



TITLE: **PRODUCT SPECIFICATION DATA SHEET  
SODIUM BICARBONATE SPECIAL FINE GRADE (4E)**

CODE: **CAM-ENG-FEP-100-002** REVISION: **19** REVISION DATE: **03/08/17** PAGE: **1/1**

<b>DENOMINATIONS:</b>	Chemical names	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Acid Hydrogen Sodium Carbonate Special Fine Grade
	Type	01249
	N° DCB	144-55-8
	N° (CAS) Chemical Abstracts Service	NaHCO <sub>3</sub>
	Formula	

<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	5 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>PARTICLE SIZE</b>	Retained in mesh 80 (180 μ)	%	2 max.
<b>PROFILE</b>	Retained in mesh 200 (75 μ)	%	90 min.
	Passed in mesh 200 (75 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 with the following information: lot number; validity of the product; date of production

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

**The product above mentioned meets the specification of U.S. Pharmacopeia, Brazilian Pharmacopeia, European Pharmacopoeia and British Pharmacopoeia being appropriated to Pharmaceutical uses.**

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

ELABORATION	REVISION		APPROVAL	
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<b>Dept.:</b> Coordination of Quality Assurance	<b>Dept.:</b> Engineer of Process	<b>Dept.:</b> Supervision of Quality Control	<b>Dept.:</b> Management of Production	<b>Dept.:</b> Management of Quality Assurance and Environment
<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>	<b>Signature:</b>