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Date: 25/08/2021

Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Sodium Carbonate Anhydrous JP Page No.: 1 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0090028/08/202127/08/2024

Change Control No. NA

Prepared By:

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: <u>26/08/2021</u>

Name : <u>Nilesh Shah</u>

(Unit Head / Designee)

Approved By: _____ Date: <u>27/08/2021</u>

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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Format No. QC/017/F/01-00

Certified By (Sign/Date):



28/08/2021

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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 Carbonate Anhydrous JP Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0090028/08/202127/08/2024

Change Control No. NA

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: 497-19-8

6.0 MOLECULAR FORMULA: Na₂CO_{3.}

7.0 MOLECULAR WEIGHT: 105.99gm/mol.

8.0 CATEGORY: Excipients.

9.0 STORAGE: In an airtight container.

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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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Sodium Carbonate Anhydrous JP Page No.: 3 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/009
 00
 28/08/2021
 27/08/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: JP

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Description	White Crystal and Crystalline powder.
2.	Solubility	It is freely soluble in water, and practically insoluble in ethanol (95 %) and in diethyl ether.
3.	Identification Qualitative Tests for sodium salt and for carbonate	To pass test
4.	Appearance of Solution	The solution is clear and colorless.
5.	Chloride (Cl)	Max. 710 ppm
6.	Heavy metal	Max. 20 ppm
7.	Arsenic (As)	Max. 3.1 ppm
8.	Loss on drying	Max. 2.0 %
9.	Assay % (Dried Basis)	Min. 99.0 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	28/08/2021	First Issuance	N A

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Format No. QC/017/F/01-00

Certified By (Sign/Date):



28/08/2021