



Dr. Paul Lohmann GmbH & 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
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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 ₄)	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 ₂ 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.

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


(QC Manager)

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