उत्पाद मैन्युअल

आई एस/आई एस ओ 15197 : 2013 के अनुसार

इन विट्रो नैदानिक परीक्षण पद्धतियाँ - डाइबिटीज मेलिटस के प्रबंधन में स्वयं - परीक्षण करने के लिए रक्त में ग्लूकोज़ की मॉनीटरिंग पद्धतियों के लिए अपेक्षाएँ के लिए

दस्तावेज़ संख्या – पीएम/आईएस/ आईएसओ 15197/1/ अगस्त 2022

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

In vitro Diagnostic Test Systems — Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus

ACCORDING TO IS/ ISO 15197 : 2013

Document No - PM/IS/ISO 15197/1/ Aug 2022

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
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New Delhi – 110002

उत्पाद मैन्युअल

इन विट्रो नैदानिक परीक्षण पद्धतियाँ - डाइबिटीज मेलिटस के प्रबंधन में स्वयं - परीक्षण करने के लिए रक्त में ग्लूकोज़ की मॉनीटरिंग पद्धतियों के लिए अपेक्षाएँ के लिए IS/ISO 15197:2013 के अनुसार

Product Manual for In vitro Diagnostic Test Systems — Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus according to IS /ISO 15197:2013

भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम की स्कीम के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचलन में रीति और पारदर्शिता के सुसंगता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों एवं लाइसेन्स धारियों द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस लाइसेन्स/प्रमाण पत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज का उपयोग किया जा सकता है।

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.	**उत्पाद** **Product**	:	IS/ISO 15197:2013
	शीर्षक **Title**	:	In vitro Diagnostic Test Systems — Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus as per IS /ISO 15197:2013
	संशोधन संख्या **No. of Amendments**	:	Nil
2.	**नमुनाकरण दिशा निर्देश** **Sampling Guidelines:**		
a)	**कच्चा माल** **Raw material**	:	NA
b)	**समूहिकरण दिशा निर्देश** **Grouping guidelines**	:	Each Model shall be tested for all parameters for considering GoL/ Inclusion of additional variety
c)	**नमूने का परिमाण** **Sample Size**	:	15 nos * (for all tests except test for Electromagnetic Compatibility, Cl. 5.4)

3.	**परीक्षण उपकरणो की सूची** **List of Test Equipment**	:	**कृपया** Annex-A **देखें** Please refer ANNEX – A
4.	**निरीक्षण व परीक्षण स्कीम** **Scheme of Inspection and Testing**	:	**कृपया** Annex-B **देखें** Please refer ANNEX – B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day:**		
	• **Vibration Test, Cl 5.10.1** • **Drop Test, Cl 5.10.2**		
6.	**लाइसेन्स का कार्यक्षेत्र/ Scope of the Licence:**		
	IS/ISO 15197:2013 **के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है** "Licence is granted to use Standard Mark as per IS/ISO 15197 : 2013 with the following scope:		
	उत्पाद का नाम **Name of the product**		In vitro Diagnostic Test Systems — Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus as per IS /ISO 15197:2013
	Model No		

NOTE:

1. The applicant shall submit the documentation with respect to compliance to Clauses 6 and 8 of IS/ ISO 15197 : 2013 for each model/ variety at the time of Grant of Licence / inclusion in existing scope of licence to BIS for its evaluation and record purposes.
2. The applicant shall submit a copy of information supplied as per Clause 7 of IS/ ISO 15197 : 2013 for each model/ variety at the time of Grant of Licence / inclusion in existing scope of licence to BIS for its record purposes.

* - The number of samples required to conduct complete testing of the product including test for Electromagnetic Compatibility, Cl. 5.4 (once in three years on factory samples) is 25 numbers.

ANNEX A

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	Protection against Electric Shock, Cl 5.2	Accessibility test panel with jointed and unjointed test finger
		Voltmeter, mill-ammeter, oscilloscope, force gauges, 2000 ohm non-inductive resistor, coulombmeter, energymeter
2	Protection against mechanical hazard, Cl 5.3	Inclined plane, masses, force gauges, test probe, Stop plate, test rod
3	Electromagnetic Compatibility, Cl 5.4	Environmental chamber, voltage dips and short voltage interruption apparatus, variable voltage supply, 3-phase auto-transformer, surge test apparatus, fast transient/burst test apparatus, ring wave surge test apparatus, conducted radiofrequency test apparatus radiated EM field test apparatus
4	Resistance to Heat, Cl 5.5	Heating Oven with Temp controller, Ball pressure Apparatus, Glow wire test apparatus Needle flame test apparatus
5	Resistance to moisture and Liquids, Cl 5.6	IP test equipment as per IS/IEC 60529, electric strength tester, conditioning chambers: heating cabinet, humidity chamber, leakage current tester Hot water bath, Freezer, IR tester, AC source
6	Protection against liberated gases, explosion and implosion, Cl 5.7	Voltmeter, mill-ammeter, pressure gauges
7	Meter Component, Cl 5.8	Voltmeter, thermometer
8	Performance Test, Cl 5.9	Glucose meter, Test strip, Humidity Chamber, Control material
9	Vibration Test, Cl 5.10.1	Vibration system including amplifier, vibrator, test fixture, specimen and control system when loaded for testing
10	Drop test, Cl 5.10.2	Drop test set up as per IEC 61010-1 (1m height, 50mm thick hardwood board having density 700kg/m3 lying on rigid base of concrete)
11	High temperature test, Cl 5.11.1	Environmental Chamber/ Oven (LC 1°C)
12	Low temperature test, Cl 5.11.2	Deep freezer
13	Equipment humidity exposure limits for storage, Cl 5.12	Humidity Chamber

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

ANNEX B

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 & MARKING – The Standard Mark as given in the Schedule of the license and Licence Number (i.e. CM/L…….) shall be incorporated, and the labelling and marking shall be done as per the provisions of the Indian Standard, provided always that the product thus marked conforms to all the requirement of the specification. 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 total quantity of Glucose meter of the same model produced in 24 hours 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 (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
5.2	Protection against Electric Shock	5.2	IS /ISO 15197	**S**	3	Once in 01 year	
5.3	Protection against mechanical hazard	5.3	IS /ISO 15197	**S**	3	Once in 01 year	
5.4	Electromagnetic Compatibility	5.4	IS /ISO 15197	**S**	3	Once in 03year	The licensee has to be submit test report to concerned BO for record
5.5	Resistance to Heat	5.5	IS /ISO 15197	**S**	3	Once in 01 year	
5.6	Resistance to moisture and Liquids	5.6	IS /ISO 15197	**S**	3	Once in 01 year	
5.7	Protection against liberated gases, explosion and implosion	5.7	IS /ISO 15197	**S**	3	Once in 01 year	
5.8	Meter Component	5.8	IS /ISO 15197	**S**	3	Once in 01 year	
5.9	Performance Test	5.9	IS /ISO 15197	**R**	10	Every 5th Control Unit	
5.10.1	Vibration Test	5.10.1	IS /ISO 15197	**R**	10	Each Control Unit	
5.10.2	Drop test	5.10.2	IS /ISO 15197	**R**	10	Each Control Unit	
5.11.1	High temperature test	5.11.1	IS /ISO 15197	**R**	10	Every 5th Control Unit	
5.11.2	Low temperature test	5.11.2	IS /ISO 15197	**R**	10	Every 5th Control Unit	
5.12	Equipment humidity exposure limits for storage	5.12	IS /ISO 15197	**R**	10	Every 5th Control Unit	
6	Analytical performance evaluation	6	IS /ISO 15197	**R**	NA	For each new model or design	Please see Note - 4
7	Information supplied by the manufacturer	7	IS /ISO 15197	**R**	NA	For each new model/ design or whenever there is change in information supplied by the manufacturer	Please see Note - 5
8	User performance evaluation	8	IS /ISO 15197	**R**	NA	For each new model or design	Please see Note - 4

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.
Note-2: Tests as per Clause 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8 to be carried out as per the Frequency in column (3). Test to be carried out again in case there is any change in design of the product.
Note-3: The control unit and levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.
Note -4: The applicant shall submit the documentation with respect to compliance to Clauses 6 and 8 of IS/ ISO 15197 : 2013 for each model/ variety at the time of Grant of Licence / inclusion in existing scope of licence to BIS for its evaluation and record purposes.
Note-5: The applicant shall submit a copy of information supplied as per Clause 7 of IS/ ISO 15197 : 2013 for each model/ variety at the time of Grant of Licence / inclusion in existing scope of licence to BIS for its record purposes.