



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

CODE: **CAM-ENG-FEP-100-002** REVISION: **01** REVISION DATE: **11/19/18** PAGE: **1/1**

DENOMINATIONS:	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 ₃
Formula		

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)	-	Test pass
	Insoluble Substances	-	Clear and bright solution
	Limit of Ammonia	ppm	20 max
Appearance of solution	-	Clear and bright solution	

	TESTS	UNIT	SPECIFICATION
PARTICLE SIZE	Retained in mesh 80 (180 μ)	%	2 max.
PROFILE	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	
Elaborated by: Érica von Glehn	Revised by: André Medeiros	Approved by Lourdes Silva	Approved by Cristina Duarte	Approved by Ascânio Pêpe
Dept.: Quality Assurance	Dept.: Production	Dept.: Quality Control	Dept.: Quality Assurance	Dept.: Director
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