Certificate of Analysis/Typical Batch Analysis

SODIUM BICARBONATE (NAHCO3)

(Chemical name/Synonyms: Natron, Baking Soda, Bicarbonate of Soda, Sodium Hydrogen Carbonate)

REGULAR PHARMACEUTICAL GRADE
EP10/BP2020/USP43 (or most recent editions)
STANDARD Particle Size (NK)

Manufactured/Analysed in accordance with the Ph.Eur/BP/USP Pharmacopoeia
GMP for Pharmaceutical Excipients Certified, EXCiPACT, Reg. No. 541966 EXCI)
GMP for Active Ingredient Certified, German Pharmaceutical Authority No. DE-ST-01-GMP-2020-0039

REACH Reg. No.		01-2119457606-32-0020
EC No.		205-633-8
CAS-No.		144-55-8
Appearance		Solid white crystalline hygroscopic powder
Molecular weight		84,01
Chemical formula		$NaHCO_3$
Packing		25 kg multiply paper bags/1.000 kg big bags
Solubility		Soluble in water, Insoluble in ethanol (96%)
Appearance of solution		Clear and colorless

Chemical Analysis:			**Limit Values**	**Typical Batch Values**	**Methods**	**Frequency**
Bulk density		g/ml	0,950 – 1,200	1,150	Ph.Eur.	1
Identification A (Sodium)			Positive/Passes Test	Positive/Passes Test	USP	1
Identification B (Bicarbonate)			Positive/Passes Test	Positive/Passes Test	USP	1
$NaHCO_3$ content		%	99,0 – 101,0	≥ 99,60	Ph.Eur.	1
Carbonate		%	≤ 0,41	≤ 0,41	CSD	1
Loss on drying (on Silicagel)		%	≤ 0,25	≤ 0,10	Ph.Eur.	1
Water insoluble substances		%	Meets USP Requirements	Meets USP Requirements	USP	1
Carbonate pH-value (5% solution)			≤ 8,60	≤ 8,20	Ph.Eur.	2
Aluminium	(Al)	ppm	≤ 2,0	≤ 1,0	CSD	2
Ammonium	(NH_4)	ppm	≤ 20,0	≤ 10,0	CSD	2
Arsenic	(As)	ppm	≤ 2,0	≤ 1,0	CSD	2
Calcium	(Ca)	ppm	≤ 100,0	≤ 80,0	CSD	1
Magnesium	(Mg)	ppm	< 40,0	≤ 5,0	CSD	1
Chloride	(Cl)	ppm	≤ 150,0	≤ 50,0	CSD	1
Heavy metals (as Pb)	(Pb)	ppm	≤ 10,0	≤ 2,0	Ph.Eur.	4 *)
Sulphate	(SO_4)	ppm	≤ 150.0	≤ 150,0	CSD	2
Copper	(Cu)	ppm	≤ 1,0	≤ 1,0	CSD	2
Iron	(Fe)	ppm	≤ 5,0	≤ 2,0	CSD	1
Limit of organics	(-)	-	Meet USP requirements	Meet USP requirements	CSD	2
Microbial. purity:						
Organic volatile impurities	(-)	%	< 0,01	< 0,01	Ph.Eur.	1
Aerobic bacteria	(-)	CFU/g	< 100,0	< 100,0	Ph.Eur.	1
Bacterial endotoxines		IU/g	< 6,0	< 0,6	Ph.Eur	1

Particle size distribution		**Limit Values**	**Typical Batch Values**	**Methods**	
< 0,500	mm/%	≥ 95	95-100%	Sieves/CSD	1
< 0,315	mm/%		90-100%	Sieves/CSD	1
< 0,200	mm/%		70-95%	Sieves/CSD	1
< 0,100	mm/%		25-65%	Sieves/CSD	1

Method: Analyzed in accordance with the present editions of the Ph.Eur/USP Pharmacopoeia + CSD (Ciech Soda Deutschland)

Frequency: Tested on 1. Every batch – 2. Per Batch – 3. Every month – 4. Every 6 months (external laboratory)

*) Externat laboratory analysis on heavy metals, dioxin and non-dioxin like compounds can be provided

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Applications	Pharmaceuticals, Cosmetics, Food/Alimentary (as E500ii), Animal Feed, Technical
Identification	Gives reactions characteristic of sodium salts and of bicarbonates
Packing	25 kg net original multiply paper bags with 1 pe-layer as photo below (or 1.000 kg big bags) 
Weight tolerance	The tolerance on 25 kg bags is +/- 1%, as per the International Organization of legal Metrology (OIML)
Stability & Storage	**Stability:** The product is stable, stability tests/records can be provided on request **Shelf life:** Minimum 24 months from manufacturing (MFG) date **Lot Code Interpretation :** **04 01 171 01 08 2021 *means:*** 04 = Internal Product Type No. 01 = Granulation Code, in this case STANDARD Particle Size (NK) 171 = Production Line 01 08 2021 = 01/Day, 08/Month, 2021/Year of Manufacturing **Storage:** Sodium Bicarbonate of all types and particle sizes is highly hygroscopic. The below must be observed during the unloading from all means of transport and throughout the storage period. Sodium Bicarbonate: • absorb humidity, causing a tendency to form lumps. This process accelerates if the Sodium Bicarbonate is compacted during storage • absorb smells from other products stored nearby • give off CO_2, a process which increases as the temperature rises In general we recommend the following conditions of storage: • keep in a covered storage facility • kept in the original unbroken packing • kept away from any source of moisture • stored cool at a constant temperature well below 30ºC • kept dry and well ventilated • store at a relative humidity of less than 50 % in a well-ventilated storage facility • avoid storing Sodium Bicarbonate close to any sources of heat • avoid compacting, that is avoid stacking the bags more than 1 pallet or 1 x 1.000 kg big bag or 4-5 x 25 kg bags high if stored loose

Ver. 2021-08-NK

Frederiksberg/Copenhagen 01.08.2021