



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.	BJ26018
COMPOSITION :EACH ML CONTAINS SODIUM BICARBONATE IP.....8.4% W/V WATER FOR INJECTION IP.....Q.S.		Mfg. Dt.	05/2026
		Exp. Dt.	04/2028
		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/26/0230
Analysis	SWETANG PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	19,607.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear colourless liquid free form visible particle and fibers.	Clear colourless liquid free form 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	7.93
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= 106.67 /Container > 25 microns= 1.67 /Container
7	Sterility test	Should be Sterile	Sterile
8	Assay	94.0 % to 106.0 % of the labelled amount of sodium bicarbonate	100.27 % 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

SWETANGP
QC OFFICER

Checked By

NUTAN PRAJAPATI
QC HEAD

Approved By

KRUNAL GAJERA
QA HEAD

SWETANGP 19/06/2026 04:32 PM

*FgAnlCert02