ASIAN GROUP
Quality Product Suppliers

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

Certificate of Analysis

Product Name	**Artecan injection 120mg (Artesunate injection IP 120 mg)**		
Batch No	GI053411	**AR. No.**	AF24- 1310
Mfg. Date	11/2024	**Batch Size**	20300 Vials
Exp .Date	10/2026	**Sample Qty.**	63 Vials
		Mfg. Lic. No.	MB/19/1061 & MNB/19/1060
Date of Received	06/12/2024	**Date of Release**	21/12/2024

Sr. No.	CHARACTERISTICS	SPECIFICATIONS	RESULTS
1.0	Description	A White Powder filled in 15 ml clear glass vial & sealed with white color flip off seal.	A 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	3.50 to 4.50	4.10
5.0	Related Substances		
	Impurity A	NMT 1.0%	Not detected
	Impurity B	NMT 0.5%	Not detected
	Impurity C	NMT 0.3%	Not detected
	Single Max	NMT 0.3%	Not detected
	All Secondary imp. Including Imp C	NMT 2.0%	Not detected
6.0	Average Fill Weight	120 mg ± 10 %	120.68 mg
7.0	Uniformity of Average Fill wt.	Not more than two of individual weights deviate from average weight by more than 10.0% & none deviates by more than 20.0%.	Min: -1.972% Max: +2.916%
8.0	Water	NMT 0.5%w/w	0.20% 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 EU/mg
12.0	Assay: Each vial contains: Artesunate (Sterile) IP 120 mg	108.0 mg to 132.0 mg (90% to 110%)	117.45 mg (97.87%)

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

	Analysed By	Checked By	Approved By
Sign			
Date	21/12/2024	21/12/2024	21/12/2024