

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

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

File No. 29/Misc./3/2014-DC (36)

Date: 7 AUG 2014

To

1. All State/UTs Drugs Controllers
2. All zonal/sub-zonal/port offices of CDSCO

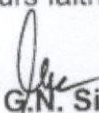
Subject: "Specification" and "Criteria for Acceptance" for test performed on blood glucose test strip and analyzer based glucose reagents- Reg.

Sir,

In order to finalize the specification and criteria for acceptance of "Blood Glucose Test Strip" and "Analyzer Based Glucose Reagents", a meeting of the expert committee was held and It was decided that before grant of license to import/ manufacture for sale of such products in the country, evaluation of three batches of such products are required to be done at NIB, Noida in addition to the random samples from the market.

In view of above, you are requested to direct all the importers/manufacturers that w.e.f. 01.11.2014, in case of "Blood Glucose Test Strip" and "Analyzer Based Glucose Reagents", three batches of the products should be got evaluated at NIB, Noida and Performance Evaluation Report should be submitted to the concerned Licensing Authority alongwith the application before considering such applications for grant of license to import/manufacture for sale of the products in the country.

Yours faithfully,


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

Copy to:

1. Medical Device & Diagnostics Associations: FICCI/CII/ ADMI etc.

C.C.:

PS to JS(R)

National Institute of Biologicals

(Ministry of Health & Family Welfare)
A-32, Sector-62, NOIDA-201 309 (UP)

Acceptance Criteria for test and examination of Blood Glucose Test Strips (Imported & Manufactured in India) and shall be effective from 01.01.2016

CURRENT	Specifications	Reference
Criteria for acceptance	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 Maximum allowable deviation should be less than 15%	System Accuracy requirement: ISO15197:2003 Who: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002