



TITLE: **PRODUCT SPECIFICATION DATA SHEET**
SODIUM BICARBONATE HEMODIALYSIS (4HF)

CODE: **CAM-ENG-FEP-100-016** REVISION: **01** REVISION DATE: **11/19/18** PAGE: **1/1**

DENOMINATIONS: Chemical name: Acid Sodium Carbonate
Other names: Monosodium Salt of Carbonic Acid
Type: Hydrogen Sodium Carbonate
N° DCB: Hemodialysis Super Granulated - HF
N° (CAS) Chemical Abstracts Service: 01249
Formula: 144-55-8
NaHCO₃

	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 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		

	CHEMICAL COMPOSITION	UNIT	SPECIFICATION
PARTICLES SIZE PROFILE	Retained mesh 60 (250 µ)	%	38 min.
	Passed mesh 100 (150 µ)	%	40 min.

STORAGE: To store in ventilated, dry place, under the protection 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 stockage conditions.

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

ELABORATION	REVISION		APPROVAL	
Elaborated by: Érica von Glehn	Revised by: André Medeiros	Approved by Lourdes Silva	Approved by Cristina Duarte	Approved by Ascânio Pêpe
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