (Part 37) Chromium - Chemicals and equipments as per IS 3025 (Part 52) Mercury - Chemicals and equipments as per IS 3025 (Part 48) Cadmium - Chemicals and equipments as per IS 3025 (Part 41) Lead - Chemicals and equipments as per IS 3025 (Part 47) Barium - Chemicals and equipments as per IS 1699 Selenium - Chemicals and equipments as per IS 15303/IS 3025 (Part 56)	Migration of Heavy metals, Clause 5.3.3 and Table 3
8	Reagents: • Sodium Hydrogen Carbonate • Sodium Chloride • Potassium Carbonate • Sodium Nitrite • Hydrochloric Acid Solution- 0.1M • Sodium Hydroxide Solution- 0.1M • Artificial Saliva Salt Solution • Dichloromethane • Kieselguhr, from Liquid-Liquid Extraction (surface 1 m²/g, pore size 3 000 nm to 8 500 nm, particle size 150 µm to 650 µm); heated to 200°C for 1 h, cooled and washed with dichloromethane. • n-Hexane • Hydrochloric Acid Solution- 0.1M • Sodium Hydroxide Solution – 1M • Purified Nitrogen • Anti Bumping Granules • Sintered Glass Frits for Columns • Acetone, or other suitable solvent • Standard solutions of N-Nitrosamines • Internal standard solution of N-Nitrodiisopropylamine (NDiPA), free from other N-Nitrosamines, 200 ng/ml in the acetone or other suitable solvent. • Anhydrous Sodium Sulphate, (granular) or suitable Whatman phase separating filter • Ammonia Solution- 0.1M • Sand, Acid washed and calcined Apparatus • Normal Laboratory Apparatus • Oven- maintained at a temperature of 40 ± 2 °C • Glass Column, with outlet and polytetrafluoroethylene (PTFE) stopper; column length approximately 300 mm, internal diameter approximately 26 mm. • Glass Column with Outlet and PTFE Stopper, column length approximately 300mm, internal diameter approximately 15 mm. • Kuderna - Danish (K-D) Evaporative Flask and Concentrator, modified with a graduated collecting vessel and an air cooler with	N-Nitrosoamines and N-Nitrosatables as per clause 5.3.4 and Annex G

	a floating or expansion sphere. • Water Bath, capable of maintaining temperatures in the range 40°C to 60°C. • Ampoules, weltd-edged and capable of being closed with flanged rings and PTFE-coated septa (to ensure that the septa are free from N-Nitrosamines). • Sealing Tongs for the Ampoules • Glass Wool, Washed with the Dichloromethane • Separating Funnel, 100 ml and 200ml • Chemiluminescence Detector, of adequate sensitivity (Thermal Energy Analyzer) • Gas Chromatograph (GC)	
	• HPLC with a 20 µl injection loop diode array detector connected to an integrator or personal computer with chromatography software. • HPLC-column capable of separating MBT from the antioxidants and fully resolving the antioxidants such that the peaks do not overlap by more than 1 percent peak area with each other and with interferences arising from other sample ingredients. Reagents: Chemicals (analytical reagent grade unless otherwise specified): • Water, HPLC Grade • Acetonitrile, HPLC Grade • Distilled water • Dichloromethane, Residue analysis grade. • Anhydrous Sodium Sulphate • Acetic Acid, 3 percent (w/v) aqueous solution Reagents – Authentic Samples (purity greater than 98%) • 2-mercaptobenzothiazole (MBT) • 2,6 bis (1,1-dimethylethyl)-4- methyl-phenol (Antioxidant BHT) • 2,2'-methylenebis [6-(1,1-demethylethyl)-4-methyl-phenol] (Antioxidant 2246) Reagents- Standard Solutions • Standard MBT Solution • Standard Antioxidants Solution	Determination of MBT as per clause 5.3.5 and Annex H and Determination of Anti Oxidants as per clause 5.3.6 and Annex H
	Humidity Chamber Hot plate Water conforming to IS 1070 Grade 3 Tear tester conforming to Annex K of IS 3565 Tensile Tester conforming to Annex L of IS 3565	Tear Resistance Test, Clause 5.4.2 and Annex K Tensile Test, Clause 5.4.3 and Annex L

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

ANNEX C
SCHEME OF INSPECTION AND TESTING
TEATS FOR FEEDING BOTTLES - SPECIFICATION
ACCORDING TO IS 3565 : 2018

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 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 marked on the packages of the product, provided always that material to which this mark is thus applied, conform to every requirement of the specification.

3.1 Marking – Each package or leaflet placed inside the product and/or the external packaging material shall be legibly marked to give the information as per clause 6.2 of IS 3565. In addition, the following details shall be marked on each package legibly and indelibly:

a) BIS Licence No. CM/L..... and

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

3.2 Packing – Each teat shall be packed in polythene and further packed as agreed to between the manufacturer and buyer and shall include clear legible instructions for the use and hygienic care of the product.

4. CONTROL UNIT – For the purpose of this scheme, Teats for feeding bottles of same Type 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
(Para 5.0 of the 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				
5.1	Material	5.1	IS 3565	S	One	Each Consignment	Shall be accompanied with test certificate.
5.2.1	Workmanship and finish	5.2.1	IS 3565	R	One	Each Hour of production	
5.2.2	Shape and Size	5.2.2	IS 3565	R	One	Each Hour of production	
5.2.3	Resistance to Autoclaving	Annex A	IS 3565	R	One	Each Control Unit	
5.3.1	Water Extract	Annex B	IS 3565	R	One	Each Control Unit	
5.3.1	Acetone Extract	Annex C	IS 3565	R	One	Once in 7 days	Also when there is any change in source of raw material or nature of raw material or change in formulation.
5.3.1	Ash Content	Annex D	IS 3565	R	One	Each Control Unit	
5.3.1	Volatile Component	Annex E	IS 3565	R	One	Each Control Unit	
5.3.1	Extractable Protein Content	Annex F	IS 3565	R	One	Once in 7 days	Also when there is any change in source of raw material or nature of raw material or change in formulation.
5.3.3	Migration of heavy metals	Table 3	IS 3565	S	One	Once in 3 months	Also when there is any change in source of raw material or nature of raw material or change in formulation.

5.3.4	N Nitrosoamines and N-Nitrosatables	Annex G	IS 3565	S	One	Once in 3 months	Also when there is any change in source of raw material or nature of raw material or change in formulation.
5.3.5	Determination of MBT	Annex H	IS 3565	S	One	Once in 3 months	Also when there is any change in source of raw material or nature of raw material or change in formulation.
5.3.6	Determination of Antioxidants	Annex H	IS 3565	S	One	Once in 3 months	Also when there is any change in source of raw material or nature of raw material or change in formulation.
5.4.2	Tear Resistance Test	Annex K	IS 3565	R	One	Once in 7 days	
5.4.3	Tensile Test	Annex L	IS 3565	R	One	Once in 7 days	

Note-1: Whether test equipment is required or subcontracting 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.