

CERTIFICATE OF ANALYSIS

Product: ARTESUNATE IP			Page 1 o	
Drugs License No.: G/2	25/2653	A. R. No.:	: A/ARS/016/24	
Batch No.	: ARS32403003	Mfg. Date	: FEB-2024	
Release Batch Qty	: 20.00 Kgs.	Exp. Date	: JAN-2028	

R. 10.	TEST	RESULTS	SPECIFICATION
1.	DESCRIPTION	A White crystalline powder	A White crystalline powder
2.	SOLUBILITY	Complies	Soluble in ethyl acetate, practically insoluble in petroleum ether.
3.	IDENTIFICATION IR Spectrophotometry	Complies	The spectrum of the sample should be concordant with spectrum of working standard.
4.	рН	4.1	Between 3.5 to 4.5
5.	OPTICAL ROTATION	+5.68°	Between +4.5° to +6.5°
	RELATED SUBSTANCE	S (by HPLC)	
	Impurity-A	0.18%	Not more than 1.0%
6.	Impurity-B	0.12%	Not more than 0.5%
	Impurity-C	NOT DETECTED	Not more than 0.2%
	Total impurity	0.30%	Not more than 2.0%
7.	HEAVY METAL	Complies	Not more than 20 ppm
8.	SULPHATED ASH	0.08%	Not more than 0.1%
9.	LOSS ON DRYING	0.21%	Not more than 0.5%
10.	. ASSAY BY HPLC 99.54%		Between 97.0% to 102.0% (%w/w) On Dried basis

Prepared By: QC Officer

Sign/Date:

Checked By: QC Head

Sign/Date:

Checked By: QA Head

Sign/Date: 04/03/2024