



Tamman Titoe Pharma Pvt Ltd
56-57, Sidco Pharmaceutical Complex,
Alathur-603 110, Tamilnadu.

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

Report No: TT/ FG/399/24-25
Report Date: 21-11-2024

Name of the product : SODICAN Injection 10ml
Generic Name : Sodium Bicarbonate Injection I.P
Batch No. : SB417
Batch Size : 51000
Mfg. Date. : NOV-2024
Exp. Date. : OCT-2027
Quantity of Sample : 50Nos
Date of Sampling : 06-11-2024
Date of Commencement of analysis : 06-11-2024
Date of Completion of analysis : 20-11-2024

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	8.30
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%	99.26%
Each ml contains : Sodium Bicarbonate I.P 7.5% w/v	7.05%w/v to 7.95%w/v	7.44%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: *[Signature]*
Date: 21/11/2024

Checked By: *[Signature]*
Date: 21/11/2024

Person In Charge of Testing: *[Signature]*
Date: 21/11/24