

Technical Specification of Combi Blister Packs for malaria for different age group under NVBDCP

<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>
A. Description of Stores	<p style="text-align: center;">PINK COLOR</p> <p>Total dose of Artesunate – 75 mg divided over three days, Sulphadoxine pyremethamine (250 mg + 12.5mg) 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 (250 mg + 12.5 mg)</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 ((250 mg + 12.5 mg)</p> <p>Second Row (Day 2): one tablet of Artesunate (25 mg)</p>	<p style="text-align: center;">YELLOW COLOR</p> <p>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>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 style="text-align: center;">GREEN COLOR</p> <p>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>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 style="text-align: center;">RED COLOR</p> <p>Total dose of Artesunate – 450 mg divided over three days, Sulphadoxine pyremethamine (1000 +50) mg single dose</p> <p>Each Combi Blister Pack containing 3 tablets of Artesunate 150 mg and 2 tablets of Sulfadoxine Pyremethamine (500mg+ 25mg)</p> <p>Each row –No. of tablets</p> <p>First Row (Day 1): One tablets of Artesunate (150 mg) and two tablets of Sulphadoxine Pyremethamine 500+25 mg) mg each</p> <p>Second Row(Day 2): One tablet of Artesunate (150 g)</p>	<p style="text-align: center;">WHITE COLOR</p> <p>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 (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 (25 mg)</p> <p>CAUTION:</p> <p><i>The blister should be superscribed that SP is not to be given to children under 5 months and should be treated with alternate ACTs.</i></p>	<p>Third Row (Day 3): One tablet of Artesunate (50mg)</p> <p><i>- for age group 1-4 years</i></p>	<p>Third Row (Day 3): one tablet of Artesunate (100mg)</p> <p><i>- for age group 5-8 years</i></p>	<p>Third Row (Day 3): One tablet of Artesunate (150 mg)</p> <p><i>- for age group 9-14 years</i></p>	<p>Third Row (Day 3): one tablet of Artesunate (200 mg)</p> <p><i>- for adults i.e. 15 years & above</i></p>
<p>Tablets Artesunate of above strengths 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.</p>					
<p>B. Shelf Life/ Efficacy</p>	<p>Tablet Artesunate: Two years</p> <p>Tablet Sulfadoxine+Pyremethamine two years.</p> <p>Each Pack will bear shelf life of 2 years on the pack with manufacturing and expiry date.</p>				

<p>C. Packing & Marking</p>	<p>All the packs in different groups will have definite colors as indicated above.</p> <p>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.</p> <p>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.</p> <p>All tablets should carry the legend “NVBDCP” on one side.</p> <p>Marking: Printing/marketing on Blister/Catch cover/corrugated box and pack will be as per Drug & Cosmetics Rules.</p> <p>Manufacturing and Expiry dates of Artesunate and Sulfadoxine-Pyremethamine tablets should be written separately on the Blister Pack/Catch Cover.</p> <p>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”.</p>
<p>D. Final Packing</p>	<p>Stores shall be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.</p>