उत्पाद मैन्युअल

आई एस 10258: 2002 के अनुसार

निर्जर्म अधोत्वचीय एक बार उपयोग की जाने वाली सिरिंजें

दस्तावेज़ संख्या - पी एम/आई एस 10258/2/मई 2021

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयाांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिर्शिता 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
STERILE HYPODERMIC SYRINGES FOR SINGLE USE
ACCORDING to IS 10258: 2002

Document No.- PM/IS 10258/2/May 2021

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.

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1.	**Product**	:	IS 10258:2002
	Title	:	STERILE HYPODERMIC SYRINGES FOR SINGLE USE
	No. of Amendments	:	NIL
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	-
b)	**Grouping guidelines**	:	Please refer ANNEX – A
c)	**Sample Size**	:	100 Syringes
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**	:	All Tests
6.	**Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS 10258: 2002 with the following scope:		
	Name of the product		Sterile Hypodermic Syringes for Single Use
	Nominal Capacity		

ANNEX A

Grouping Guidelines

1. The parameters as given below shall be considered for grouping of Sterile Hypodermic Syringes for single use as per IS 10258:2002 for GoL/Inclusion:

Group	I	II	III	IV	V	VI	VII
Nominal Capacity of Syringe, V (ml)	$V < 2$	$2 \leq V < 5$	$5 \leq V < 10$	$10 \leq V < 20$	$20 \leq V < 30$	$30 \leq V < 50$	$50 \leq V$

2. Syringe of any nominal capacity from each group, shall be tested to cover syringes of all capacities in that group.

3. Firm shall declare the Nominal capacity of syringes they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.

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

ANNEX B

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.	Limits for acidity and alkalinity (Clause 6)	pH meter, Distilled/Deionized water, Borosilicate glassware
2.	Limits for extractable metals (Clause 7)	Atomic Absorption spectrophotometer, Distilled/Deionized water, Borosilicate glassware
3.	Graduated Scale (Clause 10) Barrel Dimensions (Clause 11.1) Piston/Plunger design (Clause 12.1), Nozzle lumen (Clause 13.3)	Vernier caliper, Digital Micrometer
4.	Finger grips (Clause 11.2)	Inclined surface.
5.	Dead space (Clause 14.1 – Annex C)	Apparatus and Reagents as per C.2 of IS 10258.
6.	Freedom from air leakage past piston (Clause 14.2 – Annex B)	Apparatus and Reagents as per B.2 of IS 10258.
7.	Freedom from liquid leakage past piston (Clause 14.2 – Annex D)	Apparatus and Reagents as per D.2 of IS 10258.

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.

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

3. LABELLING AND MARKING – As per the requirements of IS 10258: 2002.

4. CONTROL UNIT – Syringes of same nominal capacity manufactured from the same material in a day shall constitute a 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 Standard 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**		
Clause	**Requirement**	**Test Methods**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
5	Cleanliness	5	IS 10258	R	10	Hourly	Please see note 1
6	Limits for acidity and alkalinity	6, Annex A			1	Each Control unit	
7	Limits for extractable metals	7, Annex A	IS 10258	S	3	Once in three months or whenever there is a change in raw material whichever is earlier.	In case any syringe does not meet the requirement, the whole control unit shall not be marked & shall be rejected. The marking shall commence only after the consignment meets this requirement
8	Lubricant	8	IS 10258	R	1	Each Control unit	For visual test and quantity. The compliance with respect to the type of lubricant shall be ensured periodically and whenever there is a change of lubricant. Also Please see note 1
9	Tolerance on graduated capacity	9, Table 1	IS 10258	R	1	Each Control unit	Please see note 1
10	**Graduated Scale**						
10.1	Scale	10.1, Table 1	IS 10258	R	1	Each Control unit	Please see note 1

10.2	Numbering of scale	10.2, Table 1	IS 10258	R	1	Each Control unit	Please see note 1
10.3	Overall length of scale to nominal capacity line	10.3, Table 1					
10.4	Position of Scale	10.4					
11	**Barrel**						
11.1	Dimensions	11.1	IS 10258	R	1	Each Control unit	Please see note 1
11.2	Finger Grips	11.2					
12	**Piston/ Plunger assembly**						
12.1	Design (Except piston detachment test as per Annex B)	12.1	IS 10258	R	1	Each Control unit	Please see note 1.
	Piston detachment test	12.1, Annex B	IS 10258	S	1	Every 15th Control Unit	
12.2	Fit of piston in barrel	12.2, Annex G	IS 10258	R	1	Each Control unit	
12.3	Fiducial line	12.3					
13	**Nozzle**						
13.1	Conical fitting	13.1	IS 10258	R	1	Each Control Unit	Please see note 1
13.2	Position of nozzle on end of barrel	13.2					
13.3	Nozzle lumen	13.3					

14	**Performance**						
14.1	Dead Space	14.1, Annex C	IS 10258	R	1	Each Control Unit	Please see note 1
14.2	Freedom from air and liquid leakage past piston	14.2, Annex B Annex D	IS 10258	S	1	Every 15th Control Unit	

Note-1: In case any syringe does not meet the requirement, the whole control unit shall not be marked & shall be rejected.

Note-2: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.

Note-3: The Control unit and the levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.