

Pace

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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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Certificate of Analysis Finished Product

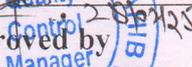
Product Name	Sodium Bicarbonate Injection IP 2ml	A.R. No.	NL/FP/24/516
Generic Name	Sodium Bicarbonate Injection IP	Sampled qty.	45 Ampoules
Batch No.	A24436	Sampled by	Rakesh
Batch Size	50,000 Ampoules	Sampled on	13/02/2025
Mfg. Date	02/2025	Date of Testing	13/02/2025
Exp. Date	01/2028	Date of Release	28/02/2025

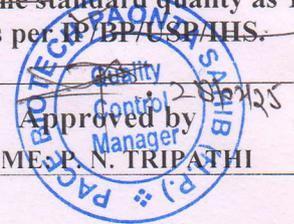
S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.		
2.	Identification	A. The residue on evaporation, When moistened with Hydrochloride Acid and introduced on a platinum wire into a flame imparts a yellow colour to the flame. B. It gives reaction of sodium salts & the reaction of carbonate.	Complies Complies		
3.	Nominal fill volume	NLT- 2ml	2.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml		
5.	pH	7.0 to 8.5	8.06		
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.	177/Ampoule 3/Ampoule Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT- 1.7 EU/ml of Sodium bicarbonate Injection.	Less then- 1.7 EU/ml of Sodium bicarbonate Injection.		
9.	Assay: Composition :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sodium Bicarbonate IP		5%w/v	5.0830%w/v	101.66%	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/CSP/IHS.

Analysis by 
NAME: SANDHYA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: P. N. TRIPATHI



SD24/068

BIOIV LABS PVT. LTD. Hadbast – 126, Village – Mussewal, Ropar Road Nalagarh, District - Solan (HP), 174101 Quality Control Department	 BIOIV LABS PVT. LTD.
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CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Product Name	Sodium Chloride (0.9% w/v) Injection IP 10 ml	A.R. No.	FSVP/0670/24
Batch No.	BIH24202	Mfg. Date	11/2024
Batch Size	2500 Liter	Exp. Date	10/2028
Test Started On	09/11/2024	Test Completed on	24/11/2024
Sample Quantity	72 × 10ml	Mfg. Lic. No.	MB/22/1207

Sr. No.	Test Performed	Specifications	Results
1.	Description	A Clear, Colourless, solution.	A Clear, Colourless, solution
2.	Identification	(a) For Sodium	A dense white precipitate should be formed. Complies
		(b) For Chloride	A curdy white precipitate should be formed. Complies
3.	pH	4.5 to 7.0	6.18
4.	Heavy Metal	NMT 0.3ppm	Complies
5.	Assay	0.85%w/v to 0.95%w/v	0.901 %w/v
6.	Particulate Contamination (Light obscuration particle count test)	≥ 10 µm NMT 6000 Particulate/Containers	115 Particles / Container
		≥ 25 µm NMT 600 Particulate/Containers	17 Particles / Container
7.	Extractable Volume	Not less than label Claim(10ml)	10.1 ml
8.	Bacterial Endotoxins	Not more than 0.5 EU/ml	Complies
9.	Sterility	There should be no microbial growth observed within 14 days.	Complies

Remarks: The Above Product ~~Complies/does not Complies~~ as per IP/ BP/ USP/ IH specification.

Prepared By:	Checked By:	Approved By:
Sign.: Sachin	Sign.: N. A.	Sign.: [Signature]
Date: 24/11/2024	Date: 24/11/2024	Date: 24/11/2024
Officer QC Name: Sachin Chauhan	Assistant Manager QC Name: Nitin Kumar	Manager QA Name: Mand. Waseem

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Title

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Certificate of Analysis Finished Product

Product Name	ARTECAN Injection	A.R. No.	NB/FP/24/370
Generic Name	Artesunate Injection IP 120mg	Sampled qty.	45 Vials
Batch No.	N24343A	Sampled by	Rakesh
Batch Size	50,000 Vials	Sampled on	19/02/2025
Mfg. Date	02/2025	Date of Testing	19/02/2025
Exp. Date	01/2027	Date of Release	06/03/2025

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)	The infrared absorption spectrum is concordant with the spectrum obtained from artesunate RS or with the reference spectrum of artesunate.	Complies	
3.	Uniformity of weight	Average weight $\pm 10\%$	-2.28% & +2.33%	
4.	Average weight	Informative.	119.4 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 solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	1035/vial 6/vial Complies	
6.	Related Substances (By HPLC w/w) 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%	Complies Complies Complies Complies Complies	
7.	Water (By K.F)	NMT- 0.5% w/w	0.08%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	117.71 mg	98.09%	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: SUFIYAN ANSARI	Checked by  NAME: SANDHYA	Approved by  NAME: R. N. TRIPATHI
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