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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 IP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/009

Revision No.:
00

Effective Date
27/08/2021

Review Date
26/08/2024


Change Control No.

NA

Prepared By: 

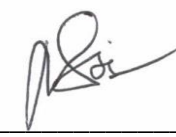
Date: 24/08/2021

Name : Pankaj Patel
(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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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:** Na₂CO₃.**7.0 MOLECULAR WEIGHT:** 106.00gm/mol.**8.0 CATEGORY:** Pharmaceutical aid (alkalizing agent).**9.0 STORAGE:** Store in tightly-closed, non-metallic containers.**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: IP**

| Sr. No. | TEST PARAMETER | SPECIFICATION |
|---------|--|--|
| 1. | Description | A white or almost white, slightly granular powder, hygroscopic. |
| 2. | Identification A The solution is strongly alkaline Identification B Test A gives reaction (A) of carbonate and sodium salts | To pass test To pass test |
| 3. | Appearance of Solution (20% Soln.) | The solution is clear and not more intensely colored than reference solution YS ₆ . |
| 4. | Alkali hydroxides and bicarbonates | The solution remains clear |
| 5. | Heavy metals | Max. 50 ppm |
| 6. | Iron (Fe) | Max. 50 ppm |
| 7. | Chlorides (Cl) | Max. 125 ppm |
| 8. | Sulfates (SO ₄) | Max. 250 ppm |
| 9. | Loss on drying | Max. 1.0 % |
| 10. | 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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