1063206/2018/NVBDCP

Technical Specification of Rapid Diagnostic Kits for Kala-azar under NVBDCP

Approved As on 28.12.2016

A. Performance:

The product should have at least 95% and above specificity and sensitivity for wider competition under field conditions.

B. Ease of use:

Kits should allow for use whole blood/serum for conducting the test.

C. Packaging:

- Each rapid test strip should be individually packed in moisture proof pouch.
- Not only the Goods, but also the packaging component should also conform to specifications suitable for use in a climate similar to that prevailing in the country of the purchaser.
- All packaging must be properly sealed and tamper-proof.
- Goods requiring refrigeration for stability must specifically indicate storage requirements on labels and containers and be shipped in the special containers to ensure stability in transit from point of shipment to the port of entry.

D. Conditions of storage:

The Kit should be stable through its Shelf life, when stored at a maximum of 30 degree Celsius.

E. Shelf life:

Minimum two years.

Shelf life from manufacturing day to expirty date should be at least 2 years and it should not pass more than $1/4^{th}$ (for imported) and $1/6^{th}$ of their effective life from the date at the time material offered for inspection. Losses due to premature deterioration as a result of biological and other activities during the life of potency of the Rapid Diagnostic Test kits will be made good by the firm at their cost.

F. Quality Assurance:

The product should be complied with ISO 13485/BIS standards.

G. **Registration of the product:**

The product should be licensed for import/ manufacture by DCG (I) / State drug controller under drugs and cosmetics Act 1940 and rules framed therein.

H. **Field Tested:**

Satisfactory field tested report should have been generated through any reputed institute(s) designated by the programme.

I. **Labeling:**

Each strip of the test should be labeled as **NVBDCP SUPPLY – NOT FOR SALE.**