

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

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

No. 29/Misc/5/2010-DC (11)

Date : **26 AUG 2010**

~~To~~

1. All State Drugs Controller
2. All Zonal/Sub-Zonal/Port Officers of CDSCO

SUB: Testing of Biochemical Kits for estimation of Glucose- Reg.

Sir,

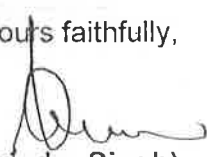
It is to inform you that this office has received a letter no. N.8-3/2010-SRRD/BCKL/777 dated 15.07.2010 from NIB, Noida stating that NIB has standardized the testing parameters for evaluation of Glucose, Biochemical Kits used in automated systems as per the clinical laboratory standards Institute (CLSI) viz. Precision, Accuracy, Linearity & range and is in a position to carry out the quality testing of these kits.

1. These kits will be tested in a fully automated system.
 2. The quantity of Glucose Biochemical kits/Reagent required for testing would be 2 x 500ml which will be adequate for performing 1000 tests and an equal quantity as retained samples.
 3. The documents that would be required by NIB:-
 - (i) Forwarding letter from the Authorized official(s) of CDSCO/Drug Licensing Authority.
 - (ii) QC protocols specific for the product.
 - (iii) Batch specific Certificate of Analysis and Quality Control Test Results.
 - (iv) Batch Release Certificate.
- Copy of Import Licence/test licence/manufacturing licence issued by the DCG (I) / Drug Licensing Authority.



Hence, you are requested to forward the subject kits to NIB, Noida for testing.

Yours faithfully,


(Dr. Surinder Singh)
Drugs Controller General (I)

~~Copy to~~
The Director
National Institute of Biologicals
A-32, Sector-62 (Institutional Area),
Noida-201309 (U.P.)

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

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

No. 29/Misc/4/2011-DC (66)

Date : **27 SEP 2011**

To

All State Drugs Controllers,

SUB:- Testing Specifications / Limits of glucose strips - Reg.

Sir,

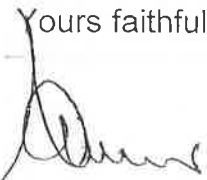
This is refer to National Institute of Biologicals, Noida letter No. N8-16/2010-SRRD/NIB/523 dated 09.06.2011 in respect of the above subject.

In this connection, it is to inform you that the Glucometer Strip samples are being tested at NIB for the parameters: Repeatability, Intermediate Precision, System Accuracy and Bias as per WHO: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002 and ISO 15197. NIB has specified following specifications for Glucose Monitoring Strips.

S. No.	Tests	Specifications/limits
1	Precision Evaluation	Value of % CV obtained between $\leq 3.0 - 7.1$ (WHO: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002)
2	System Accuracy and Bias Evaluation	<ul style="list-style-type: none">System Accuracy requirement: 95% of the individual Glucometer results shall fall within $\pm 15\text{mg/dL}$ of the results of the "Reference method" at glucose concentrations $<75\text{mg/dL}$ and within $\pm 20\%$ at glucose concentration $\geq 75\text{mg/dL}$ (ISO 15197)Maximum allowable deviation should be less than 15% (WHO: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002)



Yours faithfully,


(Dr. Surinder Singh)
Drugs Controller General (India)

Copy to:-

1. Director, National Institute of Biologicals, Plot No. A-32, Sector-62 Institutional Area, Noida-201 307 (U.P.)
2. All Zonal / Sub zonal / Port officers of Central Drugs Standard Control Organisation.
3. Association of Diagnostics Manufacturers of India, Plot No.336, 338, 340, Road No.3, GIDC, Sachin 394230, Gujarat.