

**TYPICAL CERTIFICATE OF ANALYSIS**

Product : Artemether Ph.Int.	Page 1 of 1
Reference : International Pharmacopoeia	
Manufactured By : Prism Industries Pvt Ltd.	Product code : ART
Self Life (Retest Date) : 3 years	

Sr.No	Test	Specification	Result
1	Appearance	White crystals or a white, crystalline powder.	White crystalline powder.
2	Solubility	Practically insoluble in water; very soluble in dichloromethane and acetone; freely soluble in ethyl acetate and dehydrated ethanol .	Complies
3	Identification B, C & D	B) By TLC: The principal spot obtained with solution D corresponds in position, appearance and intensity with that obtain with solution E. C) By chemical test :Yellow colour Should be produced. D) By Chemical test : Pink colour Should be produced.	Complies Complies Complies
4	Specific Optical Rotation	+166.0° To +173.0°	+ 171.42°
5	Melting Point	86.0°C To 90.0°C	87.8°C
6	Related Substance by HPLC		
6.1	Any single Impurity	Not more than 0.5%	0.12%
6.2	Not more than one such peak	Not more than 0.25%	0.08%
6.3	Total Impurity	Not more than 1.0%	0.28%
7	Loss on drying	NMT 0.5%	0.42%
8	Sulphated ash	Not more than 0.10%	0.07%
9	Assay (BY HPLC) on dry basis	97.0 % to 102.0%	99.67%

REMARK : As opinion of under signed product is Complies / Does not Complies as per Ph.Int.

	Prepared By (QC Chemist)	Checked By (QC Sr. Chemist)	Approved By (QC In charge)
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Sign & Date	 10/01/25	 10/01/25	 10/01/25

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