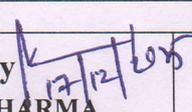
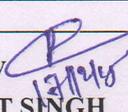


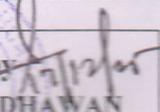
Title : Certificate of Analysis Finished Product

Product Name	ARTECAN Injection	A.R. No.	ARN/FP/25/063
Generic Name	Artesunate for Injection IP 30mg	Sampled qty.	45 Vials
Batch No.	ARN2557A	Sampled by	Rakesh
Batch Size	15,000 Vials	Sampled on	02/12/2025
Mfg. Date	11/2025	Date of Testing	03/12/2025
Exp. Date	10/2027	Date of Release	17/12/2025

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)	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. 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 Omitted Omitted Omitted
3.	Uniformity of weight	Average weight $\pm 10\%$	-4.14% & +2.86%
4.	Average weight	Informative $\pm 2\%$.	32.9 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.	126/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: RAMANJEET SINGH

Approved by 
NAME: MRS. SWATI DHAWAN



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

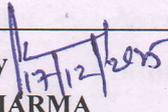
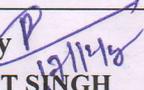
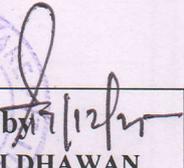
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	ARTECAN Injection	A.R. No.	ARN/FP/25/063
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Batch No.	ARN2557A	Sampled by	Rakesh
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7.	Water (By K.F)	NMT 0.5%w/w	0.01%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	30 mg	32.51mg	108.37%	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  NAME: NIKHIL SHARMA	Checked by  NAME: RAMANJEET SINGH	Approved by  NAME: MRS. SWATI DHAWAN
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