भारतीय मानक ब्यूरो
केंद्रीय मुहर विभाग – III

हमारा संदर्भ : सी.एम.डी-III/नि.प.स्की./आई एस 12227 23 अप्रैल 2020

विषय : निरीक्षण एवं परिक्षण स्कीम

सभी शाखा कार्यालयों से अनुरोध है कि उपरोक्त विषय से सम्बंधित परिपत्र का अवलोकन करें।

जगन्नाथ माझी
(वैज्ञानिक – ई)

प्रमुख (के.मु.वि.- III)

सभी क्षेत्रीय कार्यालयों/शाखा कार्यालयों को इंट्रानेट के माध्यम से परिचालित

BUREAU OF INDIAN STANDARDS
CENTRAL MARKS DEPARTMENT-III

Our Ref :CMD-III/SIT/IS 12227 23 April 2020

Subject : Scheme of Inspection and Testing for Revised IS 12227 : 2020

This has reference to the subject mentioned above.

The Scheme of Testing and Inspection for Sterile Single-Use Syringes, With or Without Needle, for Insulin according to IS 12227 : 2020 (DOC: SIT/12227/1, April 2020), duly approved by Competent Authority is enclosed for implementation.

(Jagannath Majhi)
Sc-E

Head(CMD-III)
All BOs/ROs

Scheme of Inspection And Testing
for
Sterile Single-Use Syringes, With or Without Needle, for Insulin
according to IS 12227 : 2020

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 IS12227:2020.

4. CONTROL UNIT – Syringes of same capacity and 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	#
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	

No further testing is required if the consignment is accompanied with a test certificate from supplier or ISI Marked.

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.