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Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Sodium Chloride EP

Page No.: 1 of 4

Specification No.:
ACPL/FP/SP/010

Revision No.:
00

Effective Date
29/06/2021

Review Date
28/06/2024

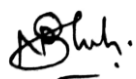
Change Control No.

NA

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Date: 26/06/2021

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1.0 SAMPLING LEVEL:

As mentioned in the “Sampling procedure” SOP.

2.0 SAMPLING METHOD TO BE FOLLOWED:

100% sampling to be done from each container.

3.0 TOTAL COMPOSITE SAMPLE TO BE COLLECTED :

100 gm

4.0 EXPIRY:

Five years from the Date of Manufacturing.

5.0 CAS No: 7647-14-5

6.0 MOLECULAR FORMULA: NaCl

7.0 MOLECULAR WEIGHT: 58.44 gm/mol.

8.0 CATEGORY: Used in treatment of electrolyte deficiency.

9.0 STORAGE: In a non-metallic, airtight container.

10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING :

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white crystalline powder or colorless crystals or white or almost white pearls.
2.	Solubility	Freely soluble in water, practically insoluble in anhydrous ethanol.
3.	Identification A Give reaction of Chloride Identification B Give reaction of Sodium	To pass test To pass test
4.	Appearance of Solution (20% Soln.)	Solution is clear & colorless
5.	Acidity or Alkalinity	NMT 0.5 ml of 0.01MHCl / NaOH
6.	Bromides	Max. 100 ppm
7.	Ferrocyanide	To pass test
8.	Iodides	To pass test
9.	Nitrites	The absorbance is not greater than 0.01 at 354 nm.
10.	Phosphates	25 ppm
11.	Sulfates	Max. 200 ppm
12.	Aluminium	Max. 0.2 ppm
13.	Arsenic (As)	Max 1 ppm

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14.	Barium (Ba)	To pass test
15.	Iron (Fe)	Max. 2 ppm
16.	Magnesium and alkaline-earth metals(as Ca)	Max. 100 ppm
17.	Potassium	Max. 500 ppm
18.	Loss on drying (105°C)	Max.0.5 %
19.	Bacterial Endotoxins	Less than 5 IU/g
20.	Assay(dried basis)	99.0 % to 100.5 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	29/06/2021	First Issuance	N A

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