



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title : Certificate of Analysis Finished Product

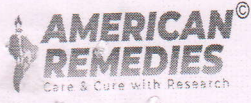
Product Name	ARTECAN Injection	A.R. No.	ARN/FP/25/105
Generic Name	Artesunate for Injection	Sampled qty.	45 Vials
Batch No.	ARN25112A	Sampled by	Rakesh
Batch Size	9,990 Vials	Sampled on	16/03/2026
Mfg. Date	02/2026	Date of Testing	17/03/2026
Exp. Date	01/2029	Date of Release	31/03/2026

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)	The absorption spectrum of the test preparation should exhibits maxima at same wavelength with that obtained with similar preparation of Artesunte working standard.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-1.46% & +3.31%
4.	Average weight	Informative $\pm 2\%$.	180.2 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	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.	242/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%	0.35% Not detected Not detected 0.05% 0.41%
7.	Water (By K.F)	NMT 0.5%w/w	0.02%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:		

Analysis by *K. K. Singh*

Checked by *P. Singh*





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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Artesunate (Sterile)	180 mg	180.5855 mg	100.33%	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

