



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

FINISHED PRODUCT ANALYTICAL TEST REPORT

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Product Name	SODICAN 8.4 % INJECTION 25 ML		
Generic Name	SODIUM BICARBONATE INJECTION IP 8.4% w/v	Batch No. /Lot No.	BJ26019
COMPOSITION : EACH ML CONTAINS SODIUM BICARBONATE IP.....8.4% W/V WATER FOR INJECTION IP.....Q.S.		Mfg. Dt.	06/2026
		Exp. Dt.	05/2028
		Receipt Dt.	05/06/2026
		Release Dt.	19/06/2026
		Sample Size	24.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0231
		Manufactured By	DERREN
Analysis	SWETANG PATEL	Theoretical Yield/Batch Size	15,686.000 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	25.0 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	7.97
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= 85.00 /Container > 25 microns= 5.00 /Container
7	Sterility test	Should be Sterile	Sterile
8	Assay	94.0 % to 106.0 % of the labelled amount of sodium bicarbonate	100.74% 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

19/06/26
SWETANGP
QC OFFICER

Checked By

19/06/26
NUTAN PRAJAPATI
QC HEAD

Approved By

19/06/2026
KRUNAL GAJERA
QA HEAD

SWETANGP 19/06/2026 04:54 PM

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