



Ciech
Soda Deutschland

CIECH Soda Deutschland GmbH & Co. KG * An der Löderburger Bahn 4a * 39418 Staßfurt

Certificate of Analysis

Contract 2022061 Order-No.: PO201037564
Delivery order 501580
Delivery date 26.04.2022

Document date : 20.04.2022

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

Batch-No.: 030117118042022
Production Date: 18.04.2022
Retest/Expiry Date: 18.04.2024

Chemical Analysis:	limit value	current value
NaHCO ₃ content	%: 99,0 - 101,0	100,47
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	8,3
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	1,151

Grain Size Distribution:

< 0,500 mm/%	: ≥ 95	99,9
< 0,315 mm/%	:	99,8
< 0,200 mm/%	:	91,1
< 0,100 mm/%	:	46,3

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

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Head of Quality

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FB-PQ-078/00