



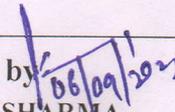
# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

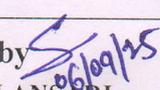
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

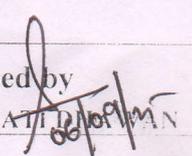
## Title : Certificate of Analysis Finished Product

Product Name	Artecan Injection	A.R. No.	ARN/FP/25/008
Generic Name	Artesunate for Injection IP 60mg	Sampled qty.	45 Vials
Batch No.	ARN2517A	Sampled by	Anuj Verma
Batch Size	14,510 Vials	Sampled on	22/08/2025
Mfg. Date	08/2025	Date of Testing	23/08/2025
Exp. Date	07/2027	Date of Release	06/09/2025

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)  (By TLC)  (By chemically) (By chemically)	<b>Test A may be omitted if test b, C and D are carried out. Test B, C and D may be omitted if test A is carried out.</b> A. Compare the spectrum with that obtained with Artesunate IPRS or with the reference spectrum of Artesunate. B. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. C. A reddish-brown colour is produced. D. A red colour is produced.	Complies  Complies  Complies Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-6.41% & +9.30%
4.	Average weight	Informative $\pm 2\%$ .	58.3 mg
5.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	3659/vial 1/vial Complies
6.	Related Substances (By HPLC) 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

Analysis by   
NAME: NIKHIL SHARMA

Checked by   
NAME: SUFIYAN ANSARI

Approved by   
NAME: MRS. SWATI

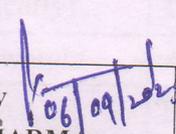
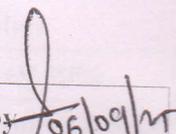


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7.	Water (By K.F)	NMT 0.5%w/w	0.03% w/w		
8.	Sterility	No microbial growth should be observed.	Complies		
9.	Bacterial Endotoxins	NMT 2.5 EU/mg of Artesunate.	Less than 2.5 EU/mg of Artesunate.		
10.	Assay: Each vial Contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Artesunate (Sterile)	IP	60 mg	58.29 mg	97.15%	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/HS.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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