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

<table>
<tr><th>Aspect</th><th>Requirement</th></tr>
<tr><td colspan="2">1. FINISHED PHARMACEUTICAL PRODUCT (FPP)</td></tr>
<tr><td>1.1 Product identification and description</td><td>
ARTEMETHER– LUMEFANTRINE co-formulated tablet for oral administration

ARTEMETHER 20 mg
LUMEFANTRINE 120 mg
Recommended regimen by weight and age 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.

Note: For 6 months to <3 years age group, dispersible tablets (DT) are preferable (WHO prequalification is mandatory for GF supported schedule).

The packing should be as under for different age groups based on Kg body weight.
<table>
<tr><th>Co-formulated tablet</th><th>5–14 kg (6 months-<3 years)</th><th>15–24 kg (≥ 3–8 years)</th><th>25–34 kg (≥ 9–14 years)</th><th>> 34 kg (> 14 years)</th></tr>
<tr><td>Dose</td><td>20 mg/ 120 mg twice daily for 3 days</td><td>40 mg /240 mg twice daily for 3 days</td><td>60 mg /360 mg twice daily for 3 days</td><td>80 mg /480 mg twice daily for 3 days</td></tr>
<tr><td></td><td colspan="4">Pack size</td></tr>
<tr><td>20 mg Artemether +120 mg Lumefantrine</td><td>6</td><td>12</td><td>18</td><td>24</td></tr>
<tr><td>Colour of the pack</td><td>Yellow</td><td>Green</td><td>Red</td><td>White</td></tr>
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</td></tr>
<tr><td colspan="2">1.2 Packaging</td></tr>
<tr><td>Protective function</td><td>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.</td></tr>
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Aspect	Requirement
1.2.1 Primary Packaging (in direct contact with the dosage form)	
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. **"for NVBDCP use only – not for sale"**. **And not recommended during the first trimester of pregnancy and for children weighing < 5 kg (or <6 months of age).**
Packaging Type	The primary package should contain 10 courses of the specified age group.
1.2.2. Secondary Packaging	
Packaging type	Each box containing 10 primary packages (10*10)of the specified age group.
1.2.3 Tertiary Packaging	
Packaging type	Each box containing 10 secondary packages (100*10)of the specified age group.
1.2.4 Other Packaging	
Batch segregation	Each unit of packaging should contain products from no more than one batch of pharmaceuticals.
1.3 Labeling 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)
1.4 Storage Instructions	
Storage instructions	Storage instructions and any special storage or handling precautions
Storage conditions during transport	Recommended temperature and humidity conditions during transport
1.5 Instructions for use	

Aspect	Requirement
Instructions for use and warnings and precautions that may be necessary (e.g. **not recommended during the first trimester of pregnancy and for children weighing < 5 kg (or <6 months of age).**	
1.6 Batch Number	
Batch number	Batch number assigned by the manufacturer
1.7 Manufacture date	Manufacture date in an uncoded form
1.8 Expiry date	Expiry date in an uncoded form, preferably in the format MM/YYYY. Four digits must be used for the year.
1. 9 Instructions for storage after opening	Limited shelf-life after the primary package is opened, if applicable, should be super scribed.
1.10 Product Information	
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.
1.11 Quality Control Standards and compliance with specifications	
Pharmacopoeial monograph	The product must comply with specific monographs of the International/ British pharmacopoeia/ Indian Pharmacopeia. Any additional specifications must be provided.
WHO Pre Qualified Product or Authorization by Stringent Regulatory Authority	Product should be either WHO-prequalified (**Mandatory for GF supported schedule**) or have marketing authorization for use in the country

1.12 Shelf life	
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.
1.13 Active Pharmaceutical Ingredient (API)	
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

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