

Dr. Paul Lohmann GmbH &amp; Co. KGaA - Postfach 12 20 - D-31857 Emmerthal

N. KRALLIS S.A  
Deligiorgi 55-59  
10437 Athina  
GREECE

**Batch No** 3150445  
Released by Dr. Sebastian Bringmann  
Man./Release Date 05/11/2024  
Retest Date 04/11/2027

## Certificate of Analysis

### Zinc Gluconate

Powder, USP-NF 2024, FCC 14

**Our. conf. No** O12408515  
Your order DPL-40/98324  
  
DPL-Code No 503077006  
Page 1(2)  
Printing Date Emmerthal, 20/12/2024

Parameters	Limits	Results
Description	powder	powder
Colour	white	white
Identification Zinc (USP/FCC)	positive	positive
Identification TLC (USP/FCC)	conforms	conforms
pH (1 %)	5.5-7.5	6.3
Chloride (Cl)	max. 0.05 %	< 0.05 %
Sulfate (SO <sub>4</sub> )	max. 0.05 %	< 0.05 %
Reducing substances	max. 1.0 %	< 1.0 %
Arsenic (As)	max. 0.0003 %	< 0.0003 %
Lead (Pb)	max. 0.0002 %	< 0.0002 %
Cadmium (Cd)	max. 0.0002 %	< 0.0002 %
Lead (Pb, ICH-Q3D)	max. 5 ppm	< 5 ppm
Cadmium (Cd, ICH-Q3D)	max. 5 ppm	< 5 ppm
Thallium (Tl, ICH-Q3D)	max. 8 ppm	< 8 ppm
Water (H <sub>2</sub> O)	max. 11.6 %	6.7 %
Assay (on anhydrous basis, USP)	97.0-102.0 %	100.7 %
Total aerobic count (TAMC)	max. 2000 CFU/g	< 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g	< 200 CFU/g

Regarding the Residual Solvents we state herewith, that the controlled production, handling and storage of this material precludes the presence of the organic solvents as specified in Ph.Eur. (ICH 283/95) and USP <467>.

The product has been tested and found in compliance with above stated parameters. Above information does, however, not release customer from making his own controls upon receipt of goods.

Dr. Paul Lohmann GmbH &amp; Co. KGaA - Postfach 12 20 - D-31857 Emmerthal

N. KRALLIS S.A  
Deligiorgi 55-59  
10437 Athina  
GREECE

**Batch No** 3150445  
Released by Dr. Sebastian Bringmann  
Man./Release Date 05/11/2024  
Retest Date 04/11/2027

## Certificate of Analysis

### Zinc Gluconate

Powder, USP-NF 2024, FCC 14

**Our. conf. No** 012408515  
Your order DPL-40/98324  
  
DPL-Code No 503077006  
Page 2(2)  
Printing Date Emmerthal, 20/12/2024

Parameters	Limits	Results
<p>Heavy metal parameters of this spec. have been set in accordance to ICH Q3D guideline for elemental impurities on basis of a product related risk assessment. The risk assessment has been conducted considering option 1 (max. daily intake of 10g/d) for an oral application. Unless otherwise indicated or specified, the elements of class 1-3 (classification acc. ICH Q3D) are not likely to be present above the ICH Q3D option 1 limit in accordance to our assessment. Further elements are not intentionally added.</p> <p>The specification comprises elemental impurities based on the corresponding monograph. These elements are furthermore considered in the specification to comply with the monograph.</p>		

Manufacturer:  
Dr. Paul Lohmann GmbH & Co. KGaA, Hauptstrasse 2, D-31860 Emmerthal



(QC Manager)

The product has been tested and found in compliance with above stated parameters. Above information does, however, not release customer from making his own controls upon receipt of goods.