

Title : Certificate of Analysis Finished Product

Product Name	Artecan Injection	A.R. No.	NB/FP/25/068
Generic Name	Artesunate for Injection IP 30mg	Sampled qty.	45 Vials
Batch No.	N25080A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	28/05/2025
Mfg. Date	05/2025	Date of Testing	28/05/2025
Exp. Date	04/2027	Date of Release	13/06/2025

S. No.	Test	Specification	Observation
1.	Description	A white or almost white crystalline powder filled in clear glass vial.	A white crystalline powder filled in clear glass vial.
2.	Identification (By IR)	The infrared absorption spectrum is concordant with the spectrum obtained from artesunate RS or with the reference spectrum of artesunate.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-5.80% & +7.92%
4.	Average weight	Informative.	32.1 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	576/vial 11/vial Complies
6.	Related Substances (By HPLC w/w) Impurity A Impurity B Impurity C Any other Impurity Total Impurity	Note more than-1.0% Note more than-0.5% Note more than-0.3% Note more than-0.3% Note more than-2.0%	Not detected Not detected Not detected Not detected Not detected
7.	Water (By K.F)	NMT- 0.5% w/w	0.12% w/w
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins	NMT 2.5 EU/mg of Artesunate.	Less than 2.5 EU/mg of Artesunate.
10.	Assay: Each vial Contains :		

Analysis by 13/06/2025
NAME: NIKHIL SHARMA

Checked by 13/06/2025
NAME: SUFIYAN ANSARI

Approved by 13/06/2025
NAME: SWATT DHAWAN

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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Artesunate (Sterile) IP	30 mg	31.45 mg	104.83%	90.0 to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/BP/USP/PHS:

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: SWATI DHAWAN

