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

Minutes of the Meeting of Technical Specification Committee held on 12.02.2009 at Nirman Bhawan under the Chairmanship of Dr. Shiv Lal, Special DG (PH)

A meeting of the technical specification committee was held on 12.02.2009 at Nirman Bhawan under the chairmanship of Dr.Shiv Lal, Special DGHS, Govt. of India. Prof. Y.K.Gupta, Deptt. of Pharmacy, AIIMS, Dr. K. D.Tripathi, Professor of Pharmacology (Rtd.), M A M College, Dr. Dinesh Srivastava, Consultant (Medicine), RML Hospital, Sh. Kamra, Director (Procurement) and Dr. Neena Valecha, Deputy Director (SG), NIMR participated in the meeting. Sh. A.K.Pradhan, Asstt. Drugs Controller (I) represented DCG(I). Dr. D. Kanungo, Addl. DG (Stores) could not attend the meeting. Dr. G.P.S.Dhillon, Director NVBDCP and member Secretary briefed the participants about the agenda items for the consideration of the technical specification meeting. The following agenda were put up and deliberated up on 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. As per the suggestion of Technical Specifications Committee on 15.1.2009, UNOPS and HLL were 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. The data / information received from M/s HLL and UNOPS was shared with DCG(I) for comments. A letter from DCG(I) was placed before the committee members by Sh. A.K.Pradhan, Asstt. Drugs Controller (I) after the examination of data / information provided to them. It was mentioned that DCG(I) has no objection in reducing the shelf life of sulphadoxine pyremethamine tablets from 5 years to 3 years. As such, the drug will not be used alone and the shelf life of blister pack of SP with AS is only 2 years.

After the deliberations and based on the the comments of DCG(I), the committed has agreed to reduce the shelf life of Sulphadoxine Pyremethamine tablets from five to three years in the

technical specification of the product. The revised technical specifications are enclosed at **Annexure – I.**

Combi blister packs :

It was also agreed upon that the shelf life of Sulphadoxine Pyremethamine tablets in the combi-blister pack would be 3 years instead of 5 years. Each Pack will bear shelf life of 2 years on the pack with manufacturing and expiry date and the revised specification are enclosed at **Annexure-II.**

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.

As per the suggestion of Technical Specifications Committee, UNOPS and HLL were 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. The data / information received from M/s HLL and UNOPS was shared with DCG(I) for comments.. The data / information received from M/s HLL and UNOPS was shared with DCG(I) for comments. A letter from DCG(I) was placed before the committee members by Sh. A.K.Pradhan, Asstt. Drugs Controller (I) after going the data / information provided to them. It was mentioned that DCG(I) has no objection in reducing the shelf life of Albendazole tablets from 5 years to 3 years as even the original manufacturer i.e. Glaxosmith supplies albendazole tablets through WHO with shelf life of three years. The committee members observed that the shelf life of this item was kept as 5 year as this item was to be procured by the programme first time and no shelf life of the product is mentioned in schedule P. As albendazole is included in the 102 essential drugs listed by Ministry of Chemicals and fertilizers to be procured through PSUs. The problem of shelf life was encountered in the bidding process by M/s HLL as none of the PSUs are manufacturing shelf life of albendazole as 5 years. After the representations from the PSUs through M/s HLL, this agenda was put up to the committee to deliberate. The

members examined the stability data carefully and observed that the 3 years shelf life is sufficient for its use in the programme as no other option is available.

After the deliberations, the committed has agreed to reduce the shelf life of Albednazole tablets from 5 to 3 years in the technical specification of the product. The revised technical specifications are enclosed at **Annexure – III**.

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Deputy Director (SG)

(Dr. K.D.Tripathi)
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(Dr. Y.K.Gupta)
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(Dr. G.P.S.Dhillon)
Director (NVBDCP)

Dr. Shiv Lal
Special DGHS

Annexure – I

The technical specifications already approved by duly constituted technical committee are as under.

Specification of Sulphadoxine Pyremethamine Combination Tablets

Description of Stores	:	Sulphadoxine Pyremethamine Combination Tablets containing Sulphadoxine I. P. 500 mg and Pyremethamine I. P. 25 mg i.e. one single dose as per IP 1996
Delivery Period	:	Completion within 90 days from the date of placement of order
Delivery Terms	:	Free delivery at consignee's place.
Shelf Life/Efficacy	:	**Three Year Life:** The articles would not pass more than 1/6th of their effective life from the date of manufacturing at the time when articles are offered for inspection and the remaining useful life that shall still be left would not be less than 5/6th of total life of five years.
Packing and Marking	:	**Packing:** The tablets should be packed only in aluminum foil taggered top tin sheet/PVC containers. All tablets should carry the legend 'NAMP' on one side. The tablets should first be tightly packed in sealed polythene bag before being placed in tin PVC containers with padding if necessary to avoid rattling of the bags and consequent damage to the tablets. **Marking:** The bottom as well as the Aluminum foil taggered top of the tin containers should be embossed with word "NAMP SUPPLY NOT FOR SALE". The tin should be gold lacquered from outside.
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.
Unit	:	Capacity of tin container: 1000 tablets only
Good Manufacturing Practices	:	The manufacturing facility must confirm GMP
De-registered/debarred/blacklisted	:	The De-registered/debarred/blacklisted firms for product or constituent of the product by Medical Stores Organization (MSO) of Directorate General of Health Services, Ministry of Health & Family Welfare, GOI, New Delhi till the due date of submission of bid, should not participate in bidding.

Annexure –

Proposed Technical Specification for Combi Blister Pack for Different Age Groups

Age groups	Infant i.e. < 1year	1-4 Years	5-8 Years	9-14 Years	Adults
Description of Stores	**PINK COLOR** Each Combi Blister Pack : containing 1½ tablet of Artesunate (50mg) and ¼th tablet of Sulfadoxine + Pyremethamine (500mg) **Each row – No. of tablets** **First Row (Day 1):** ½ tablet of Artesunate (50 mg) and ¼th tablet of Sulfadoxine-Pyremethamine (500 mg) **Second Row (Day 2):** ½ tablet of Artesunate (50 mg) **Third Row (Day 3):** ½ tablet of Artesunate (50 mg) ***- for infant***	**YELLOW COLOR** Each Combi Blister Pack : containing 3 tablets of Artesunate (50 mg) and 1 tablet of Sulfadoxine Pyremethamine (500mg) **Each row – No. of tablets**: **First Row (Day 1):** One tablet of Artesunate (50 mg) and One tablet of Sulfadoxine-Pyremethamine (500mg) **Second Row(Day 2)**:One tablet of Artesunate (50 mg) **Third Row (Day 3):** One tablet of Artesunate (50mg) ***- for age group 1-4 years***	**GREEN COLOR** Each Combi Blister Pack containing 6 tablets of Artesunate (50 mg) and 1½ tablets of Sulfadoxine Pyremethamine (500mg) **Each row – No. of tablets** **First Row (Day 1):** Two tablets of Artesunate (50 mg) and 1½ tablets of sulfadoxine – Pyremethamine (500mg) **Second Row(Day 2)**:Two tablets of Artesunate (50mg) **Third Row (Day 3):** Two tablets of Artesunate (50mg) ***- for age group 5-8 years***	**RED COLOR** Each Combi Blister Pack containing 9 tablets of Artesunate 50 mg and 2 tablets of Sulfadoxine Pyremethamine (500mg) **Each row –No. of tablets** : **First Row (Day 1):** Three tablets of Artesunate (50 mg) and two tablets of Sulfadoxine-Pyremethamine (500mg) **Second Row(Day 2):**Three tablets of Artesunate (50 mg) **Third Row (Day 3)**: Three tablets of Artesunate (50mg) ***- for age group 9-14 years***	**WHITE COLOR** Each Combi Blister Pack containing12 tablet of Artesunate 50 mg and 3 tablets of Sulfadoxine Pyremethamine (500mg) **Each row –No. of tablets:** **First Row (Day 1)**: Four tablets of Artesunate (50 mg) and three tablets of Sulfadoxine-Pyremethamine (500mg) **Second Row (Day 2)** :Four tablets of Artesunate (50 mg) **Third Row (Day 3)**: Four tablets of Artesunate (50 mg) ***- for adults i.e. 15 years & above***
	Tablet Artesunate 50 mg conforming to the specifications as per International Pharmacopoeia,latest version . Tablet Sulfadoxine Pyremethamine Combination: containing Sulfadoxine I.P. 500 mg and Pyremethamine I.P 25mg 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. 4 mg/kg body weight and 25 mg/ body weight respectively. All tablets should carry the legend **"NVBDCP"** on one side. Marking: Printing/marking 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 " **NVBDCP 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.

Annexure - III

Approved Technical Specification for Albendazole (400 mg) tablets.

1.	**Description of Stores**	Albendazole 400 mg tablets as per IP 2007 Specification.
2.	**Shelf Life/Efficacy**	**Three Years Life:-** The drug would have not passed more than 1/6th of their effective life from the date of manufacturing at the time when drug is offered for inspection and remaining useful life that shall still be left would not be less than 5/6th of total five years.
3.	**Packing and Marking**	**Packing:** - One blister strip with aluminum foil should contain 10 tablets and 25 such strips should be packed in one box. **Marking:-** All tablets should carry the legend "NVBDCP" on one side. All strips and boxes should carry label indicating strength of the tablet, NVBDCP and "NOT FOR SALE, OF INDIA SUPPLY". **Labeling:-** Labeling should be made as per Drugs & Cosmetic Rule.
4.	**Final Packing**	Tablets should be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.
5.	**Accounting Unit**	Each accounting Unit will be a strip containing 10 tablets.
6.	**Good Manufacturing Practices**	The manufacturing facility must conform to Schedule M of Drugs & Cosmetic Rules.