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

Quality Control

Standard Test Specifications

Title: Sodium Bicarbonate USP

Page No.: 1 of 4

Specification No.:
ACPL/FP/SP/008

Revision No.:
00

Effective Date
02/07/2021

Review Date
01/07/2024

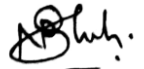
Change Control No.

NA

Prepared By: 


Date: 29/06/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 30/06/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 01/07/2021

Name : Naresh Solanki
(QA/QC In Charge / Designee)

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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: 144-55-8**6.0 MOLECULAR FORMULA:** NaHCO₃**7.0 MOLECULAR WEIGHT:** 84.01gm/mol.**8.0 CATEGORY:** Electrolyte replenisher, systemic alkaliser.**9.0 STORAGE:** Store Protected from moisture.**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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Description	White or almost white crystalline powder
2.	Identification A Test for Sodium	To pass test
	Identification B Test for Bicarbonate	To pass test
3.	Assay (dried basis)	99.0 % - 100.5 %
4.	Insoluble substance	To Pass test
5.	Carbonate	NMT 0.23 %
6.	Normal Carbonate	To Pass test
7.	Chloride	NMT0.015%
8.	Sulfur Compounds	NMT 0.015%
9.	Aluminum	NMT 2 μ g/g
10.	Arsenic (As)	Max. 2 ppm
11.	Calcium (Ca)	NMT 0.01 %
12.	Magnesium(Mg)	NMT 0.004 %
13.	Copper (Cu)	NMT 1 ppm
14.	Iron (Fe)	NMT 5 ppm

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15.	Limit of Ammonia	NMT 20 ppm
16.	Limit of Organics	NMT 0.01 %
17.	Loss on Drying	NMT 0.25 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	02/07/2021	First Issuance	N A

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