

	TITLE: PRODUCT SPECIFICATION DATA SHEET SODIUM BICARBONATE HEMODIALYSIS – 4H		
	CODE CAM-ENG-FEP-100-003	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	Hemodialysis
	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	%	0,23 max.
	Normal carbonate	-	Faint pink color
	Chloride	ppm	150 max.
	Limit of organics	ppm	100 max.
	Iron	ppm	5 max.
	Calcium	ppm	100 max.
	Heavy Metals (as Pb)	ppm	10 max.
	Arsenic	ppm	2 max.
	Aluminum	ppm	2 max.
	Magnesium	ppm	40 max
	Copper	ppm	1 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
	Ph	-	7,0 – 8,5
	Filtration in 0,45µ	-	Pass test

	TESTS	UNIT	TYPICAL VALUE
PARTICLES SIZE	Retained mesh 60 (250 µ)	%	Max. 1
PROFILE	Passed mesh 325 (45 µ)	%	Max. 95

STOCKAGE: To store in ventilated dry place, under the protection of the direct solar light. Subject to themal decomposition above of 60 °C. Maximum pile 30 bags.

PACKAGING: 25 Kg Polyethylene bag or Big-bag with inside polyethylene liner, containing 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”.