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Pace Biotech

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

Title	:	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 ≥10µm (2.) Particles ≥25µm	NMT-6000/Ampoule NMT-600/ Ampoule	177/Ampoule 3/Ampoule
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	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/USP/IHS.

Analysis by	Checked by	Approved by
NAME: SANDHYA	NAME: SUFIYAN ANSARI	NAME: P. N. TRIPATHI

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager 28/2/25

SQ/24/068

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

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 ≥ 25 µm NMT 600 Particulate/Containers	115 Particles / Container 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.:	Sign.:
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: Mohd. Waseem

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

Title	:	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 ±10%	-2.28% & +2.33%
4.	Average weight	Informative.	119.4 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm (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	Checked by	Approved by
NAME: SUFIYAN ANSARI	NAME: SANDHYA	NAME: R. N. TRIPATHI

PACE BIOTECH (H.P.) Quality Control Manager

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