DERREN HEALTHCARE PVT. LTD.

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Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi, Ahmedabad-382 213, Gujarat (India)

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Name of Product	Sodium Bicarbonate Injection 84mg/ml (SODICAN)		
Batch No.	BJ24014	**A.R. No.**	FP/24/0112
Mfg. Date	10/24	**Exp. Date**	09/26
Sampled Qty.	36 Nos.	**Date of Analysis**	19/10/24
Batch Size	500Ltr.	**Date of Release**	08/11/24
Container Type	Clear Glass Ampoules	**Fill volume**	25.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, Colourless liquid free from visible particles and fibers.	Clear, Colourless liquid free from visible particles and fibers.
2	Extractable volume	25.1 ml	NLT 25.0 ml
3	Identification		
3.1	Identification It Gives reaction (A) of sodium salts and the reaction of bicarbonate	A White Precipitated is formed A dense white precipitate is formed	A White precipitated should be formed A dense White precipitate should be formed
4	pH	7.93	7.0 to 8.5
5	Bacterial endotoxin	Less than 5.0 Eu/mg	NMT 5.0 EU/mg of Sodium bicarbonate
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
6.2	By Light Obscuration Method	≥10 microns= 20.00 /Container ≥ 25 Microns= 0.00/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml Contains: Sodium Bicarbonate IP	100.8 %	94.0% to 106.0% of the labelled amount of Sodium Bicarbonate

Conclusion: The above sample complies as per **IP** specification.
In the opinion of the undersigned the sample referred to above is of **standard** / **~~not of standard~~** quality as defined in the act and the rules made there under for the reasons given above.

Prepared By	Checked By	Approved By
08/11/24	08/11/24	08/11/24
QC OFFICER	QC EXECUTIVE	QA MANAGER

DERREN HEALTHCARE PVT. LTD. QUALITY ASSURANCE AHMEDABAD