उत्पाद मैन्युअल
आई एस/आई एस ओ 3826-1 : 2019 के अनुसार
मानव रक्त और रक्त घटकों के लिए प्लास्टिक के संकोच्य कंटेनर भाग 1 परम्परागत कंटेनर (पहला पुनरीक्षण)के लिए
दस्तावेज़ संख्या – पीएम/आईएस/आई एस ओ 3826-1/1/ मार्च 2023

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR
Plastic Collapsible Containers for Human Blood and Blood Components
Part 1 Conventional Containers (First Revision)
ACCORDING TO IS/ISO 3826-1 : 2019

Document No - PM/IS/ISO 3826-1/1/March 2023

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.

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, ९, बहादुर शाह ज़फ़र मार्ग
Manak Bhawan, 9, Bahadur Shah Zafar Marg
नई दिल्ली- ११०००२
New Delhi – 110002

PRODUCT MANUAL FOR

Plastic Collapsible Containers for Human Blood and Blood Components Part 1 Conventional Containers (First Revision)

ACCORDING TO

IS/ISO 3826-1 : 2019

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.	**Product**	:	IS/ISO 3826-1 : 2019
	Title	:	Plastic Collapsible Containers for Human Blood and Blood Components Part 1 Conventional Containers (First Revision)
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Plastic Material – Polyolefins/PVC Containing plasticizersAnti-Coagulant /Preservative Solution
b)	**Grouping guidelines**	:	Please refer **ANNEX – A**
c)	**Sample Size**	:	1 Unit 50 plastic collapsible containers (for all test except test for Cl. 6.4.3 'Biological requirements – compatibility') 30 plastic collapsible containers (only for Cl. 6.4.3 'Biological requirements – compatibility')
d)	**Sampling for surveillance**		One MS and one FS. Sample to be drawn from Dispatch point for MS for all test other than Cl. 6.4.3 'Biological requirements – compatibility'. All test other than Cl. 6.4.3 'Biological requirements – compatibility' to be carried out on FS. Test for Cl. 6.4.3 'Biological requirements – compatibility' to be carried out once in 5 years on FS.
3.	**List of Test Equipment**	:	Please refer **ANNEX – B**

4.	**Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**Possible tests in a day**	:	Please refer **ANNEX – D**
6.	**Scope of the License**	:	As per below table

Scope of Licence

"Licence is granted to use Standard Mark as per IS/ISO 3826-1 : 2019 with the following scope:"	
Name of the product:	Single Use Plastic Collapsible Containers for Human Blood and Blood Components
Type:	Single Use Conventional Plastic Collapsible sterile containers, non-vented type, with collecting tube outlets port(s) and integrated needle and without an integrated filter
No. of units:	Single/Double/Triple/Quadruple/multiple units [1]
Anticoagulant /Preservative solution	With or without anticoagulant and/or preservative solution
Nominal Capacity (ml):	100/250/400/500/600/ other Nominal Capacity [2]
Other relevant aspects may also be mentioned in the scope.	

1 – Combination of units of each variety being considered for Grant of Licence to be indicated in the scope of licence.
2 - Each nominal capacity being considered for Grant of Licence is to be indicated in the scope of licence.

ANNEX A

Grouping Guidelines

1. The parameters as given below shall be considered for grouping of Collapsible Containers for Human Blood and Blood Components as per IS/ISO 3826 -1 :2019.
   a) Single/Double/Triple/Quadruple/multiple units
   b) With or without anticoagulant /preservative solution
   c) Nominal capacity upto 600ml

2. Considering the above, the following groups have been evolved for GoL/CSoL:
   - If sample of multiple units is tested, then varieties with combination of lower number of units may be covered in the scope of licence.
     e.g. In case variety of penta containers are tested then varieties of Single/ Double/ Triple/ Quadruple containers units may be considered for grant of licence without further testing.
   - If sample with anticoagulant /preservative solution is tested, then sample without anticoagulant /preservative solution may also be covered in the scope of licence.
   - If sample with higher nominal capacity is tested, then other lower nominal capacities for which manufacturing capability is available by the manufacturer may also be covered in the scope of the licence.
   - The above relaxations apply only when the Plastic Material for Containers remain unchanged.

3. The nominal capacity of the plastic container and dimensions are to be declared by the manufacturer.

4. The firm shall submit the details (including name and complete address) of the supplier from which Plastic Material for Containers is sourced at the time of Grant of Licence along with the test certificate of relevant Indian Standard. Inclusion of new variety may be considered based on factory test report as long as the source and quality of Plastic Material for Containers remain unchanged. In case of any change in the supplier and /or change in the quality of the Plastic Material for Containers, the same shall be communicated to BIS and relevant test including 'Biological requirements - Compatibility (Cl. 6.4.3) to be carried out before manufacturing the product with new Plastic Material.

5. The Firm shall declare the varieties of Plastic Collapsible Containers for Human Blood and Blood Components they intend to cover in the scope of licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer

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

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Dimensions (Clause 4)	• Vernier Caliper • Thickness Gauge /micrometer
2	Design (Clause 5)	• Bonding Strength Equipment • Measuring Cylinder • Emptying under pressure tester, BT Tester • Rate of Collection tester • Pull test weight, BT tester • Stand for suspension • Vernier Caliper • Thickness Gauge/micrometer • Stop watch
3	Sterilization (Clause 6.2.2)	• Incubators • Laminar flow • Autoclave • Hot Air oven • Membrane filtration unit • Vacuum Pump • Bunsen Burner
4	Transparency (Clause 6.2.3)	• Hexamethylenetetramie • Hydrazine sulphate • Glass containers • Cuvette with internal light path of 1 cm
5	Thermal Stability (6.2.5)	• Deep freezer (4°C+/-2°C) • Water Bath
6	Water Vapour Transmission (6.2.6)	• Cooling chamber/refrigerator capable of maintaining temperature of 4°C+/-2°C

		(with provision to maintain specific gas exchange rate for oxygen and carbon dioxide if applicable) • Weighing Balance • Distilled Water • Beaker
7	Resistance to leakage (6.2.7)	• Refrigerated Centrifuge • Leakage Tester
8	Particulate Contamination (6.2.8)	• Purified Water • Membrane filter of pore diameter 0.2micron • Liquid particle counter
9	Residue on ignition (6.3.1)	• Weighing Balance LC -.01 mg • Hot Air Oven (100 to 200 degree) • Muffle Furnace • Desiccator
10	Test Fluid 6.3.2 Oxidizable Constituents	• Saturated Steam • Hot air oven • Pottasium Permaginate Solution 0.002 mol/l • Sulphuric Acid 1 mol/l • Potassium Iodide • Thiosulphate Solution .01 mol/l • Distilled Water • Conical Flask • Burette • Pipette • Beaker • Dropper • Standard Flask, Dilute Nitric Acid • Bellow • Weighing Balance LC .1 mg
11	Ammonia (Clause 6.3.2)	• Caustic Soda • Distilled Water • Nessler's Reagent • Ammonium Stranded Solution • Beaker • Pipette • Bellow, Weighing Balance
12	Chloride Ions (Clause 6.3.2)	• Silver Nitrate Solution

		• Dilute Nitric Acid • Chloride Stranded Solution
13	Heavy Metal Analysis (Clause 6.3.2)	• U V Visible spectrometer • HCL Solution • Or Thioacetamide reagent • Ammonium Acetate Buffer • Lead Acetate Solution • Beaker • Pipette • Bellow, Weighing Balance LC .1 mg
14	Acidity and Alkalinity (Clause 6.3.2)	• Phenolphthalein Solution • Caustic soda • Hydrochloric Acid • Methyl Red Solution • Beaker • Pipette • Bellow, Weighing Balance LC .1mg
15	Determination of Evaporation Residue (Clause 6.3.2)	• Water Bath • Weighing Balance • Beaker, • Pipette
16	Opalescence (Clause 6.3.2)	• Colour Comparison Tube • Stranded Flask • Pipette • Bellow • Opalescent Solution • Hexamethyl Sulphate • Distilled Water • Weighing Balance LC-0.1 mg
17	UV Absorbance (Clause 6,3.2)	• UV Visible Spectrometer • Cuvette • Beaker • Blank Solution
18	Extractable plasticizer (clause 6.3.2)	• Specific gravity bottle • Spectrometer • Cuvette • Beaker

		• Pipette • Bellow • Standard Flask, • glass rod • Weighing Balance LC-.1 mg • Ethanol • DEHP • Distilled Water
19	Impermeability for microorganisms	• Autoclave • Laminar air flow • Test Fluid 1(Polar extractant) • Test Fluid II (Non-Polar Extractant) • Cultural Medium- e.g. casein pepton - soyabean flour peptonebouillon and seal • Incubator • Challenge organism eg Bacillius atropheus, NCTC 10073
20	Biocompatibility tests (Table C1)	• As per ISO 10993 part -4, part -5, part -11, part -10, relevant pharmacopeia as applicable
21	Anti-coagulant /preservative solution if applicable (National Pharmacopoeia- IP)	• Ion chromatography system • Flame photometer • pH meter, Oven • Water bath

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

ANNEX C

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 a calibration plan for the test equipment's.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING - As per the requirement of IS/ISO 3826-1 : 2019. In addition, details of BIS website shall be marked as follows: "For details of BIS certification please visit www.bis.gov.in "

4. CONTROL UNIT – For the purpose of this scheme, the entire quantity of plastic collapsible containers for human blood and blood components of same type, with same anticoagulant and/or preservative solutions and same size made from same raw material and sterilized together in a single day shall be considered as one control unit.

4.1 The licencee shall maintain in records the details (including name and complete address) of the supplier from which the Plastic Material for Containers is sourced along with the test certificate of consignment received. In case of any change in the supplier and /or change in the quality of the Plastic Material for Containers, the same shall be communicated to BIS and relevant test including 'Biological requirements - Compatibility (cl. 6.4.3) shall be carried out before manufacturing the product with new Plastic Material for Containers.

Note: Raw material of same type received from same supplier shall be considered as same raw material.

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 whichis 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

(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	Dimensions	4	IS/ISO 3826-1	R	1	Each Control Unit	
5	Design	5.1	IS/ISO 3826-1, ISO 1135-4 or ISO 1134-5	R	1	Each Control Unit	
5	Air content	5.2	IS/ISO 3826-1	R	1	Each Control unit	
5	Emptying Under Pressure	5.3	IS/ISO 3826-1	R	1	Each Control Unit	
5	Rate of Collection	5.5	IS/ISO 3826-1 Annex B-B2	R	1	Each Control Unit	
5	Collection and Transfer Tube	5.6	IS/ISO 3826-1	R	1	Each Control Unit	
5	Blood Taking Needle	5.7	IS/ISO 3826-1	R	1	Each Control Unit	
5	Outlet Ports	5.8	IS/ISO 3826-1	R	1	Each Control Unit	
5	Suspension	5.9	IS/ISO 3826-1	R	1	Each control Unit	
6	Sterilization	6.2.2	IS/ISO 3826-1	R	20	Each Control unit	
6	Transparency	6.2.3	IS/ISO 3826-1 Annex B -B1	R	1	Each Control unit	
6	Coloration	6.2.4	IS/ISO 3826-1	R	1	Each Control unit	
6	Thermal Stability	6.2.5	IS/ISO 3826-1	R	4	Each Control unit	

6	Water Vapour Transmission	6.2.6	IS/ISO 3826 -1	S	1	Once in 3 months	Refer Note 1
6	Resistance toleakage	6.2.7	IS/ISO 3826-1	R	8	Each Control unit	
6	Particulate Contamination	6.2.8	IS/ISO 3826-1 Annex A	R	1	Each Control unit	
6	Requirements of raw container/sheeting - Residue on Ignition	6.3.1	IS/ISO 3826-1 Annex A.2	R	1	Each Control unit	Refer Note 2
6	Requirement for the test fluid -chemical limits on extract from plastic containers	6.3.2	IS/ISO 3826-1	R	1	Each Control unit	Refer Note 2
6	Oxidizable Constituents	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.1	R	1	Each Control unit	Refer Note 2
6	Ammonia	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.2	R	1	Each Control unit	Refer Note 2
6	Chloride Ions	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.3	R	1	Each Control unit	Refer Note 2
6	Metals /Heavy Metals	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.4.1, A.4.4.2	S	1	Once in three months for each variety being manufactured	Refer Note 2
6	Acidity or Alkalinity	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.5	R	1	Each Control unit	Refer Note 2
6	Residue on Evaporation	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.6	R	1	Each Control unit	Refer Note 2
6	Opalescence	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.7	R	1	Each Control unit	Refer Note 2

6	Colouration	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.8	R	1	Each Control unit	Refer Note 2
6	UV Absorbance	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.9	R	1	Each Control unit	Refer Note 2
6	Extractable Plasticizer	6.3.2 Table 3	IS/ISO 3826-1 Annex A.4.10	R	1	Each Control unit	Refer Note 2
6	Impermeability to micro organisms	6.4.2	IS/ISO 3826-1 Annex C.3	R	1	Once in three months for each variety being manufactured	Refer Note 1,2
6	Biological Test - Compatibility	6.4.3	IS/ISO 3826-1, Annex C.3 to C.7	S	30	Once in 5 years	Refer note 1, 3
9	Anticoagulant and/ or preservative solution	9	IS/ISO 3626-1	S		Each consignment of anticoagulant and/ or preservative solution received	Refer note 4

Note-1: Manufacturer shall carry out the type test (test indicated to be carried out once in 3 months/ once in five years) as per the Levels of Control indicated in the table above and submit the report to BIS for verification and records.
Note-2: Extract of raw container/ sheet as specified in Annex A to be taken. One raw container/ sheet can be extracted for all chemical tests.
Note-3: Biocompatibility evaluation shall be carried out by manufacturer whenever there is a change in source of Plastic Materials for container or change in the quality of Plastic Materials for container used for manufacturing the product. The variety being manufactured in the most volume shall be tested, if possible.
Note-4: The quality of anticoagulant and/ or preservative solution, if any, shall satisfy the applicable requirements (e.g. National pharmacopoeia). No test required if received with suitable test certificate/ test report.
Note-5: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.
Note-6: 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.

ANNEX D

Possible tests in a day

1. Dimensions Cl 4
2. Air content Cl 5.2
3. Emptying under pressure Cl 5.3
4. Rate of Collection Cl 5.5
5. Collection and Transfer Tubes Cl 5.6
6. Blood Taking Needle Cl 5.7
7. Outlet Port Cl 5.8
8. Suspension Cl 5.9
9. Transparency Cl 6.2.3
10. Coloration Cl 6.2.4
11. Resistance to leakage 6.2.7
12. Particulate contamination 6.2.8
13. Chemical tests 6.3