

**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-120 Injection	A.R. No.	ARN/FP/26/063
Generic Name	Artesunate for Injection IP 120mg	Sampled qty.	45 Vials
Batch No.	ARN2654A	Sampled by	Rakesh
Batch Size	9,790 Vials	Sampled on	27/08/2026
Mfg. Date	08/2026	Date of Testing	28/08/2026
Exp. Date	07/2028	Date of Release	11/09/2026

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 $\pm 10\%$	-8.42% & +8.31%
4.	Average weight	Informative $\pm 2\%$.	116.0mg
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.	281/vial 2/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%	0.047% Not Detected Not Detected 0.003% 0.050%

Name : Mrs. Swati Dhanwan

Designation : QC Head

Qualification : B.Ph. in Microbiology

Registrar Approved by

NAME: MRS. SWATI DHANWAN

Analysis by
NAME: MOHD. ZAHIDChecked by
NAME: SURJEET KAUR

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7.	Water (By K.F)	NMT 0.5%w/w	0.1%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	117.4380 mg	97.86%	90.0 to 110.0%
Remarks: In the original file, the value for the found amount is 117.4380 mg, which is less than the labeled claim of 120 mg. The percentage of labeled amount is 97.86%, which is within the limits of 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.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. 560405039593

Approved by

NAME: MRS. SWATI DHAWAN

Analysis by
NAME: MOHD. ZAID

Checked by
NAME: SURJEET KAUR