

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

CAM-ENG-FEP-100-016

REVIEW

02

PAGE 1 OF 1**DENOMINATIONS:**

Chemical name

Acid Sodium Carbonate

Other names

Monosodium Salt of Carbonic Ácid

Type

Hydrogen Sodium Carbonate

N° DCB

Hemodialysis - HF

N° (CAS) Chemical Abstracts Service

01249

Formula

144-55-8

NaHCO₃**CHEMICAL SPECIFICATIONS****TESTS****UNIT****SPECIFICATION**Assay (as NaHCO₃)

%

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 transparent solution. Soluble in
water, practically insoluble in ethanol

Solubility

-

(96%).

pH

-

7,0 – 8,5

Filtration in 0,45µ

-

Pass test

CHEMICAL COMPOSITION**UNIT****SPECIFICATION****PARTICLES SIZE**

Retained mesh 60 (250 µ)

%

38 min.

PROFILE

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.

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.