



Asian Pharma
105-106, katha Baddi Distt. Solan
Quality Control Department

(Certificate of Analysis)

Product Name	Artecan Injection 120 mg (Artesunate injection IP 120 mg)		
Batch No	GI033412	AR. No.	AF25- 023
Mfg. Date	12/2024	Batch Size	15300 Vials
Exp .Date	11/2026	Sample Qty.	63 Vials
		Mfg. Lic.No.	MNB/19/1060 & MB/19/1061
Date of Received	06/01/2025	Date of Release	20/01/2025

Sr. No.	CHARACTERISTICS	SPECIFICATIONS	RESULTS
1.0	Description	White Powder filled in 15 ml clear glass vial & sealed with white color flip off seal.	White Powder filled in 15 ml clear glass vial & sealed with white color flip off seal.
2.0	Identification	Should be Positive for Artesunate	Positive for Artesunate
3.0	Reconstituted Solution	To comply	Complies
4.0	pH	3.5 to 4.50	3.90
5.0	Related Substances:		
5.1	α- Arteminol And β- Arteminol (Impurity A)	NMT 1.0%	Not Detected
5.2	Impurity B	NMT 0.5%	Not Detected
5.3	Impurity C	NMT 0.3%	Not Detected
5.4	Any Secondary Peak	NMT 0.3%	Not Detected
5.5	All Secondary Peaks Including Impurity C	NMT 2.0%	Not Detected
6.0	Average Fill Weight	121.0 mg ± 10 %	124.11mg
7.0	Uniformity of Average Fill wt.	Not more than two of individual weights deviate from average weight by more than 10% and none deviates by more than 20%.	Max: + 1.361% Min: - 0.974%
8.0	Water	NMT 0.5% w/w	0.24 % w/w
9.0	Sterility	Should be sterile	Sterile
10.0	Particulate Matter	Reconstituted solution should be essentially free from particles of foreign matter that can be seen on visual inspection.	Reconstituted solution is free from particles of foreign matter that can be seen on visual inspection
11.0	Bacterial Endotoxins	NMT: 2.50 Endotoxin unit/mg	Less than 2.50 Endotoxin unit/mg
12.0	Assay: Each vial contains : Artesunate (Sterile) IP 120 mg	108.0 mg to 132.0 mg (90% to 110%)	122.3 mg (101.8%)

Remarks: - The sample complies/does not comply as per IP/BP/USP/IH specification.

	ANALYSED BY	CHECKED BY	APPROVED BY	AUTHORIZED BY
NAME	Upendra Singh	Avinash Kumar	Uma Shankar	Amit Kumar
DESIGNATION	Sr. Officer	QC Executive	APPROVED CHEMIST	TECHNICAL DIRECTOR
SIGN/DATE	<i>[Signature]</i> 20/01/2025	<i>[Signature]</i> 20/01/2025	<i>[Signature]</i> 20/01/2025	<i>[Signature]</i> 20/01/2025
REGISTRATION NO.			381074110	
INSTITUTE NAME & PLACE			AVIT & CHENNAI	