

Pace

Add Pace To Health

Pace Biotech

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

Title

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Certificate of Analysis Finished Product

Product Name	ARTECAN Injection	A.R. No.	NB/FP/24/357
Generic Name	Artesunate Injection IP 120mg	Sampled qty.	45 Vials
Batch No.	N24326	Sampled by	Rakesh
Batch Size	14,000 Vials	Sampled on	10/02/2025
Mfg. Date	02/2025	Date of Testing	10/02/2025
Exp. Date	01/2027	Date of conditionally Release	19/02/2025

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 $\pm 10\%$	-3.78% & +6.55%
4.	Average weight	Informative.	119.1 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.	135/vial 5/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%	Under process
7.	Water (By K.F)	NMT- 0.5% w/w	0.07%w/w
8.	Sterility	No microbial growth should be observed.	Under process
9.	Bacterial Endotoxins	NMT- 2.5 EU/mg of Artesunate.	Less than- 2.5 EU/mg of Artesunate.
10.	Assay: Each vial Contains :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Artesunate (Sterile) IP	120 mg	116.71 mg	97.26%	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 per The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/WHO.

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P.N. TRIPATHI
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