



**PRISM INDUSTRIES PVT. LTD.**

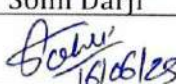
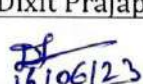
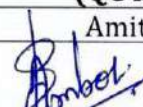
A WHO-GMP Certified Company  
(Formerly known as Prism Industries Ltd.)

**TYPICAL CERTIFICATE OF ANALYSIS**

<b>Product Name</b>	: Artemether IP	Page 1 of 1	
<b>Reference</b>	: Indian Pharmacopeia-2018		
<b>Manufactured By</b>	: Prism Industries Pvt. Ltd.	<b>Product code</b>	: ART
<b>Batch Size</b>	: 100.000 Kg	<b>Self Life (Retest Date)</b>	: 3 year

Sr.No	Test	Specification	Result
1	Appearance	A white crystals or a white crystalline powder.	A white crystalline powder.
2	Solubility	Very soluble in Dichloromethane and acetone; Freely soluble in Ethyl acetate and Practically insoluble in water	Complies
3	Identification B, C & D	B) <b>By HPLC:</b> The retention time of Artemether peak should be similar with standard.	Complies
		C) <b>By chemical test :</b> Yellow colour Should be produced.	Complies
		D) <b>By Chemical test :</b> Pink colour Should be produced.	Complies
4	Specific Optical Rotation	+166.0 <sup>0</sup> To +173.0 <sup>0</sup>	+ 168.91 <sup>0</sup>
5	Related Substance By HPLC		
5.1	Any single Impurity	Not more than 0.5 %	0.14%
5.2	Not more than one such peak	Not more than 0.25 %	0.08%
5.3	Total Impurity	Not more than 1.0 %	0.28%
6	Loss on drying	NMT 0.5 %	0.29%
7	Sulphated ash	Not more than 0.1 %	0.03%
8	Assay (BY HPLC)	97.0 % to 102.0 %	99.88%

REMARK: As opinion of under signed product is Complies / Does not Complies as per Prescribe IP-2018.

	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
Name	Sohil Darji	Dixit Prajapati	Amit Tamboli
Sign & Date	 16/06/23	 16/06/23	 16/06/23

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