

## **Annexure C**

### **TECHNICAL SPECIFICATIONS** **(AMMENDED ANNEXURE-VII OF THE BID DOCUMENT)**

#### **GLUCOMETER WITH STRIPS**

##### **Product Eligibility Criteria:**

- ☐ Product should be CE as per IVD (Invitro Diagnostic Device) or USFDA Certified.
- ☐ Manufacturer should be ISO 13485 certified for quality standards.
- ☐ Test strips should be certified by the National Institutes of Biologicals (NIB), Govt. of India.

##### **Technical Specifications**

1. Small, portable and user friendly device is required. Blood should not go into the glucometer while measurement.
2. It should be able to measure whole blood in capillary mode.
3. Measurement range: 30 to 600 in mg/dl.
4. Accuracy should be as per International Standard ISO 15197: 2013 (Requirements for Blood-glucose monitoring systems for self-testing in managing diabetes mellitus). Supporting certificate or test reports from the National Institutes of Biologicals (NIB) must be furnished of last 2years with the technical bid.
5. Reproducibility/Precision:  $\pm 5\%$
6. Display should be 40mm  $\pm 5$  mm or better measured diagonally.
7. It should be battery operated electronic system and the battery life should be for atleast 500 tests.
8. Self life of strips: Minimum 6 months at the time of delivery to consignee.
9. Packing of strips should not be more than 50 strips in a pack.
10. Strips should work for minimum 3 months after opening of strips pack.
11. Operating temperature for both device and test strip should be 10<sup>0</sup>C to 40<sup>0</sup>C.
12. Control solution for checking reliability of strips will be supplied free of cost as & when required.
13. Ready availability of reagent test strips, battery & other consumables across BIHAR for at least 5 years.
- 14. A complete user operational guide shall have to be supplied along with each machine, printed in Hindi and English language.**
- 15. A lancet applicator/ lancet holder shall have to be supplied along with each machine.**

##### **Scope of supply:**

- a) Glucometer: 1no.
- b) Standard batteries: 1Set
- c) Carrying case: 1no.
- d) Control solution/Control Strips
- e) Glucose test strips: As per Order
- f) Auto disables lancets: As per order
- g) A lancet applicator/ lancet holder**