

Minutes of the meeting of the Experts Committee to examine the 'Specifications' and 'Criteria for acceptance' for Tests performed on 'Blood Glucose Test Strips' and 'Analyzerbased Glucose Reagent' held on 05 July 2013 at CDSCO, FDA Bhavan, Kotla Road, New Delhi-110002.

Name of the Experts attended the meeting:

1. Dr.G.R.Soni., Scientist –Gr.I
National Institute of Biologicals (NIB), Noida
2. Ms.AjantaSircar., Scientist Gr. III
National Institute of Biologicals (NIB), Noida
3. Dr.ChanderSekhar., Scientist – F
Division of RCH, Indian Council of Medical Research (ICMR)
New Delhi
4. Dr.K.Ghosh(Director)
National Institute of Immunohaematology
KEM Hospital Campus Parel, Mumbai
5. Prof. N.K. Mehra,
HOD, Department of Transplant Immunology &Immunogenetics,
All India Institute of Medical sciences, New Delhi
6. Dr.Nupur Gupta
Non Teaching Specialist (Microbiology)
Division of Microbiology
National Center for Disease Control (NCDC), Directorate General of Health Services,
New Delhi

Name of the Expert absent for meeting:

1. Dr.R.Goswami
Addl.Professor, Dept. of Endocrinology,
All India Institute of Medical sciences, New Delhi

Invitees

1. Federation of Indian Chambers of Commerce and Industry(FICCI)

- I. Ms. SushmitaRoy Chowdhury- Head RA, Roche Diagnostics IndiaPvt. Ltd
- II. Mr. GauravMendiratta- Assistant Director, FICCI

2. Confederation of Indian Industry(CII)

- I. Mrs. SumatiRandeo-DirectorRA- Abbott
- II. Mr. Alok Kumar Soni- Head RA Siemens
- III. Mr. Yuvraj Chopra- Director, Johnson and Johnson

3. The Association of Diagnostics Manufacturers of India (ADMI)

I. Dr. Bharat Jindal, Managing Director, Rapid Diagnostics, Delhi

Officers form CDSCO (HQ):

1. Dr. S. Eswara Reddy, Deputy Drugs Controller (India), CDSCO HQ, New Delhi
2. Dr. Ravi Kant Sharma, Assistant Drugs Controller (India), CDSCO HQ, New Delhi
3. Sh. Sanjay Kumar Agrawal, Drugs Inspector, CDSCO HQ, New Delhi
4. Sh. Ashish Kumar Rai, Drugs Inspector, CDSCO HQ, New Delhi
5. Sh. Sella Senthil, Drugs Inspector, CDSCO HQ, New Delhi.
6. Mr. Saurabh Jain, Drugs Inspector, CDSCO HQ, New Delhi.
7. Mr. V. Suraj, Drugs Inspector, CDSCO HQ, New Delhi.

The DDC (I) welcomed the members and briefed the agenda. The objective of the meeting was to establish specifications and criteria for acceptance for tests performed on Blood Glucose Test Strips and Analyzer based Glucose Reagent proposed by NIB, Noida

Dr. Ajanta Sircar Scientist Gr. III, National Institute of Biologicals (NIB), Noida gave brief presentation on the specifications/parameters to be followed by NIB, for evaluation of Blood Glucose Test Strip and Analyzer based Glucose Reagent.

After the deliberation in the meeting and discussion with Experts and stakeholders (members of FICCI, CII and ADMI) following decision were made:-

1. Specifications and criteria for acceptance of the tests performed on Blood Glucose Test Strips and Analyzer based Glucose Reagent as per ISO 15197 and WHO guidelines proposed by NIB, Noida were accepted.
2. Recommend to have alternate "Satellite testing laboratories" preferably from Government Institution / Premier institute like C.M.C Vellore, Nizam Institute of Medical Sciences Hyderabad, AIIMS, New Delhi, etc. for testing and evaluation of the Blood Glucose test Strips and Analyser based Glucose Reagent in line with the standards and protocol

proposed by NIB, Noida. CDSCO may take initiative in consultation with NIB to identify “Satellite testing laboratories” within 60 days.

3. The fees, protocols and timelines for evaluation of Blood Glucose test Strips and Analyser based Glucose Reagent at “satellite testing Laboratories” shall be uniform as per NIB, Noida.
4. It was decided that before grant of Import License for Blood Glucose Test Strips and Analyser based Glucose Reagent, evaluation report of 3 batches conducted by NIB, Noida or other satellite testing Laboratories are required to be submitted along with the application and for this purpose 6 months transition period may be given to the stake holders.
5. It was also recommended that 3 batches of the product Blood Glucose Test Strips and Analyser based Glucose Reagent manufactured by Indigenous manufacturers shall also be tested at NIB Noida before grant of marketing authorisation in the country in addition to the random samples from the market. In this regard all the State Licensing Authorities will be informed to forward the samples of Blood Glucose Test Strips and Analyser based Glucose Reagent manufactured indigenously to NIB, Noida for evaluation.
6. Members of FICCI, CII and ADMI requested the CDSCO to conduct such meetings / interaction with industry stakeholders in future also
The meeting ended with the vote of thanks to the chair.