

Subject: Reviewed ‘Limits of Acceptance’ revised as per ISO 15197:2013, and applicability of the same as per instructions of the DCG (I), dated 09.05.18

EARLIER	Specifications	Reference
Criteria for acceptance	<p>95% of the individual Glucometer results shall fall within + 15mg/dL of the results of the ‘Reference Method’ at glucose concentrations <75mg/dL and within +20% at glucose concentrations >75mg/dL</p> <p>Maximum allowable deviation should be less than 15%</p>	<p>System Accuracy requirement: ISO15197:2003</p> <p>WHO: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002</p>
REVISED (EFFECTIVE 18.10.19)	Specifications	Reference
Criteria for acceptance	<p>System Accuracy requirement: 95% of the individual Glucometer results shall fall within ± 15mg/dL of the results of the ‘Reference Method’ at glucose concentrations <100mg/dL and within $\pm 15\%$ at glucose concentrations ≥ 100mg/dL</p> <p>Maximum allowable deviation should be less than 15%</p>	<p>ISO15197:2013</p> <p>WHO: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002</p>

**Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare**

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

F.No. 29/Misc/4/2016-DC (88)

Date: 08/10/2019

To,

1. The Director,
National Institute of Biologicals,
Plot no. A-32, Sector-62,
Institutional Area, Noida-201307
2. The Director General,
Medical Technology Association of India,
B-17, Infocity, Sector-34, Gurgaon-122001

Subject: Applicability of IS/ ISO 15197 2013 version regarding glucometer test strips-Reg

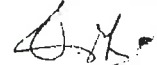
Sir,

This has reference to the letter dated 02.11.2018 received from MTAI regarding the implementation date for the applicability of revised standard of IS/ISO 15197 2013 for glucometer test strips.

This office in its earlier letter no. 29/MISC/4/2013-DC (22) dated February 16, 2016 mentioned that the revised IS/ISO 15197: 2013 will be effective after 36 months of its publication by BIS.

Further, BIS has issued final notification vide S.O. 3259 (E) dated October 19, 2016 where the date of establishment of IS/ISO 15197: 2013 is October, 19, 2016 is specified. As transition period of 36 months from the date of establishment of the said standard. Therefore, the effective date for the implementation of IS/ISO 15197: 2013 shall be October, 18, 2019.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

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1. IT Cell for uploading the information on CDSCO website

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15/5/18

Dr. S. Eswara Reddy
15/5/18
1/2 DDO (signature)

Dr. S. Eswara Reddy
Heel BKC