

Technical Specification for pharmaceutical product: co-formulated tablet of Artemether + Lumefantrine is as follows:

Aspect	Requirement																									
<b>1. FINISHED PHARMACEUTICAL PRODUCT (FPP)</b>																										
<b>1.1 Product identification and description</b>	<p><b>ARTEMETHER– LUMEFANTRINE co-formulated tablet for oral administration</b></p> <p><b>ARTEMETHER 20 mg</b> <b>LUMEFANTRINE 120 mg</b></p> <p><b>Recommended regimen by weight and age</b> Artemether 20 mg and Lumefantrine 120 mg Tablets should be yellow coloured, circular, uncoated, flat faced, bevelled edged, matt finished tablets with a break line on one side and plain on the other side.</p> <p>Note: For 6 months to &lt;3 years age group, dispersible tablets (DT) are preferable (WHO prequalification is mandatory for GF supported schedule).</p> <p>The packing should be as under for different age groups based on Kg body weight.</p> <table border="1" data-bbox="758 716 1761 1127"> <thead> <tr> <th data-bbox="758 716 1066 813">Co-formulated tablet</th> <th data-bbox="1066 716 1255 813">5–14 kg (6 months- &lt;3 years)</th> <th data-bbox="1255 716 1434 813">15–24 kg (≥ 3–8 years)</th> <th data-bbox="1434 716 1619 813">25–34 kg (≥ 9–14 years)</th> <th data-bbox="1619 716 1761 813">&gt; 34 kg (&gt; 14 years)</th> </tr> </thead> <tbody> <tr> <td data-bbox="758 813 1066 976"><b>Dose</b></td> <td data-bbox="1066 813 1255 976">20 mg/ 120 mg twice daily for 3 days</td> <td data-bbox="1255 813 1434 976">40 mg /240 mg twice daily for 3 days</td> <td data-bbox="1434 813 1619 976">60 mg /360 mg twice daily for 3 days</td> <td data-bbox="1619 813 1761 976">80 mg /480 mg twice daily for 3 days</td> </tr> <tr> <td colspan="5" data-bbox="758 976 1761 1008" style="text-align: center;"><b>Pack size</b></td> </tr> <tr> <td data-bbox="758 1008 1066 1089">20 mg Artemether +120 mg Lumefantrine</td> <td data-bbox="1066 1008 1255 1089" style="text-align: center;">6</td> <td data-bbox="1255 1008 1434 1089" style="text-align: center;">12</td> <td data-bbox="1434 1008 1619 1089" style="text-align: center;">18</td> <td data-bbox="1619 1008 1761 1089" style="text-align: center;">24</td> </tr> <tr> <td data-bbox="758 1089 1066 1127">Colour of the pack</td> <td data-bbox="1066 1089 1255 1127" style="text-align: center;">Yellow</td> <td data-bbox="1255 1089 1434 1127" style="text-align: center;">Green</td> <td data-bbox="1434 1089 1619 1127" style="text-align: center;">Red</td> <td data-bbox="1619 1089 1761 1127" style="text-align: center;">White</td> </tr> </tbody> </table>	Co-formulated tablet	5–14 kg (6 months- <3 years)	15–24 kg (≥ 3–8 years)	25–34 kg (≥ 9–14 years)	> 34 kg (> 14 years)	<b>Dose</b>	20 mg/ 120 mg twice daily for 3 days	40 mg /240 mg twice daily for 3 days	60 mg /360 mg twice daily for 3 days	80 mg /480 mg twice daily for 3 days	<b>Pack size</b>					20 mg Artemether +120 mg Lumefantrine	6	12	18	24	Colour of the pack	Yellow	Green	Red	White
Co-formulated tablet	5–14 kg (6 months- <3 years)	15–24 kg (≥ 3–8 years)	25–34 kg (≥ 9–14 years)	> 34 kg (> 14 years)																						
<b>Dose</b>	20 mg/ 120 mg twice daily for 3 days	40 mg /240 mg twice daily for 3 days	60 mg /360 mg twice daily for 3 days	80 mg /480 mg twice daily for 3 days																						
<b>Pack size</b>																										
20 mg Artemether +120 mg Lumefantrine	6	12	18	24																						
Colour of the pack	Yellow	Green	Red	White																						
<b>1.2 Packaging</b>																										
Protective function	All packaging must be designed to protect the dosage form and to render it suitable for the intended use throughout the stated shelf-life. ACTs should be prepackaged into course-of-therapy pack sizes, containing all the doses of a treatment course in a well-designed blister pack, with the individual doses in easily recognizable subunits. All packaging must be tamper-evident. Products must be supplied in the same primary, secondary and tertiary packaging in terms of material and size and with the same container or closure system as that approved.																									

Aspect	Requirement
<b>1.2.1 Primary Packaging (in direct contact with the dosage form)</b>	
Packaging materials	Primary packaging materials must be considered safe for use with the dosage form and for the intended route of administration. Containers must not interact with contents or have been adversely affected by manufacturing processes.
Marking	Primary packs should be marked as follows: (specify). Specify any required marking, e.g. <b>“for NVBDCP use only – not for sale”</b> . <b>And not recommended during the first trimester of pregnancy and for children weighing &lt; 5 kg (or &lt;6 months of age).</b>
Packaging Type	The primary package should contain 10 courses of the specified age group.
<b>1.2.2. Secondary Packaging</b>	
Packaging type	Each box containing 10 primary packages (10*10)of the specified age group.
<b>1.2.3 Tertiary Packaging</b>	
Packaging type	Each box containing 10 secondary packages (100*10)of the specified age group.
<b>1.2.4 Other Packaging</b>	
Batch segregation	Each unit of packaging should contain products from no more than one batch of pharmaceuticals.
<b>1.3 Labeling</b> The following label information is required on all unit packs:	
Label	All FPPs must be labeled as required by national legislation in the country.
Strength	Amount of each API per dosage unit, per unit of weight,
Dosage form	Pharmaceutical dosage form (e.g. tablet,)
Excipients	List any excipient contained in the product known to have a recognized action or effect (as included in guideline on Excipients in the label and package leaf let of medicinal products for human uses).
Pharmacopoeial standard	Pharmacopoeial standard as described in the International, British Pharmacopeia/ Indian Pharmacopeia if available. The current edition should always apply.
Quantity	Net quantity per unit pack labeled on that unit pack (primary, secondary, tertiary)
<b>1.4 Storage Instructions</b>	
Storage instructions	Storage instructions and any special storage or handling precautions
Storage conditions during transport	Recommended temperature and humidity conditions during transport
<b>1.5 Instructions for use</b>	

Aspect	Requirement
	Instructions for use and warnings and precautions that may be necessary (e.g. <b>not recommended during the first trimester of pregnancy and for children weighing &lt; 5 kg (or &lt;6 months of age).</b> )
<b>1.6 Batch Number</b>	
Batch number	Batch number assigned by the manufacturer
<b>1.7 Manufacture date</b>	
	Manufacture date in an uncoded form
<b>1.8 Expiry date</b>	
	Expiry date in an uncoded form, preferably in the format MM/YYYY. Four digits must be used for the year.
<b>1.9 Instructions for storage after opening</b>	
	Limited shelf-life after the primary package is opened, if applicable, should be super scribed.
<b>1.10 Product Information</b>	
Patient information leaflet (package insert)	A detailed insert or patient information leaflet must be included within the secondary package or attached to the primary pack. The manufacturer's name and license number must be indicated on the package insert.
Storage conditions	Recommended temperature and humidity during transport, storage and use, as determined in stability studies, must be stated on the package insert, giving both lower and upper limits, when applicable.
<b>1.11 Quality Control Standards and compliance with specifications</b>	
Pharmacopoeial monograph	The product must comply with specific monographs of the International/ British pharmacopoeia/ Indian Pharmacopoeia. Any additional specifications must be provided.
WHO Pre Qualified Product or Authorization by Stringent Regulatory Authority	Product should be either WHO-prequalified ( <b>Mandatory for GF supported schedule</b> ) or have marketing authorization for use in the country

<b>1.12 Shelf life</b>	
Shelf-life	Minimum 24 months. 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.
<b>1.13 Active Pharmaceutical Ingredient (API)</b>	
GMP	A GMP certificate should be supplied for each source site of APIs.
Certification	API(s) must be authorized for use in pharmaceutical products with marketing authorization in the country of manufacture

( Dr. (Mrs. Jatinder Katyal)  
Additional Professor, Pharmacology,  
AIIMS

(Dr. Anup Anvikar)  
Scientist-E, NIMR

(Mr. Sanjeev Kumar)  
Assistant Drug Controller (I)  
Office of DCG(I)

(Dr. Alok Mathur)  
CMO, Additional DG (Store)

(Mr. Gaurav Sharma)  
Deputy Director (Procurement),  
Dte. GHS

(Dr. A. C. Dhariwal)  
Director, NVBDCP,  
Member Secretary

(Dr.L.S.Chauhan)  
Director,  
NCDC, Dte. GHS

(Dr. S. Y. Kothari)  
Chairman & Special DGHS (PH),  
Dte. GHS, MOH & FW