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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Standard	<b>Test</b>	Spec	cifica	tions

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

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

 ACPL/FP/SP/009
 00
 27/08/2021
 26/08/2024

Change Control No. NA

Prepared By: \_\_\_\_\_ Date: <u>24/08/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: 25/08/2021

Name : Nilesh Shah\_\_\_\_\_

(Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: 26/08/2021

Name : Naresh Solanki\_\_\_\_\_

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

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27/08/2021

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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 BP Page No.: 2 of 3

 Specification No.:
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**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**: Na<sub>2</sub>CO<sub>3</sub>.

**7.0 MOLECULAR WEIGHT**: 106.0gm/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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**Quality Control** 

**Standard Test Specifications** 

Title: Sodium Carbonate Anhydrous BP **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/009 27/08/2021 26/08/2024 00

Change Control No. NA

#### TEST PARAMETERS AND SPECIFICATIONS **REF: BP**

Sr. No.	TEST PARAMETER SPECIFICATION			
1.	Appearance	White or almost white, slightly granular powder, hygroscopic.		
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 per cent).		
	Identification A	To pass test		
	The solution is strongly alkaline			
	Identification B	To pass test		
3.	Give reaction of Carbonates	To pass test		
3.	Identification C			
	test A gives reaction (a) of sodium	To pass test		
	Identification D			
	Loss on drying (see Tests).			
4.	Appearance of Solution (20% Soln.)	The solution is clear and not more intensely colored than reference solution $Y_6$ .		
5.	Alkali hydroxides and bicarbonates	The solution remains clear		
6.	Chlorides (Cl) Max. 125 ppm			
7.         Sulfates (SO <sub>4</sub> )         Max. 250 ppm           8.         Arsenic (As)         Max. 5 ppm		Max. 250 ppm		
		Max. 5 ppm		
9.	Iron (Fe)	Max. 50 ppm		
10.	Loss on drying	Max. 1.0 %		
11.	Assay %(Dried Basis)	99.5 % to 100.5 %		

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	27/08/2021	First Issuance	N A

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