

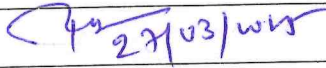




KESAR DRUGS PVT LTD
Khewat 89, Khatoni 108, Khasra No.:8/17/2 3-16, 18 10-0, Haryoli,
Raipur Rani, District-Panchkula, State-Haryana, India -134204
QUALITY CONTROL
CERTIFICATE OF ANALYSIS OF FINISH PRODUCT

Product Name	ARTEFIT Injection	A. R No.	KDPL/QC/FG/25/0017
Generic Name	Artesunate Injection IP 60 mg	Batch Size	2070 vials
Mother Batch	DATB5001	Marketed By	Oncofit solutions Pvt. Ltd
Child Batch	DATB5001C	Sampling Date	12/03/2025
Sample Quantity	77 No's	Mfg. Date	02/2025
Date of Analysis	12/03/2025	Exp. Date	01/2027
Specification No.	FP/ATS-02/SPEC/003-00	Standard Test Procedure No.	FP/ATS-02/SPEC/003-00
Mfg. Lic No.	MLF282024HR000008	Date of Release	27/03/2025

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	A white or almost white crystalline powder filled in 7.5 ml clear moulded glass vial type - III closed with rubber plug and sealed with red colour flip off aluminium seal.	A white or almost white crystalline powder filled in 7.5 ml clear moulded glass vial type -III closed with rubber plug and sealed with red colour flip off aluminium seal.
2.	Identification:	First Identification B, C & D Second Identification A	
	A) By IR	Compare the spectrum with that obtained with Artesunate WS or with the reference spectrum of Artesunate.	Complies
	B) By TLC	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution.	Not Applicable
	C) By chemically	A light red violet colour is produced.	Not Applicable
	D) By chemically	A reddish – brown colour is produced.	Not Applicable

	Prepared By	Checked By	Approved By
NAME	Ansh	Rajon	John Carlos
DESIGNATION	Senior officer	Executive	Head - QC
SIGN & DATE	 27/03/2025	 27/03/2025	 27/03/2025



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3.	Average Fill Weight	Theoretical filled weight \pm 5%	60.69 mg
4.	Uniformity of Fill Weight	Observed Average filled weight \pm 10%	Min= -4.76% Max= +4.30%
5.	Water	NMT 0.5% w/w	0.031%
6.	Related substances	Impurity A – NMT 1.0%. Impurity B – NMT 0.5%. Impurity C – NMT 0.3%. Any other secondary peak – NMT 0.3%. The sum of all the secondary peaks including impurity C – NMT 2.0%.	0.032% Not Detected Not Detected Not Detected 0.032%
7.	Particulate Matter	a) Visible: The constituted solution should be free from particle of foreign matter that can be seen on visual inspection. b) Sub visible: \geq 10 μ m – NMT 6000 particles per container \geq 25 μ m – NMT 600 particles per container	Complies 786.222 Particles 12.222 Particles

	Prepared By	Checked By	Approved By
NAME	Anil	Rajgn	John Clark
DESIGNATION	Senior officer	Executive	Head-ec
SIGN & DATE	27/03/2025	27/03/2025	27/03/2025



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8.	Constituted solution- Completeness & clarity of solution	a) Completeness of solution: The solid should be dissolve completely, leaving no visible residue as undissolved matter.	Complies
		b) Clarity of Solution: The constituted solution should not significantly less clear than an equal volume of water for injection contained in a similar vessel and examined similarly.	Complies
9.	Bacterial Endotoxins	NMT 2.5 Endotoxin units/ mg of Artesunate.	Less than 2.5 EU/mg
10.	Sterility Test	Should be Sterile	Sterile
11.	Assay: Each vial contains: Artesunate IP -----60 mg	Between 54.0 mg to 66.0 mg Between 90.00% to 110.00%	58.73mg 97.88%

Result: The above sample **Complies/ Does not Complies** as per IP/BP/USP/ IH Specification.

Conclusion: In the opinion of the under signed the sample referred to above is of **Standard Quality /is not of Standard Quality** as defined in Drug & Cosmetic Act, 1940 and the rules made here under further.

	Prepared By	Checked By	Approved By
NAME	Anil	Rajni	John Clayton
DESIGNATION	Senior officer	Executive	Head-EE
SIGN & DATE	 27/03/2025	 27/03/2025	 27/03/2025