उत्पाद मैन्युअल

मानक संख्या 19084: 2024 के अनुसार

PRODUCT MANUAL FOR
Plastic Containers and Closures for Homoeopathic Pharmaceutical Preparations — Specification
ACCORDING TO IS 19084: 2024

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 underScheme-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 19084 :2024
	शीर्षक **Title**	:	Plastic Containers and Closures for Homoeopathic Pharmaceutical Preparations
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	कच्चा माल **Raw material**	:	Manufacturer to submit test report/ test certificate in compliance to Clause 4.1 of IS 19084 :2024
b)	समूहीकरण दिशानिर्देश **Grouping Guidelines**	:	Please refer Annex– A
c)	नमूने का परिमाण **Sample Quantity**	:	100 Pcs

d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**		Name of the Product: Material: Container Type: Nominal capacity: Wall Thickness:
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, except test as per cl.4.7, 5.1, 5.5, 5.6		
6.	**लाइसेंस का दायरा /Scope of the Licence:**		
	"License is granted to use Standard Mark as per IS 19084:2024 with the following scope:		
	Name of the product		Plastic Containers and Closures for Homoeopathic Pharmaceutical Preparations
	Material		HDPE/PET/PP
	Container Type		Phial/Bottle (Screw neck or drop-dispensing plastic bottle; Wide-mouth plastic bottle.)/Jar
	Nominal capacity		In dram/ Ounce/ ml

ANNEX-A
GROUPING GUIDELINES

1. The sample of each type of material (HDPE/PET/PP) and each type of container (Phial/Bottle/Jar) shall be subjected to testing for considering grant of licence/inclusion of that type. However, sample of the highest nominal capacity of each type of material and each type of container may be subjected to testing for considering grant of licence/inclusion of that material and type of container, for all pack sizes.

2. Further, test requirement for capacity (as per Clause 4.3.1 of IS 19084:2024) may be ensured through in-house test report for all pack sizes, to be considered under the scope of licence.

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

4. During the operation of licence, BO shall ensure that all the nominal capacities of Plastic containers/phials for dispensing of homoeopathic medicine covered in the license are drawn for independent testing on rotation over a period of time.

5. Scope of licence shall be restricted based on the manufacturing and testing facilities available.

Annex– B

List of Test Equipment

(INDICATIVE LIST, FOR GUIDANCE ONLY)

S.No	Tests used in with Clause Reference	Test equipment
	Capacity	- Suitable plastic disc to cover the neck face of the container - Suitable weighing balance to an accuracy of 0.1g - Equipment to maintain temperature 27±2°C (or) Suitable measuring cylinders
	Wall Thickness	Ball ended micrometer or dial caliper gauge fitted with spherical anvils, to an accuracy of 0.02mm
	Transparency	integration ball type light transmittance measurement device as described in IS 15410
	Leakage Test	Closure leakage test -Blotting paper -Stop watch Vibration Leakage Test Device /methods as per IS 2798 Air Pressure Leakage Test Device /methods as per IS 2798
	Drop Test	- Equipment as per Cl.8.2 of IS 2798 - Scale to measure a height of 0.5m/1.0m/1.2m
	Migration Test	- Electric oven/Water bath equipped with temperature controller to maintain desired temperature up to ±1°C accuracy - Electric hot plate with temperature control regulator - Weighing balance with a sensitivity of 0.1mg □ Beaker - Evaporating Dish - Suitable scale /caliper to measure dimensions
	Collapsibility Test	- Flow measuring setup or manual squeezing arrangement to evaluate discharge (for squeeze bottles)
	Verticality Test	- Assembly for Testing Verticality, as per cl.7 of IS 2798

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 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: All the containers of the same type of material, same design/shape manufactured 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. Manufacturers have the discretion of declaring their own levels of control or accepting 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. 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 recognized/empaneled 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 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 container provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per clause 6 & 7 of the Indian Standard

3.2 Additional Marking requirements: The material shall also be marked with the following additional requirement on each consumer pack of Plastic containers/Phials for dispensing of Homoeopathic Medicine.

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

4. REJECTION - 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 samples	Frequency	Remarks
		Cl.	Reference			
4.1	Material	4.1	IS 19084	One	Every consignment	No further testing is required, if accompanied with test certificate or ISI marked
4.2	Pigments and Colorants	4.2	IS 19084	One	Every consignment	
4.3	Capacity	4.3	IS 19084	Firm to have adequate in-process controls to ensure compliance to this parameter of the Indian Standard and appropriate records shall be maintained for evidence of conformity.		
4.3.2	Brim-full capacity		IS 2798			
4.4	Design, Shape and Dimension	4.4	IS 19084			
4.5	Odour	4.5	IS 19084	One	Each Control Unit	
4.6	Mass	4.6	IS 19084	One	Each Control Unit	
4.7	Overall Migration		IS 9845	One	Once in 6 months	
4.8	Wall Thickness	4.5	IS 2798	One	Each Control Unit	
4.9	Workmanship and Finish	4.9	IS 19084	Firm to have adequate in-process controls to ensure compliance to this parameter of the Indian Standard and appropriate records shall be maintained for evidence of conformity.		
5	PERFORMANCE TESTS					
5.1	Environmental Stress – Crack Resistance	Method I	IS 8747	One	Once in 6 months	
5.2	Leakage Test	6	IS 2798	One	Each Control Unit	
5.3	Drop Impact Test	8	IS 2798	One	Each Control Unit	
5.4	Collapsibility Test	5.4	IS 19084	One	Each Control Unit	
5.5	Compatibility Test	12	IS 2798	One	Once in 6 months	
5.6	Container Material Test	4.3	IS 7803	One	Each Control Unit	
5.7	Verticality test	7	IS 2798	One	Each Control Unit	
5.8	Transparency	Annex A	IS 15410	One	Each Control Unit	
5.9	Stack Load Test	9	IS 2798	One	Once in 6 months	