



TITLE: PRODUCT SPECIFICATION DATA SHEET
SODIUM BICARBONATE HEMODIALYSIS – GRANULATED (4HG)

CODE
CAM-ENG-FEP-100-009

REVIEW
02

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DENOMINATIONS:	Chemical name	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Acid
	Type	Hydrogen Sodium Carbonate
	Nº DCB	Hemodialysis Granulated - HG
	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
	Characters	-	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

	TESTS	UNIT	SPECIFICATION
PARTICLES SIZE	Retained mesh 60 (250 µ)	%	Max. 5
PROFILE	Through mesh 200 (75 µ)	%	Max. 5

STORAGE: To store in ventilated, dry place, under the cover of the direct solar light. Subject to thermal decomposition above of 60 °C.

PACKAGING: Big-bag of 1000Kg with the following information: lot number; validity of the product; date of production, specifying use for hemodialysis.

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

Meets the specifications required by the United States Pharmacopeia for use in hemodialysis. The product is suitable for pharmaceutical use, according to the current legislation approved by the National Health Surveillance Agency and the Products Division of the Ministry of Health.