



DERREN HEALTHCARE PRIVATE LIMITED

PLOT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI,
TA : SANAND. DIST.AHMEDABAD - 382213, GUJARAT,INDIA

Page 1 of 1

FINISHED PRODUCT ANALYTICAL TEST REPORT

Product Name	SODICAN 8.4 % INJECTION 25 ML		
Generic Name	SODIUM BICARBONATE INJECTION IP 8.4% w/v	Batch No. /Lot No.	BJ26011
COMPOSITION : EACH ML CONTAINS SODIUM BICARBONATE IP8.4% W/V WATER FOR INJECTION IPQ.S.		Mfg. Dt.	05/2026
		Exp. Dt.	04/2028
		Receipt Dt.	05/05/2026
		Release Dt.	20/05/2026
		Sample Size	24.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0195
		Manufactured By	DERREN
Analysis	DHAVAL GHANSHYAMBHAI PATEL	Theoretical Yield/Batch Size	19,607.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear colourless liquid free from visible particle and fibers.	Clear colourless liquid free from visible particle and fibers.
2	Extractable volume	NLT 25.0 ml	25.1 ml
3	Identification Identification A by reaction (b) of Acetates	A White Precipitated is formed A dense white precipitated is formed	A White Precipitated is formed A dense white precipitated is formed
4	pH	7.0 to 8.5	8.2
5	Bacterial Endotoxin test	NMT 1.7 Eu/mg of Sodium Bicarbonate	Less than 1.7 Eu/mg
6	Particulate matter By Visual inspection By light obscuration method	The solution is free from particle that is observed by inspection with the unaided eye. > 10 microns= NMT 6000/Container > 25 microns= NMT 600/Container	The solution is free from particle that is observed by inspection with the unaided eye. > 10 microns= 396.67/Container > 25 microns= 53.33/Container
7	Sterility test	Should be Sterile	Sterile
8	Assay	94.0 % to 106.0 % of the labelled amount of sodium bicarbonate	99.63% of the labelled amount of sodium bicarbonate

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By DHAVAL QC OFFICER 20/05/26	Checked By NUTAN PRAJAPATI QC HEAD 20/05/24	Approved By KRUNAL GAJERA QA HEAD 20/05/2026
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DHAVALP 20/05/2026 12:06 PM

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