



Via Leonardo da Vinci, 43
I 20090 Trezzano sul Naviglio (MI)

Certificate of Analysis

Contract 2021012 Order-No.: P0201033986

Delivery order 494592

Delivery date 19.11.2021

Document date : 19.11.2021

Product: Sodium Bicarbonate, pharmaceutical grade
Standard granulation (NK)

Batch-No.: 030117114112021

Production Date: 14.11.2021

Retest/Expiry Date: 14.11.2023

Chemical Analysis:	limit value	current value
NaHCO ₃ content	%: 99,0 - 101,0	100,14
Normal Carbonate	%: meets USP requirements	
loss on drying %:	< 0,25 < 0,25	
Aspect of solution	: clear and colorless	clear and colorless
water-insoluble substances	%: meets USP requirements	
Carbonate pH		
(5 % solution in water)	: ≤ 8,6	8,4
Ammonium (NH ₄)	%: < 0,0020	< 0,0020
Aluminium (Al)	%: < 0,0002	< 0,0002
Arsenic (As)	%: < 0,0002	< 0,0002
Calcium (Ca)	%: < 0,0100	< 0,0100
Magnesium (Mg)	%: < 0,0040	< 0,0040
Copper (Cu)	%: < 0,0001	< 0,0001
Iron (Fe)	%: < 0,0005	< 0,0005
Heavy metals (Pb)	%: < 0,0010	< 0,0005
Chloride (Cl)	%: < 0,0150	< 0,0150
Sulfur Compounds (SO ₄)	%: < 0,0150	< 0,0150
Bulk density (g/ml)	: 0,950 - 1,200	1,153

Grain Size Distribution:

< 0,500 mm/%	: ≥ 95	99,9
< 0,315 mm/%	:	97,8
< 0,200 mm/%	:	85,1
< 0,100 mm/%	:	42,2

We hereby confirm that the above product complies with the requirements (limits) of the current PH. EUR/ USP/ BP Pharmacopoeia.

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Schug
Head of Quality

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