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Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,									
Ta- Savli, Dist. Vadodara, Gujarat, India Quality Control									
Quality Control Standard Test Specifications									
Title: Sodium Chloride IP Page No.: 1 of 3									
Specification No.: ACPL/FP/SP/010	Revision No.: 00	Effective Date 25/06/2021	Review Date 24/06/2024						
Change Control No.	NA								
	aj Patel Officer / Designee)	Date: <u>22/06/20</u>	<u>021</u>						
	<u>sh Shah</u> Head / Designee)	Date: <u>23/06/20</u>	<u>)21</u>						
	<u>esh Solanki</u> QC In Charge / Designee)	Date: <u>24/06/2(</u>	<u>)21</u>						
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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 IP	Page No.: 2 of 3		
Specification No.: ACPL/FP/SP/010	Revision No.:	Effective Date 25/06/2021	Review Date 24/06/2024
Change Control No.	NA	25/00/2021	

1.0 SAMPLINGLEVEL:

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: 58.40 gm/mol.

8.0 CATEGORY: Pharmaceutical aid (tonicity agent); fluid and electrolyte replenisher.

9.0 STORAGE: Store protected light.

10.0 SAFETY PRECAUTIONS TO BE TAKENWHILE SAMPLING AND HANDLING :

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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Certified By (Sign/Date) :

25/06/2021

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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 IPPage No.: 3 of 3								
Specificat		Revision N 00	Revision No.:		Effective Date	Review Date		
	ACPL/FP/SP/010 Change Control No.				25/06/2021	24/06/2024		
		NA						
	TEST PARAMETERS AND SPECIFICATIONS REF: IP							
Sr. No.	TEST PARAMETER		SPECIFICATION					
1.	Description	Description		White or colorless crystals or white crystalline powder				
	Identification	ı A	То ра	ass test				
	Give reaction of Chloride							
2.	Identification B		To pass test					
	Give reaction of Sodium salt							
3.	Appearance of Solution			Solution is clear & colorless				
4.	Acidity or Alkalinity		NMT 0.5 ml of 0.01MHCl / NaOH					
5.	Arsenic (As)		Max 1 ppm					
6.	Barium (Ba)		To pass test					
7.	Bromides		Max. 100 ppm					
8.	Calcium & Magnesium(as Ca)		Max. 50 ppm					
9.	Ferrocyanide		To pass test					
10.	Heavy metals (as Pb)		Max. 5 ppm					
11.	Iodide		To pass test					
12.	Iron (Fe)		Max. 20 ppm					
13.	Sulfate (SO ₄)	ulfate (SO ₄)		Max. 300 ppm				
14.	Loss on dryin	ing (105°C)		Max. 1.0%				
15. PEVISION			NLT	NLT 99.0 % -NMT 100.5 %				
	REVISION HISTORY:Revision No.Effective Date		te	Re	vision Description	Change Control No.		
	00				First Issuance	N A		
						1		
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Format No. QC	C/017/F/01-00			Ce	ertified By (Sign/Date	e): 125/06/2021		