



Nixi Laboratories Pvt. Ltd.
VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P.)

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	Artecan-60	AR. No.	NL/DI/FG/24/659
Generic Name	Artesunate Injection IP		
Mother Batch No.	D24AD012	Reference	IP
Child Batch No.	D24AD012B	Batch Size	10210 Vials
Mfg. Date	06/2024	Exp. Date	05/2026
Specification No. (STS No)	QC/DPI/FG/STS/002-01	Standard Test Procedure No.	QC/DPI/FG/STP/002
Sample Quantity	45 Vials	Sample Date	13/07/2024
Release Date	13/08/2024		

Sr. No.	Test	Specification	Observation
1.	Description	White or almost white crystalline powder filled in clear glass vial, plugged with rubber stopper and sealed with flip off aluminum seal.	White crystalline powder filled in clear glass vial, plugged with rubber stopper and sealed with flip off aluminum seal.
2.	Identification: Test A may be omitted if test B, C and D are carried out. Test B, C and D may be omitted if test A is carried out.		
	A. By Infrared Absorption Spectroscopy (IR)	Compare the spectrum with that obtained with Artesunate WS or with the reference spectrum of Artesunate.	Complies
	B. By Thin-layer Chromatography (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.	Complies
	C. By Chemical	A light red violet colour is produced.	Complies
	D. By Chemical	A reddish-brown colour is produced.	Complies
3.	Clarity of solution	The solid dissolve completely, leaving no visible residue as undissolved matter.	Complies
		The constituted injection is not	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Akhilak	QC Aditya Singh
Signature			APPROVED
Date	13/08/2024	13/08/24	13/08/24

Format No.: SOP/QC/013/F03-03



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		significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container and examined in the same manner.	
4.	Average filled Weight	64 mg \pm 5%	64.6 mg
5.	Uniformity of filled Weight	Average filled weight \pm 5%	-3.7% to +4.7%
6.	Particulate matter		
	Visible particles:	Should be free from visible particles	Complies
	For sub visible particles : (i) Equal to or greater than 10 μ m	NMT 6000particles/container	1021.0 particles/container
	(ii) Equal to or greater than 25 μ m	NMT 600particles/container	10.5 particles/container
7.	Sterility	Should comply the test of sterility	Complies
8.	Bacterial Endotoxins	NMT 2.5 EU /mg of Artesunate.	Complies
9.	Water Content	NMT 0.5%	0.03%
10.	Related substances		
	(i) Impurity A	Not more than 1.0%	0.047%
	(ii) Impurity B	Not more than 0.5%	Not Detected
	(iii) Impurity C	Not more than 0.3%	0.09%
	(iv) Any other secondary Imp	Not more than 0.3%	Not Detected
	(v) Sum of all impurities	Not more than 2.0%	Not Detected

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Akhilak	Aditya Singh
Signature			
Date	13/08/2024	13/08/24	13/08/24



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
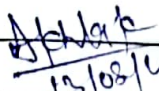

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11.	Assay: Each Vial Contains: Artesunate (Sterile) IP 60 mg	54.00 mg to 66.00 mg (90.00 % to 110.00 %)	64.78 mg (107.96%)
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Result: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No-QC/DPI/FG/STS/002-01.

Conclusion : In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS NOT STANDARD QUALITY** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

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Name	Tarun Kumar	Akhilak	Aditya Singh
Signature			
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