

Technical Specification of co-formulated tablet of Artemether + Lumefantrine (ACT-AL) under NCVBDC

Aspect	Requirement			
1. FINISHED PHARMACEUTICAL PRODUCT (FPP)				
1.1 Product identification and description	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 abreak line on one side and plain on the other side.			
	The packing should be as under for different age groups based on Kg body weight.			
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)
Dose	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
Pack size				
20 mg Artemether +120mg Lumefantrine	6	12	18	24
Colour of the pack	Yellow	Green	Red	White
Note: For 6 months to <3 years age group, Artemether 20mg and Lumefantrine 120mg Tablets to be procured either in dispersible formulation or dry syrup. For dry syrup, dosage to be given as per the recommended dose only.				

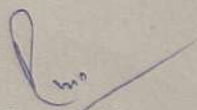
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2 Packaging	
Protective function	All packaging must be designed to protect the dosage form and to render it suitable for the intended use throughout the stated shelf-life. ACTs should be prepackaged into course-of-therapy pack sizes, containing all 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.
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.
2.2 Primary Packaging	
Packaging Type	The primary package should contain 10 courses of the specified age group.
2.3 Secondary Packaging	
Packaging type	Each box containing 10 primary packages (10*10) of the specified age group.
2.4 Tertiary Packaging	
Packaging type	Each box containing 10 secondary packages (100*10) of the specified age group.
Marking	Primary, Secondary and Tertiary packaging should be marked as follows (specify): "NVBDCP, Dte.GHS SUPPLY- NOT FOR SALE". And not recommended during the first trimester of pregnancy and for children weighing < 5 kg (or <6 months of age) in contrasting colour.
Storage conditions during transport	Recommended temperature and humidity conditions during transport as per IP recommendations of the Product.
Labeling	The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.
3. Instructions for use:	
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)).	
4. 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.

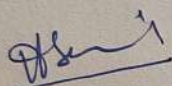
10-1/2018-19/NVBDCP(P&S)Tech.Specification

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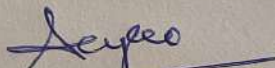
Storage & use	As determined in stability studies, must be stated on the package insert, giving both lower and upper limits, when applicable.
5. Quality Control Standards and compliance with specifications	
Pharmacopoei almonograph	The product must comply with Indian pharmacopoeia, latest version and must be accompanied by in-house test report of the batch supplied.
6. 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 shelflife in the offered package.

Technical Specifications approved as on 03 October 2022


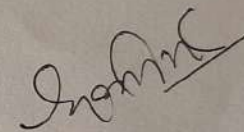
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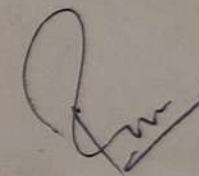
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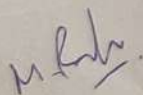
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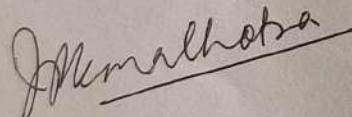
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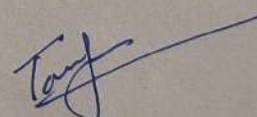
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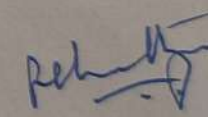
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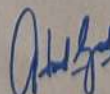
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