

QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product
 (Under Drug And Cosmetic Act. 1940 & The Rules There Under)

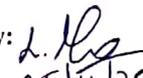
Report No: TT/ FG/410/24-25
Report Date: 25-11-2024

Name of the product	: SODICAN Injection 10ml
Generic Name	: Sodium Bicarbonate Injection I.P
Batch No.	: SB419
Batch Size	: 51000
Mfg. Date.	: NOV-2024
Exp. Date.	: OCT-2027
Quantity of Sample	: 50Nos
Date of Sampling	: 10-11-2024
Date of Commencement of analysis	: 10-11-2024
Date of Completion of analysis	: 24-11-2024

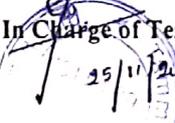
TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution.
Identification:		
A. Residue on evaporation, when moistened with hydrochloric acid and introduced on platinum wire into a flame .	Imparts a yellow colour to the flame	Complies to IP specification
B. Reaction (A) of sodium salt	A dense white precipitate is formed	Complies to IP specification
Reaction of Bicarbonates	A white precipitate is formed	Complies to IP specification
pH	7.0 to 8.5	8.25
Extractable Volume	NLT - 10ml/ Ampoule	10.5ml
Bacterial Endotoxins	NMT 1.7 EU/ml of Sodium Bicarbonate.	LT 1.7 EU/ml
Particulate matter	No visible particles	No visible particles
Sterility Test	To comply as per IP	Comply as per IP
Assay	94.0% - 106.0%	99.86%
Each ml contains : Sodium Bicarbonate I.P 7.5% w/v	7.05%w/v to 7.95%w/v	7.49%W/V

OBSERVATION: In the opinion of the undersigned the sample referred to above is of **Standard Quality/Not Standard Quality** as in the act and the rules made there under for the reason given below.

REMARKS : COMPLIES AS PER IP/IHS WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By: 
 Date: 25/11/2024

Checked By: 
 Date: 25/11/2024

Person In Charge of Testing
 Date: 
 25/11/24