

METAPHARMACEUTICAL

N DE LOTE:

0210222

LOTE: 3101495



Dr. Paul Lohmann®

Dr. Paul Lohmann GmbH & Co. KGaA • Postfach 1220 • D-31057 Emmerthal

Batch No : 3101495
Released by : T. Poppe
Man. /Release : 06/2021
Expiry/Retest Date : 05/2023

Our. conf. No : 012200778
Your order : 4500072987
Quantity : 50.0 kg
Packing Unit : 25.0 kg
DPL-Code No : 515009001
Page : 1(2)
Printing Date : Emmerthal, 28.01.2022

Certificate of Analysis
Zinc Sulfate 7-Hydrate

Cryst., Ph.Eur.10.Ed.

Parameters	Limits	Results
Description	Crystals	Crystals
Colour	colourless	colourless
Identification Zinc (Ph.Eur.)	positive	positive
Identification Sulfate (Ph.Eur.)	positive	positive
Appearance of solution (5 %)	conforms	conforms
pH (5 %)	4.4-5.6	5.2
Chloride (Cl)	max. 0.0300 %	< 0.0300 %
Iron (Fe)	max. 0.0100 %	< 0.0100 %
Cadmium (Cd, ICH-Q3D)	max. 5 ppm	< 5 ppm
Lead (Pb, ICH-Q3D)	max. 5 ppm	< 5 ppm
Nickel (Ni, ICH-Q3D)	max. 20 ppm	< 20 ppm
Thallium (Tl, ICH-Q3D)	max. 8 ppm	< 8 ppm
Assay ZnSO ₄ ·7H ₂ O (Ph.Eur.)	99.0-104.0 %	100.4 %
Total aerobic count (TAMC)	max. 2000 CFU/g	< 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g	< 200 CFU/g

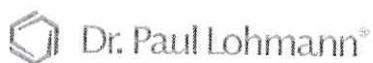
Regarding the Residual Solvents we state herewith, that the controlled production, handling and storage of this material precludes the presence of the organic solvents as specified in Ph.Eur. (ICH 283/95). Heavy metal parameters of this specification have been set in accordance to ICH Q3D guideline for 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.

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. This is a computer generated document and requires therefore no signature
Dr. Paul Lohmann GmbH & Co. KGaA, Hauptstrasse 2, D-31860 Emmerthal / Germany, Tel. +49 5155 63-0

RB - 009 / 032



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Further elements are not intentionally added.

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

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RB - C06 / C02