



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

CODE: **CAM-ENG-FEP-100-001** REVISION: **01** REVISION DATE: **11/13/18** PÁGE: **1/1**

<b>DENOMINATIONS:</b>	Chemical names	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Acid Hydrogen Sodium Carbonate
	Type	Special Granulated Grade
	N° DCB	01249
	N° (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)	-	Test pass
	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</b>	Retained mesh 60 (250 µ)	%	5 max.
<b>PROFILE</b>	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.

Complies with the specifications required by the Brazilian Pharmacopeia, American Pharmacopeia and British Pharmacopeia. The product is appropriate for pharmaceutical use, according to the legislation in force approved by the National Agency of Sanitary Supervision and Product Division of the Brazilian Ministry of Health.

**“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> Lourdes 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>