Asian Pharma
105-106, katha Baddi Distt. Solan
Quality Control Department
(Certificate of Analysis)

Product Name	**Artecan (Artesunate For Injection IP 60 mg)**		
Batch No	GI029411	**AR. No.**	AF24-1210
Mfg. Date	11/2024	**Batch Size**	10327 Vials
Exp .Date	10/2026	**Sample Qty.**	63 Vials
		MFg.Lic.No.	MB/19/1061& MNB/19/1060
Date of Received	07/11/2024	**Date of Release**	21/11/2024

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	4.0	3.5 to 4.50
5.0	Related Substances:		
5.1	α- Artenimol And ß-Artenimol (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	59.29 mg	60.0 mg ± 10 %
7.0	Uniformity of Average Fill wt.	Max: + 3.511% Min: - 3.522%	Not more than two of individual weights deviate from average weight by more than10% and none deviates by more than20%.
8.0	Water	0.22% 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	60. mg (100.35%)	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	21/11/2024	21/11/2024	21/11/2024