

**TITLE: PRODUCT SPECIFICATION DATA SHEET TITLE:
SODIUM BICARBONATE FINE GRADE (4F)****CODE
CAM-ENG-FEP-100-013****REVIEW
02****PAGE 1 OF 2**

| | | |
|-----------------------|-------------------------------------|---|
| DENOMINATIONS: | Chemical name | Acid Sodium Carbonate |
| | Other names | Monosodium Salt of Carbonic Acid Hydrogen Sodium Carbonate |
| | Type | Fine Grade |
| | Nº (CAS) Chemical Abstracts Service | 144-55-8 |
| | Formula | NaHCO ₃ |

| CHEMICAL SPECIFICATIONS | TESTS | UNIT | SPECIFICATION |
|------------------------------------|--------------------------------------|-------------|---|
| | Assay (as NaHCO ₃) | % | 99,0 – 100,5 |
| | Characteristics | - | White crystalline powder, odorless, subject to agglomeration |
| | Loss on Drying | % | 0,25 max. |
| | Carbonates (pH) | - | 8,6 max. |
| | Normal carbonate | - | Faint pink color |
| | Chloride | ppm | 150 max. |
| | Iron | ppm | 5 max. |
| | Calcium | ppm | 100 max. |
| | Heavy Metals (as Pb) | ppm | 10 max. |
| | Arsenic | ppm | 2 max. |
| | Sulfate | ppm | 150 max. |
| | Limit of sulfur compounds | ppm | 150 max. |
| | Identification (sodium, bicarbonate) | - | Pass test |
| | Insoluble Substances | - | Clear and transparent solution. Soluble in water, practically insoluble in ethanol |
| | Solubility | - | (96%). |
| | Limit of Ammonia | ppm | 20 max |
| | Appearance of solution | - | Clear and bright solution |

| | TESTS | UNIT | SPECIFICATION |
|-----------------------------------|--------------------------|-------------|----------------------|
| PARTICLES SIZE PROFILE | Retained mesh 60 (250 µ) | % | 1 max. |
| | Retained mesh 325 (45 µ) | % | 80 min. |
| | Passed mesh 325 (45 µ) | % | 20 max |

STORAGE: To store in ventilated, dry place, under the cover of the direct solar light. Subject to thermal decomposition above of 60 °C. Maximum pile 30 bags.

PACKAGING: 25 Kg Polyethylene bag with the following information: lot number; validity of the product; date of production

VALIDITY: 36 months from the date of production, observed the stockage conditions.

Meets the specifications required by the Brazilian Pharmacopoeia, United States Pharmacopeia, and British Pharmacopoeia. The product is suitable for pharmaceutical use (oral route) according to the current legislation approved by the National Health Surveillance Agency and the Products Division of the Ministry of Health.

“This product is not applicable for use in hemodialysis”.