

Azelis Italia S.r.l

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

Certificate of Analysis 3.1. n. EN 10204 (2005)

Contract 2017089 Bestellung: 047240
Delivery order 399568
Date 06.03.2017

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

Chargen-/Batch-/Lot-No.: 05032017
 Retest/Expiry Date: 05.03.2017

Chemical Analysis:	limit value	current value
NaHCO ₃ content	%: > 99,0	99,88
Carbonate	%: < 0,23	0,21
loss on drying	%: < 0,25	0,08
water-insoluble substances	%: < 0,010	0,003
Carbonate pH (5 % solution in Water)	< 8,6	8,2
Aspect of solution	clear and colorless	clear and colorless
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	< 0,0005
Iron (Fe)	%: < 0,0005	< 0,0005
Heavy metals (Pb)	%: < 0,0005	< 0,0005
Chloride (Cl)	%: < 0,0150	< 0,0150
Sulfate (SO ₄)	%: < 0,0150	< 0,0150
Bulk density (g/ml)	: 0,950 – 1,200	1,125

Grain Size Distribution:	limit value	current value
< 0,500 mm/%	: 95 - 100	100,0
< 0,315 mm/%	: 90 - 100	95,3
< 0,200 mm/%	: 70 - 90	79,3
< 0,100 mm/%	: 25 - 60	50,2

We hereby certify that the above product is up to and analyzed in accordance with
 The present edition of the PH.EUR/USP/BP Pharmacopoeia.

Schug

Quality Manager

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