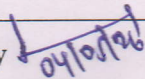


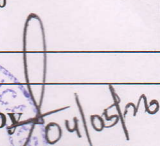
Title : Certificate of Analysis Finished Product

Product Name	ARTECAN-120 Injection	A.R. No.	ARN/FP/26/003
Generic Name	Artesunate for Injection IP 120mg	Sampled qty.	45 Vials
Batch No.	ARN25120A	Sampled by	Rakesh
Batch Size	14,330 Vials	Sampled on	19/04/2026
Mfg. Date	03/2026	Date of Testing	20/04/2026
Exp. Date	02/2028	Date of Release	04/05/2026

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	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.	Complies
	(By IR)	A. Compare the spectrum with that obtained with Artesunate IPRS or with the reference spectrum of Artesunate.	
	(By TLC)	B. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	
	(By chemically) (By chemically)	C. A reddish-brown colour is produced. D. A red colour is produced.	
3.	Uniformity of weight	Average weight $\pm 10\%$	-3.74% & +4.40%
4.	Average weight	Informative $\pm 2\%$.	117.9mg
5.	Particulate Matter	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.	1,154/vial 8/vial Complies
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle		
6.	Related Substances (By HPLC)	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%	0.034% Not Detected 0.009% Not Detected 0.043%
	Impurity A		
	Impurity B		
	Impurity C		
	Any other Impurity		
	Total Impurity		

Analysis by 
NAME: NIKHIL SHARMA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI DHAWAN



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title : Certificate of Analysis Finished Product

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7.	Water (By K.F)	NMT 0.5%w/w	0.2%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	120 mg	118.2347 mg	98.53%	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/HIS.

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