



Asian Pharma
105-106, katha Baddi Distt. Solan

Quality Control Department

(Certificate of Analysis)

Product Name	Artecan Injection Artesunate Injection IP 60 mg		
Batch No	GI010409 C	AR. No.	AF24-1008
Mfg. Date	09/2024	Batch Size	10,237 Vials
Exp .Date	08/2026	Sample Qty.	63 Vials
Date of Received	01/10/2024	Mfg. Lic No.	MB/19/1061& MNB/19/1060
		Date of Release	16/10/2024

Sr. No.	CHARACTERISTICS	RESULTS	SPECIFICATIONS
1.0	Description	White Powder filled in 10 ml clear glass vial & sealed with red colour flip off seal	White Powder filled in 10 ml clear glass vial & sealed with red colour flip off seal
2.0	Identification	Positive for Artesunate	Should be Positive for Artesunate
3.0	Reconstituted Solution	Complies	To comply
4.0	pH	4.33	3.5 to 4.50
5.0	Related Substances:		
5.1	α - Arteminol And β -Arteminol (Impurity A)	Not Detected	NMT 1.0%
5.2	Impurity B	Not Detected	NMT 0.5%
5.3	Impurity C	Not Detected	NMT 0.3%
5.4	Any Secondary Peak	Not Detected	NMT 0.3%
5.5	All Secondary Peaks Including Impurity C	Not Detected	NMT 2.0%
6.0	Average Fill Weight	65.17 mg	60.0 mg \pm 10 %
7.0	Uniformity of Average Fill wt.	Max: + 3.575% Min: - 4.864%	Not more than two of individual weights deviate from average weight by more than 10% and none deviates by more than 20%.
8.0	Water	0.19 % w/w	NMT 0.5% w/w
9.0	Sterility	Sterile	Must be sterile
10.0	Particulate Matter	Reconstituted solution is free from particles of foreign matter that can seen on visual inspection	Reconstituted solution is essentially free from particles of foreign matter that can seen on visual inspection
11.0	Bacterial Endotoxins	Less than 2.50 Endotoxin unit/mg	NMT 2.50 Endotoxin unit/mg
12.0	Assay: Each vial contains : Artesunate (Sterile) IP 60 mg	61.71 mg (102.84%)	54.0 mg to 66.0 mg (90% to 110%)

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

	Analysed By	Checked By	Approved By
Sign			
Date	16/10/2024	16/10/2024	16/10/2024