ASIAN GROUP
Quality Product Suppliers

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

(Certificate of Analysis)

Product Name	**Artecan (Artesunate for Injection IP 120 mg)**		
Batch No	GI006411	**AR. No.**	AF24- 1212
Mfg. Date	11/2024	**Batch Size**	15300 Vials
Exp .Date	10/2026	**Sample Qty.**	63 Vials
		Mfg. Lic. No.	MB/19/1061 & MNB/19/1960
Date of Received	07/11/2024	**Date of Release**	21/11/2024

Sr. No.	CHARACTERISTICS	SPECIFICATIONS	RESULTS
1.0	Description	A White colour powder filled in 15 ml clear glass vial & sealed with white colour flip off seal.	A White colour powder filled in 15 ml clear glass vial & sealed with white colour 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	4.01
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	120.0 mg ± 10 %	121.82 mg
7.0	Uniformity of Average Fill wt.	Not more than two of individual weights deviate from average weight by more than 10.0%and none deviates by more than 20.0%.	Min.: - 1.450% Max.: +1.971%
8.0	Water	NMT 0.5%w/w	0.19%w/w
9.0	Sterility	Should be sterile	Sterile
10.0	Particulate Matter	Reconstituted solution is essentially free from particles of foreign matter that can seen on visual	Reconstituted solution is free from particles of foreign matter that can 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 to132.0mg (90% to110%)	120.11 mg (100.09%)

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

	Analysed By	Checked By	Approved By
Sign			
Date	21/11/2024	21/11/2024	21/11/2024