



TÍTULO: **PRODUCT SPECIFICATION DATA SHEET  
SODIUM BICARBONATE FINE GRADE (4F)**

CODE: **CAM-ENG-FEP-100-013** REVISION: **01** REVISION DATE: **11/19/18** PÁGINA: **1/1**

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

<b>CHEMICAL SPECIFICATIONS</b>	TESTS	UNIT	SPECIFICATION
	Assay (as NaHCO <sub>3</sub> )	%	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 bright solution
Limit of Ammonia	ppm	20 max	
Appearance of solution	-	Clear and bright solution	

	TESTS	UNIT	SPECIFICATION
<b>PARTICLES SIZE PROFILE</b>	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.

The product meets the specification of U.S. Pharmacopeia, Brazilian Pharmacopeia and British Pharmacopeia being appropriated for PHARMACEUTICAL uses.

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

ELABORATION	REVISION		APPROVAL	
<b>Elaborated by:</b> Érica von Glehn	<b>Revised by:</b> André Medeiros	<b>Approved by</b> Loures Silva	<b>Approved by</b> Cristina Duarte	<b>Approved by</b> Ascânio Pêpe
<b>Dept.:</b> Quality Assurance	<b>Dept.:</b> Production	<b>Dept.:</b> Quality Control	<b>Dept.:</b> Quality Assurance	<b>Dept.:</b> Director
<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>