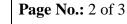
| MASTER COPY | | | Annexe | |
|--|--|---------------------------------|---------------------------|--|
| Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775, | | | | |
| Ta- Savli, Dist. Vadodara, Gujarat, India Quality Control | | | | |
| | Standard Test S | | | |
| Title: Sodium Bicarbonate JP | | | Page No.: 1 of 3 | |
| Specification No.: ACPL/FP/SP/008 | Revision No.: 00 | Effective Dat 28/06/2021 | te Review Date 27/06/2024 | |
| Change Control No. N. | A | | | |
| Prepared By: Name : <u>Pankaj</u> (QC Of | Patel ficer / Designee) | Date: 2 | <u>24/06/2021</u> | |
| Reviewed By: Name : <u>Niles</u> (Unit F | Head / Designee) | Date: <u>2</u> | <u>25/06/2021</u> | |
| | <u>n Solanki</u> C In Charge / Designee) | | <u>26/06/2021</u> | |
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| Format No. QC/017/F/01-00 | Format No. QC/017/F/01-00 Certified By (Sign/Date): 28/06/2021 | | | |

MASTER COPY Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India Quality Control Standard Test Specifications Title: Sodium Bicarbonate JP



| Specification No.: | Revision No.: | Effective Date | Review Date |
|--------------------|----------------------|----------------|--------------------|
| ACPL/FP/SP/008 | 00 | 28/06/2021 | 27/06/2024 |
| 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: 144-55-8

6.0 MOLECULAR FORMULA: NaHCO3.

7.0 MOLECULAR WEIGHT: 84.1gm/mol.

8.0 CATEGORY: Antacid; use in treatment of electrolyte deficiency.

9.0 STORAGE: Store Protected from moisture.

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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|----|---|------------------------------------|--|----------|---------------------------|-------------------------------|
| L | Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775, Ta- Savli, Dist. Vadodara, Gujarat, India | | | | | |
| | | | Qua | lity Con | trol | |
| Т | tla: Sadin | m Bicarbonate JP | Standard 7 | Fest Spe | cifications | Page No.: 3 of 3 |
| 11 | ue. Soulu | ini Dicai Donate Ji | | | | 1 age 110 5 01 5 |
| | | cation No.: | Revision No.: | | Effective Date | Review Date 27/06/2024 |
| | ACPL/FP/SP/008 Change Control No. NA | | | | | 27/00/2024 |
| | TEST PARAMETERS AND SPECIFICATIONS REF: JP | | | | | |
| | Sr. No. | TEST PAI | RAMETER | SPECI | FICATION | |
| | 1. | Description | | white, | crystals or crystalline p | powder |
| | 2. Solubility | | Soluble in water, and practically insoluble in ethanol (95%) and in diethyl ether. | | | |
| | Identification | | To pass test | | | |
| | 3. | Qualitative Tests for bicarbonate. | or sodium salt and | | | |
| | 4. pH of 5% Soln. | | 7.9 to 8.4 | | | |
| | 5. Appearance of Solution | | The solution is clear and colorless. | | | |
| | 6. Chlorides (Cl) | | Max. 400 ppm | | | |
| | 7. Carbonate | | To Pass test | | | |
| | 8. Ammonium (NH ₄) | | To Pass test | | | |
| | 9. Heavy metals | | Max. 5 ppm | | | |
| | 10. Arsenic (As) | | Max. 2 ppm | | | |
| | 11. Assay % | | Min. 99.0 % | | | |

REVISION HISTORY:

| Revision No. | Effective Date | Revision Description | Change Control No. |
|--------------|----------------|-----------------------------|--------------------|
| 00 | 28/06/2021 | First Issuance | N A |

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