



Ciech
Soda Deutschland

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Azelis Italia S.r.l.

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I 20090 Trezzano sul Naviglio (MI)

Certificate of Analysis

Contract 2021012 Order-No.: PO201030498
Delivery order 487649
Delivery date 19.07.2021

Document date : 19.07.2021

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

Batch-No.: 030117117072021
Production Date: 17.07.2021
Retest/Expiry Date: 17.07.2023

Chemical Analysis:	limit value	current value
NaHCO ₃ content	%: 99,0 - 101,0	100,42
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	8,2
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	1,154

Grain Size Distribution:

< 0,500 mm/%	: ≥ 95	99,9
< 0,315 mm/%	:	95,9
< 0,200 mm/%	:	80,6
< 0,100 mm/%	:	41,4

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

This document was created using computer system.

FB-PQ-078/00

BULLETIN ANALYTIQUE / CERTIFICATE OF ANALYSIS

REFERENCE PRODUIT : Actilight 950P " Fructo-Oligosaccharides"
PRODUCT

FICHE TECHNIQUE : S-STR-050 / Version 16
TECHNICAL SPECIFICATION

DATE DE FABRICATION : 23/08/21
MANUFACTURING DATE

DLUO / USE BEFORE : 23/08/23

LOT N° / BATCH N° : 0175012351

COMPOSITION GLUCIDIQUE : *SUGAR CONTENT :*

Glucose + Fructose + Saccharose % MS	4,6 %
<i>Glucose + Fructose + Sucrose %DM</i>	
GF2%FOS	35,5 % FOS
GF3%FOS	48,8 % FOS
GF4%FOS	15,6 % FOS
Total FOS % MS	95,4 %
<i>Total FOS % DM</i>	

BULLETIN ANALYTIQUE / CERTIFICATE OF ANALYSIS

Actilight 950P " Fructo-Oligosaccharides" -
0175012351

MICROBIOLOGIE :

MICROBIOLOGY :

Mésophiles totaux <i>Total plate count</i>	1 UFC / 10g MS
Levures <i>Yeasts</i>	Moins de 1 / 10 g MS
Moisissures <i>Moulds</i>	Moins de 1 / 10 g MS
Entérobactéries <i>Enterobacteria</i>	Moins de 1 / 10g MS
Coliformes totaux <i>Entero coliformes</i>	Moins de 1 / 10g MS

PHYSICO-CHIMIE :

PHYSICO-CHEMICAL DATA :

Humidite <i>Moisture</i>	2,86 %
pH <i>pH</i>	5,95
Couleur ICUMSA <i>Colouration</i>	16,9 Icumsa
Cendres conductimétriques <i>Conductimetric ashes</i>	0,0117 g%g de MS

Chevrières, le 26/10/2021

Laboratoire FOS / SLI