



**TITLE:PRODUCT SPECIFICATION DATA SHEET  
SODIUM BICARBONATE SPECIAL GRANULATED (4G)**

**CODE**

CAM-ENG-FEP-100-001

**REVIEW**

02

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<b>DENOMINATIONS:</b>	Chemical names	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Acid
	Type	Hydrogen Sodium Carbonate
	Nº DCB	Special Granulated Grade
	Nº (CAS) Chemical Abstracts Service	01249
	Formula	144-55-8
		NaHCO <sub>3</sub>

<b>CHEMICAL SPECIFICATIONS</b>	<b>TESTS</b>	<b>UNIT</b>	<b>SPECIFICATION</b>
	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)	-	Test pass
	Insoluble Substances	-	Clear and bright solution
	Limit of Ammonia	ppm	20 max
	Appearance of solution	-	Clear and bright solution

	<b>TESTS</b>	<b>UNIT</b>	<b>SPECIFICATION</b>
<b>PARTICLES SIZE PROFILE</b>	Retained mesh 60 (250 µ)	%	5 max.
	Accumulated retained mesh 60 and 120 (250 µ and 125 µ)	%	90 min.
	Passing mesh 120 (125 µ)	%	10 max.

**STOCKAGE:** 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 or Big-bag with the following information: lot number; expire date; production date.

**VALIDITY:** 36 months from the date of production, observed the storage 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”.**