



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

CODE

CAM-ENG-FEP-100-002

REVIEW

02

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DENOMINATIONS:	Chemical names	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Ácid
	Type	Hydrogen Sodium Carbonate
	Nº DCB	Special Fine Grade
	Nº (CAS) Chemical Abstracts Service	01249
	Formula	144-55-8
		NaHCO ₃

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 transparent solution. Soluble in water, practically insoluble in ethanol
	Solubility		(96%).
	Limit of Ammonia	ppm	20 max
	Appearance of solution	-	Clear and bright solution

	TESTS	UNIT	SPECIFICATION
PARTICLE SIZE PROFILE	Retained in mesh 80 (180 µ)	%	2 max.
	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.

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”.