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उत्पाद मैन्युअल
कांच के प्रायोगिक उपकरण - बोतलें
भाग 1 स्क्रू नेक बोतलें
IS 1388 Part 1: 2019 के अनुसार

PRODUCT MANUAL FOR
LABORATORY GLASS WARE — BOTTLES
PART 1 SCREW NECK BOTTLES — SPECIFICATION
ACCORDING TO IS 1388 (Part 1): 2019

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 uniformity 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.

1.	मानक संख्या **IS No.**	:	IS 1388 (Part 1): 2019
	शीर्षक **Title**	:	Laboratory Glass Ware — Bottles Part 1 Screw Neck Bottles
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	नमूना दिशानिर्देश **Sampling Guidelines**		
a)	कच्चा माल **Raw material**	:	(i) Bottles shall be constructed of clear, colourless or amber borosilicate glass 3.3 in accordance with ISO 3585. (ii) Bottles shall be provided with closures of a suitable inert plastics material, e.g. polypropylene 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 refer Annex – A

c)	**नमूने का परिमाण** **Sample Quantity**	:	5 Nos. 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**	:	1. Nominal Capacity 2. Plastic Coating 3. Colour 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 to Annex – B
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer to Annex - C
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	All tests 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:**		
	IS 1388 (Part 1): 2019 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेंस निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है "Licence is granted to use Standard Mark as per IS 1388 (Part 1) : 2019 with the following scope:		
	उत्पाद का नाम **Name of the product**	Laboratory Glass Ware — Bottles Part 1 Screw Neck Bottles	
	Nominal Capacity	25 ml, 50 ml, 100 ml, 150 ml, 250 ml, 500 ml and 750 ml, 1 l, 2 l, 3.5 l, 5 l, 10 l, 15 l and 20 l	
	Plastic Coating	With/Without	

ANNEX – A

Grouping Guidelines

1. IS 1388 (Part 1) : 2019 for LABORATORY GLASS WARE — BOTTLES, SCREW NECK BOTTLES, states the following

   a) Nominal Capacity: The nominal capacities of the SCREW NECK BOTTLES as given in the IS are:

   25 ml, 50 ml, 100 ml, 150 ml, 250 ml, 500 ml and 750 ml

   1 l, 2 l, 3,5 l, 5 l, 10 l, 15 l and 20 l.

   b) Plastic Coating: The IS provides that the outer glass surface of the bottles may be coated with a suitable plastics material which shall be resistant to steam sterilization at 135 °C

2. For the purpose of inclusion of capacity in the scope of Licence, the following group of capacities shall be considered

   a) GROUP 1- Capacity less than 1 litre, i.e., 25 ml, 50 ml, 100 ml , 150 ml, 250 ml, 500 ml and 750 ml

   b) GROUP 2- Capacity more than 1 litre i.e., 1 l, 2 l , 3.5 l, 5 l, 10 l, 15 l and 20 l.

3. The highest and lowest nominal capacity of Laboratory Glassware – Screw Neck Bottle from each of the above group shall be tested to include all the nominal capacities of Screw Neck Bottle in the GROUP in the scope of License.

4. If the manufacturer intends to cover the Screw Neck Bottles with Plastic Coating on the outer surface, separate sample of Screw Neck Bottles with Plastic Coating of any nominal capacity from each of the above groups shall be tested to cover the plastic coating aspect for all the capacities in the Group. If Screw Neck Bottles with Plastic Coating is tested, the Screw Neck Bottles without Plastic Coating may be covered in the Scope of License for all the nominal capacities in the Group.

5. The Firm shall declare the varieties of Laboratory glassware – Screw Neck Bottles intended to be covered in the License. It shall also be ensured that the firm is having all the necessary manufacturing and testing facilities for the manufacture and testing of the varieties to be covered in the licence.

6. During the operation of the License, BO shall ensure that all the varieties covered in the Licence are tested in rotation.

ANNEX– B

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Nominal Capacity, Cl 3	Weighing Balance (L.C 0.1 mg for 100 ml ≤ *Volume* ≤ 10 ml, 1.0 mg for 10 ml < *Volume* ≤ 1 000 ml, and 10 mg for *Volume* > 1 000 ml) Distilled Water Receiving Vessels Thermometer Arrangement for Measurement of Pressure
2	Dimension, Cl 4	Steel Scale/Height Gauge Micrometer Vernier Calipers
3	Construction, Cl 5.1.2	Hot and Cold Water Bath Oven
4	Design, Cl 5.2	Flat Surface Radius Gauge
5	Resistance to steam sterilization	Autoclave (Applicable for the bottles coated with a suitable plastics material as a protection and to limit leakage of liquid if the bottle is damaged).
6	AC	General Lab Conditioning

ANNEX C

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan 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 defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

For the guidance of manufacturers, the recommended definition of control unit is: All Screw Neck Bottles of same variety (capacity and plastic coating, if done) and design manufactured under similar conditions from same raw material in a day.

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.2 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. Alternatively,the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirementsof the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is givenbelow. Column 2 of Table 1 indicates routine tests where test equipment is required in house as “R” or other tests which can be subcontracted as “S”. Subcontracting is permitted to BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as perIS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as “R” in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilitiesor get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least withtest facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different testsgiven in the specification shall be carried out in accordance with the method given in the specification**.** They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 **TEST RECORDS**- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratoryor any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be 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 Laboratory Glassware-Screw Neck Bottle, 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**: The Screw Neck Bottle or its packaging shall also be marked with the following additional requirement

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

4. REJECTION - All 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

(ONLY FOR GUIDANCE PURPOSE)

(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**				
3	**Capacity**						
3.1	Capacity	-		**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		
4	Dimension	-	IS 1388 (Part 1)	**R**			
5	**Construction**						
5.1.1 & 5.1.2	Material	-	IS 1388 (Part 1)	**-**	-	Each Consignment	No testing is required in case, Test Certificate is received with each consignment
5.2	**Design**						
5.2.1, 5.2.2	Base	-	IS 1388 (Part 1)	**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		
5.2.3	Shoulder	-	IS 1388 (Part 1)	**R**			
5.2.5	vall thickness		IS 1388 (Part 1)	**R**			
5.2.6	Neck	-	IS 1388 (Part 1)	**R**			
5.2.7	lastic Coating	-	IS 1388 (Part 1)	**R**			

5.2.7 5.3	Resistance to steam sterilization	-	IS 1388 (Part 1)	**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		If applicable
	Closures	-	IS 1388 (Part 1)	**R**	One	Each Control unit	
					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		