

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Devices & Diagnostics Division)

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

File No.: 29/Misc/4/2013-DC(22)


Date: 16 FEB 2016

Subject: Acceptance criteria for test and examination of Blood Glucose Test Strips & Analyzer based glucose reagent-Reg.

Please refer to your email dated 27 & 28 Jan. 2016 with regard to implementation of acceptance limits for Blood Glucose Test Strips as per ISO-15197. The matter was discussed with expert committee in its meeting held on 12.01.2016 and it has been decided that there is IS/ISO-15197:2003 is published by BIS. Therefore the Blood Glucose test Strips shall conform only IS/ISO-15197.

As regard to revised ISO-15197:2013 published in 2013 which also adopted by Bureau of Indian Standards (BIS) for evaluation of Blood glucose test strips. Therefore the revised IS/ISO-15197:2013 will be applicable only after 36 months from the date of its publication by BIS.

In view of above, you are requested to take appropriate action and release test reports of Blood glucose test strips accordingly.


(Dr. G.N.Singh)
Drugs Controller General (India)

To,

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