

Minutes of the Technical Specification Committee meeting held on 31.8.2009 under the chairmanship of Dr. Shiv Lal, Special DGHS (PH), Govt. of India to discuss and revise the specifications of Combi blister packs for malaria for different age groups

A meeting of the Technical Specification Committee was held on 31.8.2009 under the Chairmanship of Dr. Shiv Lal, Special DGHS (PH), Govt. of India to discuss and revise the specifications of Combi blister packs for malaria. All the members of the committee were present except Dr. Y.K. Gupta, Dept. of Pharmacology, AIIMS. Dr.S.N.Sharma, Joint Director and Mrs. Usha Arora, SRO assisted for conduct of the meeting

Dr. Shiv Lal, Special DGHS welcomed the members and requested Director, NVBDCP to put agenda before the committee. Dr.GPS Dhillon, Director NVBDCP briefed the members that the technical specifications for combi blister packs were formulated for all age groups in the meeting of technical specification committee held on 15.1.2009 and the same were submitted to UNOPS for the procurement. In the pre-bid meeting, some difficulties were encountered by the manufacturers in the CBP with respect to the respective strengths of sulphadoxine pyremethamine tabs. and artesunate tablets. There is need to re-look on the earlier specifications and amend the same after detail discussions by the members.

The draft specifications with proposed strengths were deliberated at length by the members and agreed upon in view of the point that now, the manufacturers would be able to participate in the bidding. The amended technical specifications of CBP for all age groups is placed at annexure-I.

The meeting ended with a vote of thanks.

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2/9/09
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DD(SG), NIMR

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2/9/09
Dr. Dinesh Srivastava
Consultant, RML Hospital

A.K. Pradan
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Sh. A.K. Pradan
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A.K. Kamra
2/9/09
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K.D. Tripathi
2/9/09
Prof. K.D. Tripathi (Rtd.)
Dept. of Pharmacology, MAMC

G.P.S. Dhillon
Dr. GPS Dhillon
Director, NVBDCP

D. Kanungo
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Dr. D. Kanungo
Addl. DG (Stores)

Shiv Lal
Dr. Shiv Lal
Sp. DGHS & Chairman

Annexure - I

Technical Specifications Approved on 31.8.2009

<u>Age groups</u>	<u>Infant i.e. < 1year</u>	<u>1-4 Years</u>	<u>5-8 Years</u>	<u>9-14 Years</u>	<u>Adults</u>
Description of Stores	<p>PINK COLOR Total dose of Artesunate – 75 mg divided over three days, Sulphadoxine pyremethamine – 125 mg + 6.25mg single dose</p> <p>Each Combi Blister Pack : containing 3 tablet of Artesunate (each tablet of Artesunate 25mg strength) and 1 tablet of Sulphadoxine Pyremethamine (125 mg + 6.25mg)</p>	<p>YELLOW COLOR Total dose of Artesunate – 150 mg divided over three days, Sulphadoxine pyremethamine – (500+ 25)mg single dose</p> <p>Each Combi Blister Pack : containing 3 tablets of Artesunate (50 mg each) and 1 tablet of Sulphadoxine Pyremethamine (500+25)mg</p>	<p>GREEN COLOR Total dose of Artesunate – 300 mg divided over three days, Sulphadoxine pyremethamine (750 +37.5) mg single dose</p> <p>Each Combi Blister Pack containing 3 tablets of Artesunate (100mg each) and 1 tablet of Sulphadoxine Pyremethamine (750+ 37.5) mg</p>	<p>RED COLOR Total dose of Artesunate – 450 mg divided over three days, Sulphadoxine pyremethamine – (1000 +50) mg single dose</p> <p>Each Combi Blister Pack containing 6 tablets of Artesunate (3 tablets of 100mg each & 3 tablets of Artesunate 50mg each) and 2 tablets of Sulphadoxine Pyremethamine (500+25) mg each</p>	<p>WHITE COLOR Total dose of Artesunate – 600 mg divided over three days, Sulphadoxine pyremethamine – (1500 +75)mg single dose</p> <p>Each Combi Blister Pack containing 3 tablets of Artesunate (each 200 mg) and 2 tablets of Sulphadoxine Pyremethamine (750+37.5)mg each or 3 tablets of Sulphadoxine Pyremethamine (500+25) mg each</p>
	<p>Each row – No. of tablets</p> <p>First Row (Day 1): One tablet of Artesunate (25 mg) and one tablet of Sulphadoxine-Pyremethamine ((125 mg + 6.25mg)</p> <p>Second Row (Day 2): one tablet of Artesunate (25 mg)</p> <p>Third Row (Day 3): one tablet of Artesunate (25 mg)</p> <p><i>- for infant</i></p>	<p>Each row – No. of tablets:</p> <p>First Row (Day 1): One tablet of Artesunate (50 mg) and One tablet of Sulphadoxine Pyremethamine (500+25)mg</p> <p>Second Row (Day 2): One tablet of Artesunate (50 mg)</p> <p>Third Row (Day 3): One tablet of Artesunate (50mg)</p> <p><i>- for age group 1-4 years</i></p>	<p>Each row – No. of tablets</p> <p>First Row (Day 1): one tablet of Artesunate (100mg) and one tablet of sulphadoxine Pyremethamine (750mg+ 37.5) mg</p> <p>Second Row (Day 2): one tablet of Artesunate (100mg)</p> <p>Third Row (Day 3): one tablet of Artesunate (100mg)</p> <p><i>- for age group 5-8 years</i></p>	<p>Each row –No. of tablets :</p> <p>First Row (Day 1): two tablets of Artesunate (i.e one tablet of 100 mg & one tablet of Artesunate 50mg) and two tablets of Sulphadoxine Pyremethamine (500+25) mg each</p> <p>Second Row (Day 2): two tablets of Artesunate i.e one tablet of 100 mg and one tablet of Artesunate 50mg</p> <p>Third Row (Day 3): two tablets of Artesunate i.e one tablet of 100 mg and one tablet of Artesunate 50mg</p> <p><i>- for age group 9-14 years</i></p>	<p>Each row –No. of tablets:</p> <p>First Row (Day 1): one tablet of Artesunate (200 mg) and two tablets of Sulphadoxine pyremethamine (750+37.5) mg each or three tablets of Sulphadoxine Pyremethamine (500+25) mg each</p> <p>Second Row (Day 2) one tablet of Artesunate (200mg)</p> <p>Third Row (Day 3): one tablet of Artesunate (200 mg)</p> <p><i>- for adults i.e. 15 years & above</i></p>

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A. S.

S. S.

Y. S.

	Tablets Artesunate of above strengths conforming to the specifications as per International Pharmacopoeia, latest version . Tablets Sulfadoxine Pyremethamine Combination: containing above strength (i.e Sulfadoxine I.P. 500 mg and Pyremethamine I.P 25mg per tablet and Sulfadoxine I.P. 750 mg and Pyremethamine I.P 37.5mg per tablet) as per IP latest version.
Shelf Life/ Efficacy	Tablet Artesunate: Two years Tablet Sulfadoxine+ Pyremethamine: three years. Each Pack will bear shelf life of 2 years on the pack with manufacturing and expiry date.
Packing & Marking	All the packs in different groups will have definite colors as indicated above. The tablets will be placed in three rows with transparent top. Each row should be clearly marked as Day 1, Day 2 and Day 3 giving number of tablets in each row. Each pack should indicate dose schedule per kg body weight for both Tablet Artesunate and Tablet Sulphadoxine-Pyremethamine i.e. AS-4 mg/kg body weight and 25mg/ kg bw of sulphadoxine + 1.25 mg per kg bw of pyrimethamine respectively. All tablets should carry the legend "NVBDP" on one side. Marking: Printing/markings on Blister/Catch cover/corrugated box and pack will be as per Drug & Cosmetics Rules. Manufacturing and Expiry dates of Artesunate and Sulfadoxine-Pyremethamine tablets should be written separately on the Blister Pack/Catch Cover. Each Blister Strip will be stuffed in a paper catch cover. 25 Blister Strips will be placed in a pack and 100 such packs will be packed in a corrugated box. Each Blister Strip/Catch Cover/Pack and Box should be marked " NVBDP SUPPLY- NOT FOR SALE".
Final Packing	Stores shall be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.

Alrocha *fknm*

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DR

Yalcha

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

Minutes of the Meeting of Technical Specification Committee held on 22.7.2010 at Nirman Bhawan under the Chairmanship of Dr. D.C. Jain, Special DGHS (ME)

A meeting of the technical specification committee was held on 22.7.2010 at Nirman Bhawan under the Chairmanship of Dr. D.C.Jain, Special DGHS (ME), Dte. GHS (MOHFW) Govt. of India. All members of the committee attended the meeting except Prof. Y. K. Gupta, Head of Pharmacology, AIIMS. Dr. H. S. Rehan, Prof. of Pharmacology, LHMC attended the meeting as special invitee. Dr. C.M.Agrawal and Dr. G.S.Sonal, SAG Officers and Dr. S.N.Sharma Joint Director, NVBDCP assisted the meeting. Dr. C.M. Agrawal SAG Officer presented the agenda on behalf of Director NVBDCP & Member Secretary as he has to attend the DDT Mandate Committee Meeting under the Chairpersonship of Secretary (Health&FW), GOI. The item-wise agenda was discussed.

Agenda Note-I: Reduction in number of tablets to be taken by the patients.

It was mentioned that Directorate of NVBDCP is procuring ACT Combi Blister packs for the treatment of P.falciparum cases. The technical specifications of ACT were finalized in the meeting held on 31.8.2009 (**Annexure – I**). For the age-group of 9-14 Years, the presently available ACT Combi Blister Pack may not be operationally feasible due to the 3 tablets of Artesunate in the ACT Combi Blister Pack. Hence, it has been proposed to reduce the number from three tablets of 50 mg each to single tablet of 150 mg. The members deliberated at length and agreed to the single strength of 150 mg tablet of Artesunate in ACT pack. The no. of Sulpha-doxine Pyremethamine Tablets will remain unchanged.

Age Group 9-14 Years
Each row –No. of tablets :
First Row (Day 1): One tablet of Artesunate (150 mg) and two tablets of Sulphadoxine Pyremethamine (500+25) mg each
Second Row (Day 2): One tablet of Artesunate (150 mg)
Third Row (Day 3): One tablet of Artesunate (150 mg)

There will be no change in the strengths of drugs for other age groups as approved by the last Technical Specification Committee in its meeting held on 31/8/2009.

Agenda-II: Shelf life for Combi Blister Pack (Tablet artesunate + Tab. Sulphadoxine pyremethamine)

The last Technical Specification Committee in its meeting held on 31.08.2009 has approved the following Shelf life / Efficacy of ACT Combi Blister Pack:

Tablet Artesunate: Two years

Tablet Sulfadoxine+ Pyremethamine: three years.

(Handwritten signatures and notes)

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(Handwritten signature: K. Jain)

(Handwritten signature: S. N. Sharma)

(Handwritten signature: C. M. Agrawal)

(Handwritten signature: H. S. Rehan)

(Handwritten signature: G. S. Sonal)

(Handwritten signature: Y. K. Gupta)


(Handwritten signature: D. C. Jain)

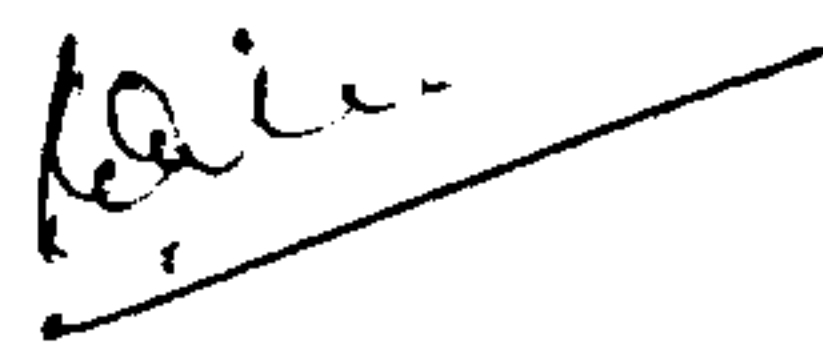
Each Pack will bear shelf life of 2 years on the pack with manufacturing and expiry date."

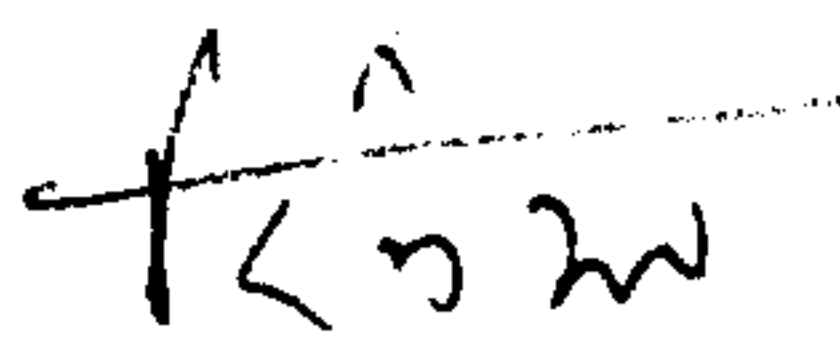
It has been observed in the field that printing of the above version on the pack indicating two periods & expiry create confusion among patients. Therefore, the committee was requested to give approval for printing of following on pack only and not printing of two different periods of expiry:

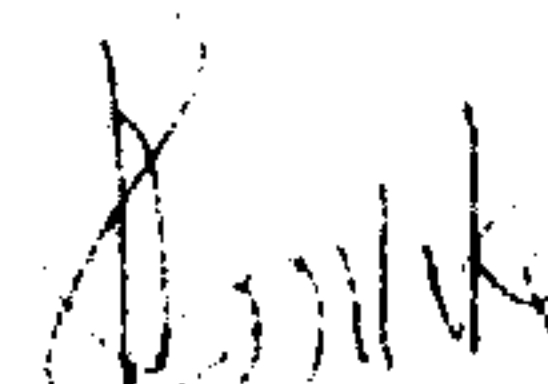
"Each pack will bear shelf life of 2 years with manufacturing & expiry date."


The committee deliberated in detail and agreed to the proposal.


 (Dr. Neena Valecha)
 Deputy Director (SG)
 NIMR

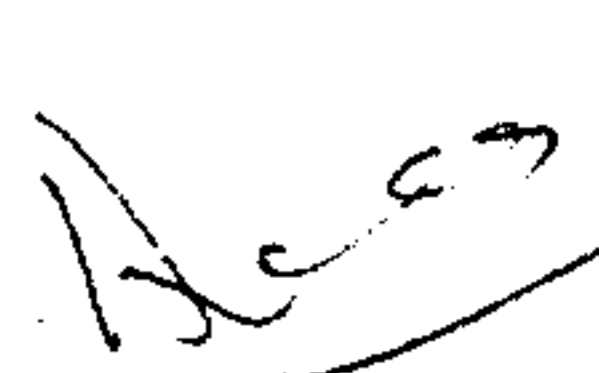

 (Dr. K.D. Tripathi)
 Ex-Professor of Pharmacology
 M A M C



 (Dr. Dinesh Srivastava)
 Consultant (Medicine)
 Dr. RML Hospital

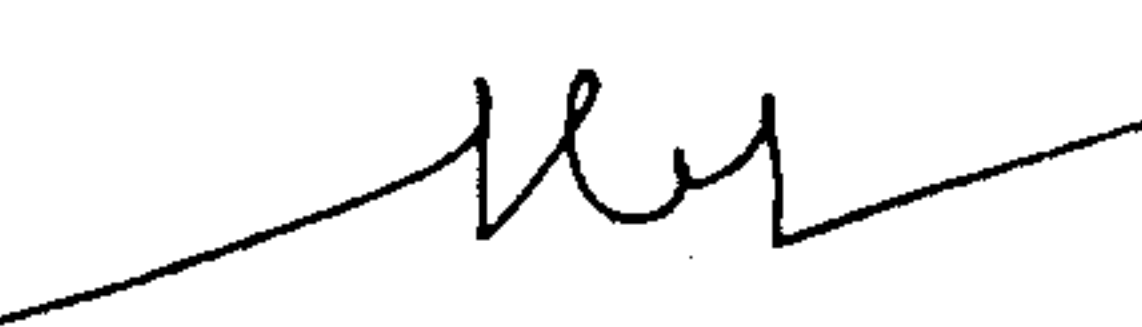

 (Sh. A.B. Ramteke)
 Joint DCG(I)
 CDSCO


 (Sh. A. K. Kamra)
 Director (Procurement)
 Dte. GHS


 (Dr. H.S. Rehan)
 Prof. of Pharmacology,
 LHMC


 (Dr. D. Kanungo)
 Addl. DG (Stores)
 MSO


 (Dr. C. M. Agrawal)
 SAG Officer
 Representing Director (NVBDCP)


 (Dr. Shiv Lal)
 Advisor Public Health
 & Ex. Special DG (PH)


 (Dr. D. C. Jain)
 Special DGHS (ME)
 & Chairman