RAY LIFE SCIENCES

Registered Office:
Ray House, HIG NO-2000, Next to
Yelahanka Newtown, Police Station,
Yelahanka Newtown, Bengaluru-560 064

CERTIFICATE OF ANALYSIS

Generic Name	: **ARTEMETHER INJECTION 80 MG/ML**		
Brand Name	: **Falcismart 80**	**Product Code**	: AR
Batch Number	: **ARA26006**	**Batch Size**	: 50 LTS
Mfg. Date	: AUG.2026	**Exp. Date**	: JUL.2029
A.R.No.	: RLS/FP/260472	**Specification No.**	: FPS009-02
Date of Sampling	: 06/08/2026	**Completed Date**	: 12/10/2026

Sr. No.	Test Parameter	Method	Specification Limits	Results
1.	Description	Ph.Int.	A clear, colourless or almost colourless, oily solution filled in glass container..	A clear, colourless oily solution filled in USP type-I, 1ml amber ampoule with red ring
2.	Identification A	Ph.Int.	The Infrared absorption spectrum is concordant with the spectrum obtained from Artemether RS or with the Reference spectrum of Artemether	Complies
	Identification B	Ph.Int.	The principal spot obtained with the Solution D corresponds in position, appearance and intensity with that obtained with Solution E.	Complies
	Identification C	Ph.Int.	A pink colour is produced.	Complies
3.	Extractable volume	IH	NLT nominal volume	1.0ml
4.	Particulate matter	IH	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
5.	Related substances	Ph.Int.	The area of secondary peak is NMT 0.5%	**0.291%**
			Any one secondary peak is NMT 0.25%	**Not Detected**
			The sum of all secondary peak is NMT 1.0%	**0.291%**

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6.	Assay (Each ml of solution contains 80 mg Artemether)	Ph.Int.	NLT 90.0% and NMT 110.0%	**99.6% (79.7090 mg/ml)**
7.	BET	Ph.Int.	NMT 1.56 IU/ mg	Less than 0.78 EU/mg
8.	Sterility	IH	Should be sterile	Sterile

REMARK.: The product complies as per Ph. Int and In-house specification

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Department	Quality Control	Quality Control	Quality Control	Quality Assurance
Name	Sangeeta.G	Sumit Kumar	Manoj Kr Ranjpat	Pandit Patil
Designation	User Dept./ QC	Reviewer / QC	Dept. Head / Designee	Head QA / Designee
Sign & Date	12/10/2026	12/10/2026	12/10/2026	12/10/2026