

### CERTIFICATE OF ANALYSIS

<b>Generic Name</b>	Artemether Injection 80 mg/ml, 1 ml		
<b>Brand Name</b>	Falcismart 80	<b>Product Code</b>	AR
<b>Batch No.</b>	ARA25006	<b>Batch Size</b>	60 Liters
<b>Mfg. Date</b>	OCT.2025	<b>Exp. Date</b>	SEP.2028
<b>Date of Sampling</b>	22/11/2025	<b>Completed Date</b>	22/11/2025
<b>A. R. No.</b>	RLS/FP/250341	<b>Specification No.</b>	FPS009-02

Sr. No.	Tests	Method	Specification	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.	1.0 ml
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%	Not detected
			Any one secondary peak is NMT 0.25%	Not detected
			The sum of all secondary peak is NMT 1.0%	Not detected
6	Assay (Each ml of solution contains 80 mg Artemether)	Ph.Int	NLT 90.0% and NMT 110.0%	99.1 % (79.292 mg/ml)
7	BET	Ph.Int	NMT 1.56 IU/ mg	Less than 0.78 EU/mg
8	Sterility	IH	Should be sterile	Sterile

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

	Prepared by	Reviewed by	Approved by	Authorized by
<b>Department</b>	Quality Control	Quality Control	Quality Control	Quality Assurance
<b>Name</b>	Sudeep	Sumit Kumar	Samjiv Kumar	Pandit Patil
<b>Designation</b>	Trainee Chemist	Executive	Manager	Manager
<b>Signature</b>				
<b>Date</b>	22/11/2025	22/11/2025	22/11/2025	22/11/2025