PRODUCT MANUAL FOR STERILE SINGLE-USE SYRINGES, WITH OR WITHOUT NEEDLE, FOR INSULIN ACCORDING TO IS 12227: 2020

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 12227: 2020
	Title	:	Sterile Single-Use Syringes, With or Without Needle, for Insulin
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per clause 5.1(m) and 5.2 of IS 12227:2020
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 12227: 2020 with the following scope:		
	Name of the product		Sterile Single-Use Syringes, With or Without Needle, for Insulin
	Type		
	Unit Scale		
	Nominal Capacity		
	Any other aspect required as per the Standard		Other design features (if applicable)

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ANNEX A

Grouping Guidelines

1. The guidelines given below shall be followed for GoL/CSoL of Insulin Syringes as per IS 12227: 2020:

   (a) Various types of Syringes are grouped as follows:

Group	Type of Syringe
1	1 and 2
2	3 and 4
3	5 and 6
4	7 and 8

   (b) Any type of syringe from each group having any nominal capacity from each unit scale shall be tested to cover syringes of all nominal capacities for the particular unit scale for both the types of syringes in that group.

   (c) If syringes of type 3 or 4 is tested, then syringes of type 1 and 2 for the corresponding varieties may also be covered.

   (d) Syringes indicated for use with devices or accessories that provide automated functions (e.g. needle insertion and retraction) shall be tested separately.

   (e) Syringes with integrated or add-on sharps protection shall be tested separately.

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

3. During the operation of the Licence, BO shall ensure that all 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	Graduated Capacity [Clause 5.1 e)]	(i) AC Unit (ii) Bunsen Burner (iii) Measuring Flask (iv) Thermometer
2	Limits for Extractable Matter (Clause 5.4.3)	(i) Conical Flasks (ii) Distilled water (iii) Oven (iv) Pipette (v) Round Bottom Flasks (vi) Spectrophotometer (vii) Stopwatch, Timer (viii) Thermometer
3	General Requirements [Clause 5.1 g)]	(i) Pipette (ii) Measuring Flask (iii) Vernier Calliper, Micrometer (iv) T Gauge (v) Measuring Scale
4	Barrel and Plunger Stopper (Clause 5.6.1)	(i) 10 degrees Inclination Plane (ii) Measuring Flask (iii) Pipette (iv) Suitable Liquid (v) Vernier Calliper
5	Piston/Plunger Stopper (Clause 5.7.1)	(i) Air Bleed Control (ii) Apparatus for Aspiration Test (iii) Bottle Trap (iv) Bunsen Burner, Clamps (v) Manometer (vi) Measuring flask, Pipette (vii) Rubber Bung/Diaphragm (viii) Steel Female Conical Fitting (ix) Stopwatch (x) Vacuum pump (xi) Vacuum Tight Valve
6	Fit of plunger stopper in barrel (Clause 5.7.2)	(i) Clamps (ii) Cotton Pads (iii) Distilled Water

		(iv) Force Gauge (v) Measuring Flasks (vi) Pipette
7	Needles (Clause 5.9.1, 5.9.2 and 5.9.3)	(i) Diameter Gauges (ii) Force Gauges (iii) Measuring Scale (iv) Micrometer, Vernier Calliper (v) Stylet Gauges
8	Dead Space (Clause 5.11.1)	(i) AC Unit (ii) Distilled Water (iii) Electronic Balance,(LC- 0.0001 g) (iv) Force Gauge (v) Freezer (vi) Measuring Flask (vii) Stopwatch (viii) Thermometer (ix) Torque gauge
9	Freedom from leakage at needle (Clause 5.11.2)	(i) Cotton Pads (ii) Force Gauge (iii) Measuring Flasks (iv) Pipette (v) Steel Female Conical Fitting (vi) Stopwatch (vii) Torque Gauge
10	Freedom from leakage past plunger stopper (Clause 5.11.3)	(i) Apparatus used in Aspiration Test (ii) Bottle Trap (iii) Cotton Pads (iv) Fine Bleed Control (v) Force Gauge (vi) Manometer (vii) Measuring Flasks, Pipette (viii) Rubber Ring/Diaphragm (ix) Steel Female Conical Fitting (x) Stopwatch (xi) Torque Gauge (xii) Vacuum Pump, Vacuum Tight Valve

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 equipments.

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 12227: 2020.

4. CONTROL UNIT – Syringes of same type, capacity, unit scale produced from the same material and manufactured under similar conditions 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

(1)				(2)	(3)		
Test Details				Test Equipment Requirement R: Required S: Subcontracting permitted	Levels of Control		
Clause	Requirement	Test Methods			No. of samples	Frequency	Remarks
		Clause	Reference				
Visual and Physical Test							
5.1	General Requirements	5.1	IS 12227	R	5 Pieces from production line	Hourly	In case any syringe does not meet the requirement, the whole control unit shall not be marked & shall be rejected
5.2	Material Selection	5.2	IS 12227	R	5 Pieces from production line	Hourly	
5.3	Colour Coding	5.3	IS 12227	R	5 Pieces	Each Control Unit	
5.4.1	Extraneous matter	5.4.1	IS 12227	R	5 Pieces		
5.5.1	Lubrication of syringes	5.5.1	IS 12227	R	5 Pieces		
5.5.2	Lubrication of needle tube	5.5.2	IS 12227	R	5 Pieces		
5.6.1	Barrel and plunger stopper	5.6.1	IS 12227	R	5 Pieces		
5.6.2	Finger grips	5.6.2	IS 12227	R	5 Pieces		
5.7.1	Plunger/plunger stopper - General	5.7.1	IS 12227	R	5 Pieces		
5.7.2	Fit of plunger stopper in barrel	5.7.2	IS 12227	R	5 Pieces		
5.8.1	Nozzle - Conical fitting	5.8.1	IS 12227	R	5 Pieces		
5.8.2	Position of nozzle on end of barrel	5.8.2	IS 12227	R	5 Pieces		
5.9.3	Bond between hub and needle tube	5.9.3	IS 12227	R	5 Pieces		

Test on Needle tubing and Needles							
5.9.1	Needles for syringe - types 3 and 4	5.9.1	IS 12227 ISO 7864	S	5 Pieces	Each Consignment	No further testing is required if the consignment is accompanied with a test certificate from supplier or ISI Marked.
5.9.2	Needle tubing for syringe- types 5, 6, 7 and 8	5.9.2	IS 7864 ISO 7864	S	5 Pieces	Each Consignment	
Test on Performance of Assembled syringe							
5.4.2	Limits of acidity or alkalinity	5.4.2, Annex A	IS 12227	R	10 pieces	Each Control Unit	In case any syringe does not meet the requirement, the whole control unit shall not be marked & shall be rejected.
5.4.3	Limits for extractable metals	5.4.3, Annex A	IS 12227	S	10 Pieces	Once in six months or whenever there is change in raw material consignment	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.
5.11.1	Dead space	5.11.1, Annex D	IS 12227	R	10 Pieces	Each Control Unit	In case any syringe does not meet the requirement, the whole control unit shall not be marked & shall be rejected.
5.11.2	Freedom from leakage at needle	5.11.2, Annex E, Annex F	IS 12227	R	10 Pieces	Each Control Unit	
5.11.3	Freedom from leakage past plunger stopper	5.11.3, Annex B, Annex E	IS 12227	R	10 Pieces	Each Control Unit	

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: The control unit and levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.