

	TITLE: PRODUCT SPECIFICATION DATA SHEET SODIUM BICARBONATE EXTRA FINE GRADE (4X)		
	CODE CAM-ENG-FEP-100-005	REVIEW 02	PAGE 1 OF 1

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

	TESTS	UNIT	SPECIFICATION
CHEMICAL SPECIFICATIONS	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)	-	Pass test
	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
SIZE PARTICLES	Retained in mesh 140 (106 µ)	%	10 max.
PROFILE	Passed in mesh 140 (106 µ)	%	90 min.

STOCKAGE: To store in ventilated dry place, under the protection 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 stockage 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”.