



M N CHEMICALS LIMITED

Manufacturers of Bulk Drugs & Fine Chemicals

An ISO 9001 : 2015 & GMP Certified

Certificate of Analysis

PRODUCT : SODIUM CHLORIDE BP (For Injectable Preparations)

BATCH No. : 1224 – 339/AB

BATCH SIZE : 5000 Kgs

MFG. DATE : 12/2024

EXP. DATE : 11/2029

Q.C. REPORT No. : 339/AB

Sl. No.	TEST PARAMETERS	SPECIFICATION	TEST RESULTS
1.	Description	White or colourless crystals or a white crystalline powder.	White crystalline powder.
2.	Solubility	Freely soluble in water, practically insoluble in Ethanol.	Freely soluble in water, practically insoluble in Ethanol.
3.	Identification	a) It gives reaction of Chlorides. b) It gives the reactions of sodium salts.	a) It gives reaction of Chlorides. b) It gives the reactions of sodium salts.
4.	Appearance of solution	20 % w/v solution is clear and colourless (Solution S).	20 % w/v solution is clear and colourless (Solution S).
5.	Acidity or alkalinity	Not more than 0.5 ml of 0.01 M Hydrochloric acid or 0.01 M Sodium hydroxide is required to change the colour of indicator.	0.12 ml of 0.01 M Sodium hydroxide is required to change the colour of indicator.
6.	Arsenic	Not more than 1 ppm	Less than 1 ppm
7.	Iron	Not more than 2 ppm	Less than 2 ppm
8.	Magnesium and alkaline earth metals	Not more than 100 ppm	9.8 ppm
9.	Barium	Any opalescence in the solution is not more intense than that in a mixture of 5 ml of solution S and 7 ml of distilled water.	The opalescence of test solution is less intense than control solution.
10.	Sulphates	Not more than 200 ppm	Less than 200 ppm
11.	Iodides	No blue colour develop within 5 minutes.	No blue colour is develops.
12.	Bromides	Not more than 100 ppm	Less than 100 ppm
13.	Nitrites	The absorbance is not greater than 0.01	Less than 0.01
14.	Phosphates	Not more than 25 ppm	Less than 25 ppm
15.	Ferrocyanides	No blue colour develop within 10 minutes.	No blue colour is develops within 10 minutes.
16.	Loss on drying	Not more than 0.5 %	0.21%
17.	Assay	Not less than 99.0 % and not more than 100.5 % of Sodium chloride, calculated on the dried basis.	99.78 %
18.	Potassium	Not more than 500 ppm	Less than 500 ppm
19.	Aluminium	Not more than 0.2 ppm	Less than 0.2 ppm
20.	Bacterial endotoxins	Not more than 5 IU / gm	Less than 5 IU / gm

REMARKS: ALL TEST RESULTS OF ABOVE SAMPLE COMPLIES WITH PRESCRIBED BP STANDARD.

Manager Q. A.

Analytical Chemist