



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

(Certificate of Analysis)

Product Name	Artecan Injection (Artesunate injection IP 30 mg)		
Batch No	GI017409	AR. No.	AF24- 1011
Mfg. Date	09/2024	Batch Size	6333 Vials
Exp .Date	08/2026	Sample Qty.	63 Vials
		Mfg. Lic No.	MNB/19/1060 & MB/19/1061
Date of Received	05/10/2024	Date of Release	19/10/2024

Sr. No.	CHARACTERISTICS	RESULTS	SPECIFICATIONS
1.0	Description	White Powder filled in 10 ml clear glass vial & sealed with green color flip off seal	White Powder filled in 10 ml clear glass vial & sealed with green color flip off seal
2.0	Identification	Positive for Artesunate	Should be Positive for Artesunate
3.0	Reconstituted Solution	Complies	To comply
4.0	pH	4.32	3.5 to 4.50
5.0	Related Substances:		
5.1	α- Artemimol And β- Artemimol (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	31.08 mg	30.0 mg ± 10 %
7.0	Uniformity of Average Fill wt.	Max: + 4.568% Min: - 3.474%	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	0.28 % w/w	NMT 0.5% w/w
9.0	Sterility	Sterile	Should be sterile
10.0	Particulate Matter	Reconstituted solution is free from particles of foreign matter that can seen on visual inspection	Reconstituted solution should be 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 30 mg	31.83 mg (106.10%)	27.0 mg to 33.0 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	19/10/2024	19/10/2024	19/10/2024