

Pace

Add Pace To Health

Pace Biotech

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

Title :

Certificate of Analysis Finished Product

Product Name	Artecan Injection	A.R. No.	NB/FP/23/387
Generic Name	Artesunate Injection IP 30mg	Sampled qty.	45 Vials
Batch No.	N23390A	Sampled by	Arvind
Batch Size	4583 Vials	Sampled on	10/02/2024
Mfg. Date	01/2024	Date of Testing	10/02/2024
Exp. Date	12/2025	Date of Release	25/02/2024

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 %	-8.95% & +5.92%		
4.	Average weight	Informative.	32.3 mg		
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles \geq 10 μ m (2.) Particles \geq 25 μ 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.	958/vial 12/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 %	Complies Complies Complies Complies Complies		
7.	Water (By K.F)	NMT- 0.5%w/w	0.15%w/w		
8.	Sterility	No microbial growth should be observed.	Complies		
9.	Bacterial Endotoxins	NMT- 2.5 IU/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		30 mg	31.95 mg	106.50%	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/IHS.

Analysis by 

Checked by 

