

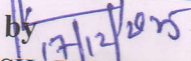
**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**  
 Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

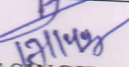
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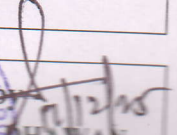
**Certificate of Analysis Finished Product**

Product Name	ARTECAN- 60mg Injection	A.R. No.	ARN/FP/25/064
Generic Name	Artesunate for Injection IP	Sampled qty.	45 Vials
Batch No.	ARN2570A	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)	<b>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.</b> 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 $\pm 10\%$	-8.76% & +6.11%
4.	Average weight	Informative $\pm 2\%$ .	60.9 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.	90/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 DHANWAN



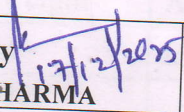
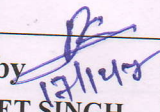
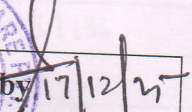
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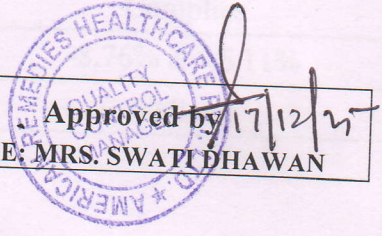
**Title** : **Certificate of Analysis Finished Product**

<b>Product Name</b>	ARTECAN- 60mg Injection	<b>A.R. No.</b>	ARN/FP/25/064
<b>Generic Name</b>	Artesunate for Injection IP	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARN2570A	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	15,000 Vials	<b>Sampled on</b>	02/12/2025
<b>Mfg. Date</b>	11/2025	<b>Date of Testing</b>	03/12/2025
<b>Exp. Date</b>	10/2027	<b>Date of Release</b>	17/12/2025

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:				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Artesunate (Sterile) IP		60 mg	57.39 mg	95.65%	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.

<b>Analysis by</b>  NAME: NIKHIL SHARMA	<b>Checked by</b>  NAME: RAMANJEET SINGH	<b>Approved by</b>  NAME: MRS. SWATI DHAWAN
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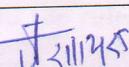
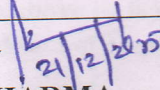

**Title**

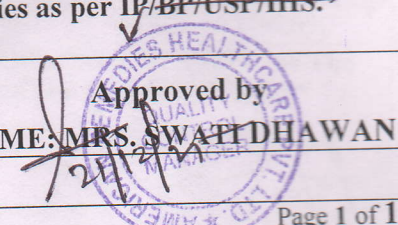
**Certificate of Analysis Finished Product**

<b>Product Name</b>	Sodium Bicarbonate Injection IP 1ml	<b>A.R. No.</b>	ARN/FP/25/068
<b>Generic Name</b>	Sodium Bicarbonate Injection IP	<b>Sampled qty.</b>	60 Ampoules
<b>Batch No.</b>	ARN2571	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	35 Litres	<b>Sampled on</b>	06/12/2025
<b>Mfg. Date</b>	11/2025	<b>Date of Testing</b>	07/12/2025
<b>Exp. Date</b>	10/2028	<b>Date of Release</b>	21/12/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.		
2.	Identification	<b>A.</b> The residue on evaporation, When moistened with Hydrochloride Acid and introduced on a platinum wire into a flame imparts a yellow colour to the flame. <b>B.</b> It gives reaction of sodium salts & the reaction of carbonate.	Complies  Complies		
3.	Nominal fill volume	NLT 1ml	1.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml		
5.	pH	7.0 to 8.5	8.31		
6.	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/Ampoule NMT 600/ Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	6/Ampoule 0/Ampoule  Complies		
7.	Sterility	No microbial growth should be observed.	Under Process		
8.	Bacterial Endotoxins	NMT 1.7 EU/ml of Sodium bicarbonate.	Less than 1.7 EU/ml of Sodium bicarbonate.		
9.	Assay: (By Titration) Composition :				
	Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
	Sodium Bicarbonate IP	5%w/v	5.1495%w/v	102.99%	94.0% to 106.0%

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: FIROJ KHAN	Checked by  NAME: NIKHIL SHARMA	Approved by  NAME: MRS. SWATI DHAWAN
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Title : Certificate of Analysis

Product Name	Sodium Chloride Injection IP 5ml		
A.R. No.	SC/25/033	Sampled qty.	45 PCS
Batch No.	BIG25001	Sampled by	Jyoti
Batch Size	126000 PCS	Sampled on	09/06/2025
Mfg. Date	02/2025	Date of Testing	09/06/2025
Exp. Date	01/2029	Date of Release	25/06/2025

S.No.	Tests	Specification	Observation	
1.	Description	A clear, colourless solution filled in FFS ampoule.	A clear, colourless solution filled in FFS ampoule.	
2.	Identification	Yields the reactions characteristic of sodium salt and reaction A characteristic of chlorides.	Complies	
3.	Nominal fill volume	NLT 5ml	5.0 ml	
4.	Extractable Volume Nominal Fill	NLT Nominal volume or NMT 110 % of nominal Volume	5.1 ml	
5.	pH	4.5 to 7.0	5.93	
6.	Heavy Metals	NMT 0.3ppm	Complies	
7.	Particulate Matter (A). Light Obscuration Particle Count Test. 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$  (B). Visual	NMT 6000/Ampoule NMT 600/Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally that can be observed on visual inspection.	3/Ampoules 0/Ampoules  Complies	
8.	Sterility	No microbial growth should be observed.	Complies	
9.	Bacterial Endotoxins	NMT 0.5 EU/ml.	Complies	
10.	Assay: (By Chemically) Composition			
Ingredients		Labeled Claim	Found	Limit % of labeled amount
Sodium Chloride IP		0.90%w/v	0.89%w/v	0.85 to 0.95%w/v

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug and Cosmetic Act 1940 and the rules made there under. Complies/Not Complies as per IP/DP/HIS.

Analysis by Jyoti	Checked by Nikhil Sharma	Approved by Mrs. Swati Dhawan
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