

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

Delivery order

Date

2016219

Bestellung: 044670

389610

12.09.2016

Product:

Sodium Bicarbonate, pharmaceutical grade

Standard granulation (NK)

Chargen-/Batch-/Lot-No.:

Retest/Expiry Date:

22082016

22.082018

| Chemical Analysis:         | limit value     | current value |
|----------------------------|-----------------|---------------|
| NaHCO3 content             | %: 99,0 - 101,0 | 99,63         |
| Carbonate                  | %: ≤ 0,23       | 0,21          |
| loss on drying             | %: < 0,25       | 0,10          |
| water-insoluble substances | %: < 0,010      | 0,004         |
| Carbonate pH               |                 |               |
| (5 % solution in water)    | : ≤ 8,6         | 8,2           |
| Ammonium (NH4)             | %: < 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     | 0,0002        |
| Heavy metals (Pb)          | %: < 0,0005     | < 0,0005      |
| Chloride (Cl)              | %: < 0,0150     | 0,0029        |
| Sulfate (SO4)              | %: < 0,0150     | < 0,0150      |

Bulk density (g/ml)

:

0,950 - 1,200

1,127

## Grain Size Distribution:

|              |            |       |
|--------------|------------|-------|
| < 0,500 mm/% | : 95 - 100 | 100,0 |
| < 0,315 mm/% | : 90 - 100 | 98,2  |
| < 0,200 mm/% | : 70 - 90  | 87,4  |
| < 0,100 mm/% | : 25 - 60  | 43,5  |

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

Head of Quality Control

This document was created using computer system.