

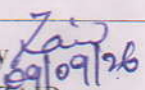
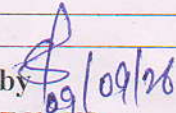
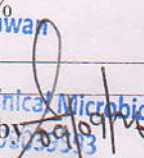
**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

Title : Certificate of Analysis Finished Product

Product Name	ARTECAN-30 Injection	A.R. No.	ARN/FP/26/056
Generic Name	Artesunate for Injection IP 30mg	Sampled qty.	45 Vials
Batch No.	ARN2651A	Sampled by	Rakesh
Batch Size	10,120 Vials	Sampled on	25/08/2026
Mfg. Date	08/2026	Date of Testing	26/08/2026
Exp. Date	07/2028	Date of Release	09/09/2026

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 (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 Complies Complies Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-8.13% & +8.98%
4.	Average weight	Informative $\pm 2\%$.	30.2 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.	424/vial 7/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%	0.086% Not Detected Not Detected 0.024% 0.110%

Analysis by 
NAME: MOHD. ZAIDChecked by 
NAME: SURJEET KAURName : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 550403/2013
Approved by 
NAME: MRS. SWATI DHAWAN

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7.	Water (By K.F)	NMT 0.5%w/w	0.04%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	30.3659 mg	101.22%	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/THS.

Analysis by <i>Zaid</i> NAME: MOHD. ZAID	Checked by <i>Surjeet</i> NAME: SURJEET KAUR	Name : Mrs. Swati Dhawan Designation : QC HOD Qualification : M.Sc. Clinical Microbiology Approved by <i>Swati</i> NAME: MRS. SWATI DHAWAN Faculty, Jalandhar
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