



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

CODE: **CAM-ENG-FEP-100-009** REVISION: **18** REVISION DATE: **03/08/17** PAGE: **1/1**

DENOMINATIONS:	Chemical name	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Acid Hydrogen Sodium Carbonate Hemodialysis Granulated - HG
	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
	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	5 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 bright solution
	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	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.

In compliance with the specifications demanded for U. S. Pharmacopeia used for HEMODIALYSIS.

ELABORATION	REVISION		APPROVAL	
Elaborated by: Antonia Soraia M. Neto	Revised by: André Medeiros	Approved by Ivonete Mota	Approved by Inamar Cruz	Approved by Ascânio Pêpe
Dept.: Coordination of Quality Assurance	Dept.: Process Engineer	Dept.: Supervision of Quality Control	Dept.: Management of Quality Assurance Environment	Dept.: Management of Production
Signature:	Signature:	Signature:	Signature:	Signature: