

SODIUM BICARBONATE – Pharmaceutical & Hemodialysis Grade (Ph.Eur./USP)
Brand Name: Nephrocarb

Product Information

Chemical Name:	Sodium Bicarbonate / Sodium hydrogen Carbonate
EC Number:	205-633-8
CAS Number:	144-55-8
Storage Conditions:	Store in dry Place, protected from Heat and moisture.
Packaging and Delivery:	25 Kg bag; 1000 Kg big-bag
Use:	Use as acidity regulator; blowing agent; absorbent; excipient

PHYSICAL PROPERTIES

Chemical Formula:	NaHCO ₃
Molecular Weight:	84.01
Appearance:	White or almost white Crystalline powder

PHYSICAL & CHEMICAL COMPOSITION

No.	Particle Size Distribution	Sieve Fraction	Analysis Method	Typical Value
1	Hemodialysis coarse grade	>150 µm	In House	50-70%
2	Pharmaceutical fine grade	<100 µm	In House	80-90%
No.	Parameter	Specification	Analysis Method	Typical Value
1	Appearance	White or almost white Crystalline powder	BP2019 EP2019	Passes Test
2	Bulk Density	0.8-1.3g/cm ³	In House	1-1.2
3	Solubility	Soluble in water-Practically insoluble in ethanol 96%	BP2019 EP2019	Passes Test
		A-Chemical test	BP2019 EP2019	Passes Test
4	Identification	B-Reaction of carbonates & bicarbonates	BP2019 EP2019	Passes Test
		C-Reaction of sodium	USP42	Passes Test
5	Appearance of solution	Clear & colourless	BP2019 EP2019	Passes Test
6	Sodium bicarbonate Assay	99-101%	BP2019 EP2019	99.9-100.5%

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7	Carbonates	The pH of freshly prepared solution S (5%) is not greater than 8.6. ≤0.35%	BP2019 EP2019 In House	≤8.2 ≤0.35%
8	Normal Carbonate	The solution does not assume more than a faint pink color immediately	USP 42	Passed Test
9	Moisture/Loss on Drying	<0.25% Moisture	BP2019	≤0.1%
10	Chloride	≤150 ppm	EP2019	≤150 ppm
11	Sulphate	≤150 ppm	USP42	≤150 ppm
12	Heavy metal	≤5 ppm	BP2017	≤5 ppm
13	Ammonia	≤20 ppm	BP2019 EP2019	≤20 ppm
14	Iron	≤20 ppm	BP2019 EP2019	≤20 ppm
15	Insoluble Substances	1g dissolve completely in 20 ml of water to give a clear and colorless solution.	USP42	Meet USP
16	Arsenic	≤2 ppm	BP2019 EP2019 USP42	≤2 ppm
17	Aluminum	≤2 ppm	USP42 BP2019	≤2 ppm
18	Calcium	≤100 ppm	EP2019 USP42	≤100 ppm
19	magnesium	≤40 ppm	USP42	≤40 ppm
20	copper	≤1 ppm	USP42	≤1 ppm
21	Limit of organics	≤0.01%	USP42	ND
22	There is no residual solvent as Nova pharmed Chemia manufacturing process is free from solvent.			
23	Microbiological characteristics can be provided on demand, typical values are respectively ≤100 CFU/gr TAMC & ≤10 CFU/gr TYMC & ≤ 5 EU/gr bacterial Endotoxins			

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