



TITLE: **PRODUCT SPECIFICATION DATA SHEET**
SODIUM BICARBONATE HEMODIALYSIS – 4H

CODE: **CAM-ENG-FEP-100-003**

REVISION: **01**

REVISION DATE: **11/13/18**

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DENOMINATIONS:	Chemical name	Acid Sodium Carbonate
	Other names	Monosodium Salt of Carbonic Acid Hydrogen Sodium Carbonate
	Type	Hemodialysis
	N° DCB	01249
	N° (CAS) Chemical Abstracts Service	144-55-8
	Formula	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	%	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 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	TYPICAL VALUE
PARTICLES SIZE	Retained mesh 60 (250 µ)	%	Max. 1
PROFILE	Passed mesh 320 (45 µ)	%	Max. 95

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 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.

The product is appropriate for pharmaceutical use, according to the legislation in force approved by the National Agency of Sanitary Supervision and Product Division of the Ministry of Health.

Complies with the specifications required by the American Pharmacopeia for use in HEMODIALYSIS.

ELABORATION	REVISION		APPROVAL	
Elaborated by: Érica von Glehn	Revised by: André Medeiros	Approved by Lourdes Silva	Approved by Cristina Duarte	Approved by Ascânio Pêpe
Dept.: Quality Assurance	Dept.: Production	Dept.: Quality Control	Dept.: Quality Assurance	Dept.: Director
Signature:	Signature:	Signature:	Signature:	Signature: