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National Vector Borne Disease Control Programme, Delhi – 110 054.

Minutes of the Meeting of Technical Specification Committee held on 15.01.2009 at Nirman Bhawan under the Chairmanship of Dr. Shiv Lal, Special DG (PH)

A meeting of the technical specification committee was held on 15.01.2009 at Nirman Bhawan under the chairmanship of Dr. Shiv Lal, Special DGHS, Govt. of India. Dr. D. Kanungo, Addl. DG (Stores), Sh. Surinder Singh, DCG(I), Dr. K.D. Tripathi, Ex-Professor of Pharmacology M A M College, Dr. Dinesh Srivastava, RML Hospital and Dr. Neena Valecha, Deputy Director (SG), NIMR participated in the meeting. Director (Procurement) and Dr. Y.K. Gupta, Department of Pharmacology, AIIMS could not attend the meeting. Dr. G.P.S. Dhillon, Director NVBDCP and member Secretary of the meeting briefed the participants about the agenda items for the consideration of the technical specification meeting. The following agenda were put up and deliberated upon by the members.

Agenda Note-I: To reduce shelf life of Tablet Sulphadoxine Pyremethamine (500 mg) Combination Tablets to 3 years

It was mentioned that Directorate of NVBDCP procures tablets Sulphadoxine Pyremethamine to treat the patients in Chloroquine resistance areas, however the tablets Sulphadoxine Pyremethamine is co-administered with tablets Artesunate for children as well as adult dose. The Artesunate tablet has a shelf life of 2 years while tablet Sulphadoxine Pyremethamine is having shelf life of 5 years as per earlier Technical specification. Recently, during the procurement through M/s HLL and UNOPS, many bidders have pointed out that shelf life of raw material of said item is only four years. Hence, firms will be able to supply the same with shelf life of 3 years.

After deliberations, the members of Technical Specifications Committee suggested that UNOPS and HLL may be requested to ask the concerned manufacturers to submit supportive data for reduction for shelf life which interalia includes source of raw material, stability data etc. This information may be examined by DCG(I) and then this issue may be put up to the Technical Specification Committee.

Agenda-II

Subject: - To reduce the shelf life Albendazole tablets (400 mg) from 5 years to 3 years

This Directorate is procuring the Albendazole Tablets for the first time through procurement agency M/s HLL for elimination of Lymphatic filariasis and its Technical Specifications were approved by Technical Specification Committee meeting held on 10.07.08. This indent was placed with M/s HLL who have informed that Tablet Albendazole is to be procured from Public Sector Pharmaceuticals and in addition M/s HLL vide their letter no. HLL /PCD /NVBDCP-01/08-09/2726 dated 5th December, 2008 has informed that during the bid evaluation of said item it has been observed bidders have quoted shelf life of this product only for 3 years instead of 5 years as approved by Technical Specification Committee on 10.7.08. Requesting this Directorate to recommend the shelf life of 3 years, as the aforesaid procurement is exclusive purchase from Pharma CPSE's and their subsidiaries and they all are having the product with three year's shelf life.

After deliberations, the members technical specifications suggested that HLL may be requested to ask the concerned manufacturers to submit supportive data for reduction for shelf life which interalia includes source of raw material, stability data etc. This information may be examined by DCG(I) and then this issue may be put up to the Technical Specification Committee.

Shiv Lal

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Agenda Note-III: To prepare Technical Specifications for Combi Blister Packs (Tablet Artesunate (50 mg) + Tablet Sulphadoxine Pyremethamine (500mg) for all age groups.

It was briefed that at present Combi-Blister Packs (Tablet Artesunate 50 mg +Tablet Sulphadoxine Pyremethamine 500 mg) are being procured by this Directorate to treat the patient in chloroquine resistance areas as a adult dose. For children Directorate is procuring loose tablets of Artesunate 50 mg and Sulphadoxine Pyremethamine 500 mg separately and are being prescribed to children according to their does requirement. At present Technical Specifications for Combi Blister Packs (Tablet Artesunate (50mg + Tablet Sulphadoxine Pyremethamine (500 mg) for peadiatric age group have not been formulated.

After detailed discussion the committee agreed to Technical Specification of Combi Blister Packs for all age group as enclosed at Annexure-I.

Agenda-IV

Subject:- Modifications in the Technical Specifications of RDK for Malaria as suggested by World Bank

Rapid Diagnostic Kits for Malaria are being procured by UNOPS from World Bank Budget. While procuring Rapid Diagnostic Kits for Malaria in 2008-09, Technical Specifications were sent by UNOPS to World Bank for their approval, World Bank suggested some changes.

After deliberations, the technical specification Committee agreed to suggested change and approved the following specifications:

TECHNICAL SPECIFICATIONS OF Rapid Diagnostic Test Kits

(a) Description of the Test Kit

The Rapid Diagnostic Kit (RDK) for Malaria should comprise of test card/strips/ cassettes and reagents including buffer solution in a dropper bottle. The test kit should be able to conduct the Rapid Diagnosis for P. falciparum alone. The test should be based on the principle of capture of parasite antigen from blood using monoclonal antibodies specific for antigen target. Tracer antibodies should be present as immobile phase. Each test kit should contain all the material required for conducting the test including individually packed sterile lancets for pricking, heparinised capillary tubes (diameter – 1mm) with relevant markings and reaction tubes with stand/wells it required. The required packing standards and labeling should meet the Good Manufacturing Practices (GMP) standards. One should be able to perform the test with the blood taken by finger prick of the patient. Each batch of RDKs should be tested during time of delivery to ensure sensitivity and specificity at minimum of 95% at parasite density level of 200 asexual parasites per microlitre of blood.

(b) Content of the kit.

Each Kit should be packed in a hermetically sealed and non permeable ppuch and should have moisture absorbent material. 25 such test cards/ strips should be packed in a box containing the reagents and the test plates. Adequate literature detailing the components methodologies, validity criteria, storage conditions, expiry date and limitations of test should be provided.

S. S. Pal

Amrith

Prakash

H. Williams

J. J. J.

The small box should be packed in bigger cardboard carton containing 5 such small boxes. The carton should be sealed with a sealing tape.

(c) **Shelf life**

Shelf life from manufacturing day to expiry date should be at least 2 years and it should not pass more than 1/6th of their effective life from the date at the time, the material is 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.

(d) **Marking/Labeling:**

(i) Each card/strip cassettes should have space for Patient's particulars and date of the test.

(ii) The small box containing 25 tests should have the following marking

- Name of the test
- Lot Number
- Manufacturing and expiry date
- Name of the manufacturer with address
- Details of contents
- Storage conditions
- Handling procedure
- Disposal Instructions for the box and its contents
- NVBDCP supply - NOT FOR SALE

(iii) The large carton containing 5 small boxes should have the following markings.

- Name of the test
- Lot Number
- Manufacturing and Expiry date
- Name of the manufacturer with address
- Details of contents
- Storage conditions
- Handling procedure
- Disposal Instructions for the box and its contents
- NVBDCP supply - NOT FOR SALE

e) **Details regarding approval or license**

(i) Manufacturing and Marketing License for the manufacturing of Rapid Malaria Diagnostic Kits should have been obtained from the concerned Regulatory authority in the country of manufacturer at the time of tender opening.

(ii) The Bidders must submit scientific study report in support of their claim of sensitivity and specificity of the offered product from an institution recognized for the purpose. RDK should be stable up to 40°C. Claim should be supported by actual shelf life studies. Reports of proven performance of the offered product in conditions similar to Indian field conditions (room temperature up to 40°C), with certification of no adverse report for the offered product from the end users during the last five years must also be submitted with the bid.

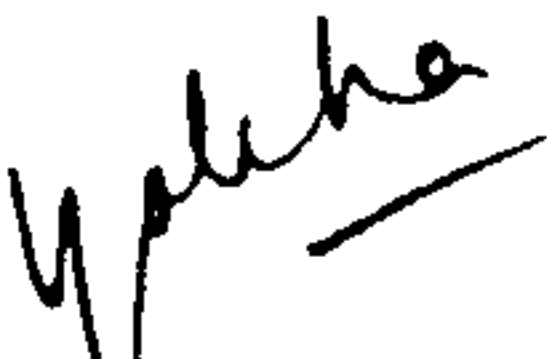
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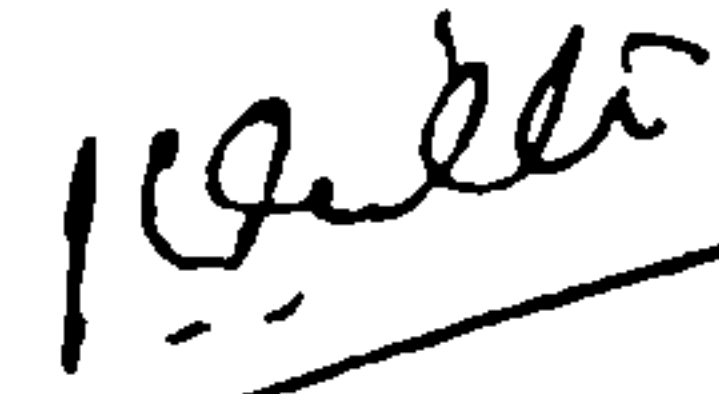
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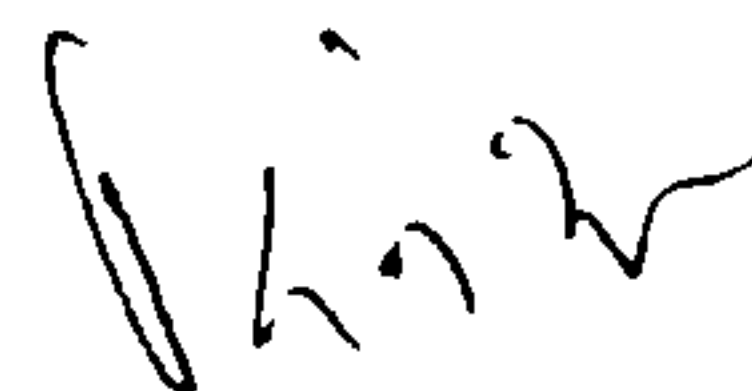
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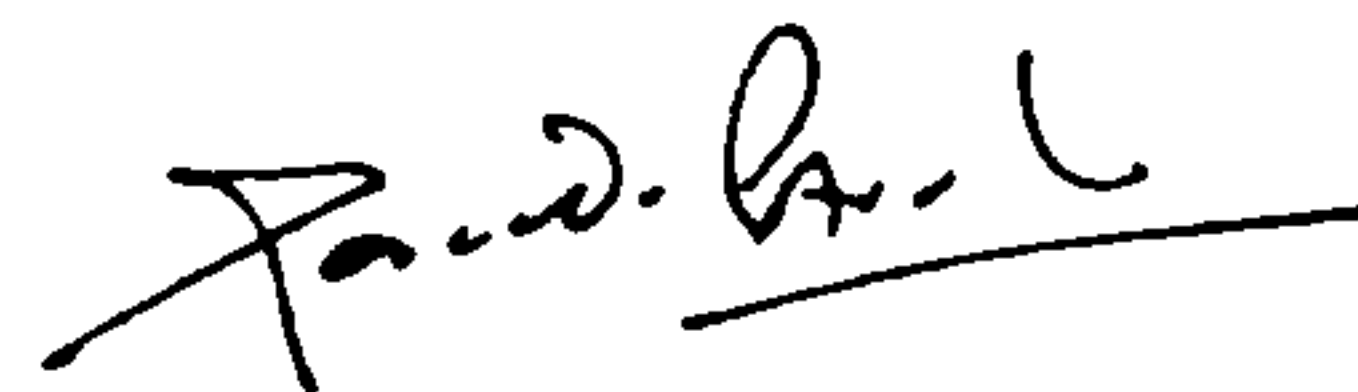
- (iii) The Bidders must submit a sample of their product (for example as two kits to UNOPS for assessment of user-friendliness by UNOPS and NVBDCP technical staff.
- (f) Recommended condition for storage (e.g. room temperature) and shelf life should clearly be mentioned on the label of RDK


 (Dr. Neena Valecha)
 Deputy Director (SG)

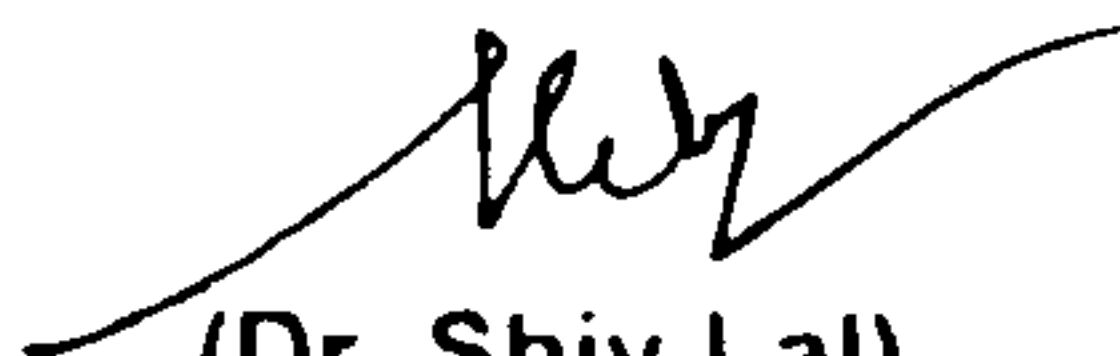

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