



TECHNICAL DATA SHEET

Sodium Bicarbonate

PHARMACEUTICAL GRADE-Course

CHEMICAL INFORMATION

- NaHCO_3
- Molecular weight: 84g/mol
- Natrii hydrogenocarbonas
- (Sodium bicarbonate)
- N^o CAS: 144-55-8
- N^o EINECS: 205-633-8

IDENTIFICATION

- In compliance with European
- and British Pharmacopoeias and
- USP (latest editions in force)

ASPECT

White Crystalline powder

SOLUBILITY

Freely soluble in water, practically insoluble in ethanol 96%
5% aqueous solution: pH < 8.3

CHEMICAL CHARACTERISTICS	Specification	EUR.ph BP	USP
Sodium Bicarbonate (NaHCO_3)	99.0-100.5	✓	✓
Sodium Carbonate (Na_2CO_3) in %	≤1		
Carbonate (CO_3) in %	pH ≤ 8.6	≤ 8.3	
Loss on drying (H_2O) in %	≤ 0.25		✓
Chloride (Cl) in mg/kg	≤ 150	✓	✓
Sulfate (SO_4^{2-}) in mg/kg	≤ 150	✓	✓
Iron (Fe) in mg/kg	≤ 20	✓	≤ 5
Calcium (Ca) in mg/kg	≤ 100	✓	✓
Ammonium (NH_4) in mg/kg	≤ 20	✓	✓
Magnesium (Mg) in mg/kg	-		≤ 40
Aluminum (Al) in mg/kg	-		≤ 2
Arsenic (As) in mg/kg	≤ 2	✓	✓
Heavy metals in mg/kg	≤ 5	✓	✓
Insoluble substances	Conform		✓
Copper (Cu) in mg/kg	-		
Limit of organics in %	≤ 0.01		✓
Physical CHARACTERISTICS	Specification		
Particle size ≥ 150 micron	Min 50%	-	-

There is no residual solvent as Nova pharmed chemia manufacturing process is free from solvent.

Microbiological characteristics can be provided on demand. typical values are respectively ≤ 100 CFU/ml TAMC & ≤ 10 CFU/ml TYMC & ≤ 5 EU/ml bacterial Endotoxins. Specification value is the most restrictive between USP, European, British Pharmacopoeia. Values in "USP" column apply for hemodialysis grade only.