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**	**Akhlak**	**QC Aditya Singh**
Signature			APPROVED
Date	13/08/2024	13/08/24	13/08/24

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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 ± 5%	64.6 mg
5.	**Uniformity of filled Weight**	Average filled weight ± 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 10µm (ii) Equal to or greater than 25µm	NMT 6000particles/container NMT 600particles/container	1021.0 particles/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 **(ii) Impurity B** **(iii) Impurity C** **(iv) Any other secondary Imp** **(v) Sum of all impurities**	Not more than 1.0% Not more than 0.5% Not more than 0.3% Not more than 0.3% Not more than 2.0%	0.047% Not Detected 0.09% Not Detected Not Detected

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

Nixi Laboratories Pvt. Ltd. QC APPROVED Vill. Ogli Kala Amb

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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%)

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.

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

QC APPROVED