



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

Product Name	SODICAN 8.4 % INJECTION 25 ML		
Generic Name	SODIUM BICARBONATE INJECTION IP 8.4% w/v	Batch No. /Lot No.	BJ25002
COMPOSITION : EACH ML CONTAINS SODIUM BICARBONATE IP.....8.4% W/V WATER FOR INJECTION IP.....Q.S.		Mfg. Dt.	02/2025
		Exp. Dt.	01/2027
		Receipt Dt.	05/02/2025
		Release Dt.	22/02/2025
		Sample Size	36.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0022.
Analysis	DHIREN MUKESHBHAI PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	9,000.000 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 dence white precipitated is formed	A White Precipitated is formed A dence white precipitated is formed
4	pH	7.0 to 8.5	7.8
5	Bacterial Endotoxin test	NMT 5.0 Eu/mg	Less than 5.0 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= 236.67/Container > 25 microns= 5.00/Container
7	Sterility test	sterilite	sterilite
8	Assay	94.0 % to 106.0 % of the labelled amount of sodium bicarbonate	100.9% 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 22/02/25	Checked By 22/02/25	Approved By 22/02/25
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