

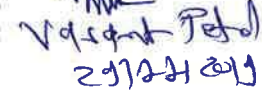
Vill – Sachana, Tal – Viramgam, Dist.– Ahmedabad – 382150, Gujarat. Phone : 02715-248001-5 Fax : 248007

CERTIFICATE OF ANALYSIS

PRODUCT : Sodium Chloride Injection BP (0.9% w/v) (NS 20ml)	
Batch No. : 766210351	Insp Lot NO. : 040000515863
Mfg. Date : NOV-2019	Exp. Date : OCT-2024
Batch Size : 2000 LTR.	Qty sampled : 45 AMPOULES.
Testing Date: 13/11/2019	Completion Date : 29/11/2019

Sr. No.	Tests	Observation	Specification
01	PACKAGING	Ampoule of Low Density Polyethylene, labeled in printed cardboard case.	
02	CHARACTERISTIC	Colorless, transparent and free of foreign particles solution	Colorless, transparent and free of foreign particles solution.
03	HERMETIC SEAL	Complies	Should Comply
04	IDENTIFICATION (1)A, Reaction of sodium salt B, Reaction of sodium salt (2) Reaction of chloride salt	Complies Complies Complies	(1)A, A dense white precipitate is formed. B, No precipitate is formed. (2) Gives reaction of Chloride
05	BACTERIAL ENDOTOXINS	< 0.25 IU/ML Complies	Not more than 0.25 IU/ml
06	ASSAY SODIUM CHLORIDE	99.53 % of labeled	95.0 to 105.0 % of labeled
07	PARTICULATE CONTAMINATION	57.0prc/ct 12.0 prc/ct	Counts Per Container ≥10 micron- Max 6000 ≥25 micron- Max 600
08	EXTRACTABLE VOLUME	21.0 ml Complies	Not less than nominal volume.
09	STERILITY	Sterile Complies	Should comply
10	pH	5.424 Complies	Between 4.50 to 7.00

Report: The product complies with the prescribed standards of the quality as per specification.

ANALYST : 
NAME : 
29/11/2019

QA MANAGER : 
NAME : 

