

Technical Specification of Combi Blister Packs of ACT-SP for different age group under NCVBDC

<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>
Age-group wise colour code of Combi Blisters =>	PINK COLOR	YELLOW COLOR	GREEN COLOR	RED COLOR	WHITE COLOR
Description of Drug / product A)	Total dose of Artesunate –75 mg divided over three days, Sulphadoxine Pyremethamine (250 mg + 12.5mg) single dose Each Combi Blister Pack : containing 3 tablet of Artesunate (each tablet of Artesunate 25mg strength) and 1 tablet of Sulphadoxine Pyremethamine (250mg + 12.5mg)	Total dose of Artesunate – 150mg divided over three days, Sulphadoxine Pyremethamine – (500mg+25mg) single dose Each Combi Blister Pack : containing 3 tablets of Artesunate (50 mg each) and 1 tablet of Sulphadoxine Pyremethamine (500mg+25mg)	Total dose of Artesunate – 300mg divided over three days, Sulphadoxine Pyremethamine (750mg+37.5mg) single dose Each Combi Blister Pack containing 3 tablets of Artesunate (100mg each) and 1 tablet of Sulphadoxine Pyremethamine (750mg+ 37.5mg)	Total dose of Artesunate – 450mg divided over three days, Sulphadoxine Pyremethamine (1000mg+50mg) single dose Each Combi Blister Pack containing 3 tablets of Artesunate 150 mg and 2 tablets of Sulfadoxine Pyremethamine (500mg+ 25mg)	Total dose of Artesunate – 600mg divided over three days, Sulphadoxine Pyremethamine – (1500+75)mg single dose Each Combi Blister Pack containing 3 tablets of Artesunate (each 200mg) and 2 tablets of Sulphadoxine Pyremethamine (750+37.5)mg each or 3 tablets of Sulphadoxine Pyremethamine (500mg+25mg) each

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	First Row (Day 1) One tablet of Artesunate (25 mg) and one tablet of Sulphadoxine-Pyremethamine (250 mg +12.5 mg)	First Row (Day 1) One tablet of Artesunate (50 mg) and One tablet of Sulphadoxine Pyremethamine (500+25mg)	First Row (Day 1) One tablet of Artesunate (100mg) and one tablet of sulphadoxine Pyremethamine (750mg+ 37.5)mg	First Row (Day 1) One tablets of Artesunate (150 mg) and two tablets of Sulphadoxine Pyremethamine (500+25mg)	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
B) Each Row - No. of tablets :	Second Row (Day 2) One tablet of Artesunate (25mg)	Second Row (Day 2) One tablet of Artesunate (50mg)	Second Row (Day 2) One tablet of Artesunate (100mg)	Second Row (Day 2) One tablet of Artesunate (150mg)	Second Row (Day 2) One tablet of Artesunate (200mg)
	Third Row (Day 3) One tablet of Artesunate (25mg)	Third Row (Day 3) One tablet of Artesunate (50mg)	Third Row (Day 3) One tablet of Artesunate (100mg)	Third Row (Day 3) One tablet of Artesunate (150mg)	Third Row (Day 3) One tablet of Artesunate (200mg)
CAUTION:	The blister strip should be superscribed that SP not to be given to children under 5 months.	-	-	-	-

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C) Pharmacopoeial Requirement	<p>Tablets Artesunate 25mg, 50mg, 100mg, 150mg & 200mg containing Artesunate IP 25mg, 50mg, 100mg, 150mg & 200mg respectively.</p> <p>Tablets Sulfadoxine Pyremethamine Combination: containing above strength (i.e Sulfadoxine I.P. 250mg and Pyremethamine I.P. 12.5mg per tablet; 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>The product must be accompanied by in-house test reports of the batch supplied. <i>(IP stands for Indian Pharmacopoeia)</i></p>
D) Shelf Life/ Efficacy	<p>Tablet Artesunate: Minimum Two years</p> <p>Tablet Sulfadoxine + Pyremethamine: Minimum two years.</p> <p>Each Pack will bear shelf life of minimum 2 years on the pack with manufacturing and expiry date.</p> <p>At least 5/6th of the minimum shelf life must remain at the time of delivery to the consignee. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.</p>
E. Packing & Marking	<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>Marking: Printing/markings on Blister/Catch cover/corrugated box and pack will be as per Drug & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.</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 corrugated Box should be marked "NVBDGP, Dte.GHS SUPPLY- NOT FOR SALE" in contrasting colour.</p>

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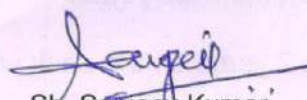
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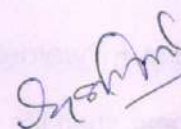
F. Labelling	The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.
G. Final Packing	Supplies shall be securely packed in normal trade packing of corrugated boxes to avoid loss or damage during the transit by rail/road.


Technical Specifications approved as on 15th March 2023

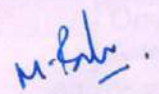

Dr. Roop Kumari
Representative-WHO-India

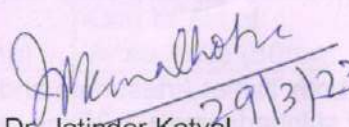

Sh. Manoj Kumar Sinha,
Deputy Secretary
(Procurement), MoHFW

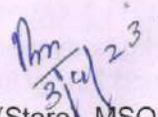

Sh. Sanjeev Kumar
DDC (I), CDSCO



Dr. Manik Shankaroo,
Asst. Prof & HOD
(Pharmacology),
RML, Delhi


Dr. Rinku Sharma
Jt. Dir (NCVBDC)

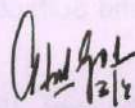

Dr. Manju Rahi
Director-In-Charge, NIMR
(ICMR)


Dr. Jatinder Katyal
Prof. (Pharmacology),
AIIMS, Delhi
29/3/23


DDG (Store), MSO
3/4/23


Dr. Tanu Jain
Director (NCVBDC)

Director (Procurement),
Dte.GHS, MoHFW


Prof. (Dr.) Atul Goel, DGHS,
Dte.GHS, MoHFW & Chairperson