

**Mineral Salts
Low in
Endotoxins**

for parenteral Medicines



Dr. Paul Lohmann®

High value mineral salts

www.lohmann-minerals.com

Low in Endotoxin Products

Endotoxins are lipopolysaccharides (LPS) which are outer membrane components of gram-negative bacteria. By decomposing, these bacteria release lipopolysaccharides, which are toxic.¹

Parenteral medicines such as solutions for dialysis, hemofiltration and osmotherapy constitute a marked quality standard. Systemic parenteral application of infusions or injections with endotoxin quantities as low as 0.1 ng per kilogram of bodyweight can cause various physiological reactions, including fever, inflammation and sickness behavior in humans and animals². Due to the high sensitive application form, the manufacture of parenteral medicines requires particular caution: it is subject to strict and specific regulatory requirements and is regulated by Chapter 2.6.14 of the European Pharmacopoeia (Ph.Eur.)³. In order to support manufacturers of parenteral products to comply with legal and quality requirements, Dr. Paul Lohmann® offers Mineral Salts with a very low content of endotoxins.

Within the biotech industry, Low in Endotoxin qualities are of special interest for cell cultures. Endotoxins can cause undesirable effects on cell proliferation or cell function. Due to the high purity of our products, highly sensitive cell lines can develop in an optimal and laboratory controlled environment.



Low in Endotoxin Qualities of Dr. Paul Lohmann® Products

In 2017, a purpose-built plant was brought into service. This plant is GMP-certified and solely dedicated for the production of low endotoxin qualities. Thus our production process of high purity mineral salts including the use of low endotoxin process water is especially conceptualized for the purpose of the production of parenteral medicines.

- ◆ LAL test* according to Ph.Eur. is performed on every single batch.
- ◆ Our customers can optimally integrate our low in endotoxin qualities in their process chain for the manufacture of parenteral dosage forms (please see blue text on the next page).



- ◆ Low in Endotoxin Minerals – exceeding purity
- ◆ For the production of parenteral medicines and biopharmaceuticals
- ◆ For optimal environment of cell lines
- ◆ GMP certified

Applications

Low in Endotoxin mineral compounds can be used for the production of the following products:

- ◆ Solutions for parenterals:
 - ◆ Injections
 - ◆ Infusions
 - ◆ Nutrition
- ◆ Solutions for inhalants
- ◆ Solutions for
 - ◆ Dialysis
 - ◆ Peritoneal dialysis
 - ◆ Haemofiltration
 - ◆ Osmotherapy
- ◆ Ophthalmic preparations
- ◆ Biopharmaceuticals

Pharmaceutical manufacturers of preparations for infusion or injection are obliged to observe special regulations specified by the relevant pharmacopoeia and good manufacturing practices. We emphasize that our products are low in endotoxin content but not entirely free of endotoxins and not sterile. Therefore, these products must be treated with special procedures prior to their use in finished pharmaceutical products.

The pharmaceutical manufacturer must ensure that our products undergo special procedures and tests prior to being processed for infusion or injection preparations in order to induce their suitability for their intended purpose.

References

¹ Fennrich, S. et al.: More than 70 years of pyrogen detection: Current state and future perspectives; Alternatives to laboratory animals: ATLA, 06/2016, pp 239-53

² Salema, V., Pattnaik, P.: Removing endotoxin from biopharmaceutical solutions; Pharmaceutical Technology Europe, 10/2009, pp 36-38

³ European Medicines Agency (EMA): Guideline on the Replacement of Rabbit Pyrogen testing by an Alternative Test for Plasma Derived Medicinal Products; 04/2009

The information given in the document corresponds to our current knowledge. We warrant in the frame of our General Terms and Conditions of Sale that our products are manufactured in accordance with the specifications. However, we disclaim any liability with regard to the suitability of our products for a particular purpose or application or their compatibility with other substances. Tests have to be performed by the customer who also bears the risk in this respect. Nothing herein shall be construed as a recommendation to use our products in conflict with third parties' rights.

Products in Low in Endotoxin Quality

Product	Product no.	Quality***	Metal content (per 100 g)	Endotoxins (LAL*)
Acetates				
Calcium Acetate	515001001	Ph.Eur. USP-NF	approx. 24 % Ca	max. 6 EU**/g
Magnesium Acetate 4-hydrate	511019001	Ph.Eur.	approx. 11 % Mg	max. 6 EU**/g
Potassium Acetate, anhydrous	515002001	Ph.Eur.	approx. 40 % K	max. 6 EU**/g
Sodium Acetate 3-hydrate	511016001	Ph.Eur. USP-NF	approx. 17 % Na	max. 6 EU**/g
Zinc Acetate 2-hydrate	515006004	Ph.Eur.	approx. 30 % Zn	max. 25 EU**/g
Aspartates				
Magnesium DL-Aspartate 4-hydrate	501064001	DAB	approx. 6 % Mg	max. 6 EU**/g
Potassium DL-Aspartate 0.5 hydrate	501069001	DAB	approx. 21.5 % K	max. 6 EU**/g
Citrates				
Monosodium Citrate, anhydrous	502015001	DAC	approx. 10.5 % Na	max. 6 EU**/g
Trisodium Citrate 2-hydrate	502009001	Ph.Eur. USP-NF	approx. 23.5 % Na	max. 6 EU**/g
EDTA				
Calcium Disodium EDTA	511085002	Ph.Eur. USP-NF	approx. 10 % Ca approx. 11 % Ca	max. 6 EU**/g
Disodium EDTA 2-hydrate	505062001	Ph.Eur. USP-NF JP	approx. 12 % Na	max. 5 EU**/g
Glycerophosphates				
Sodium Glycerophosphate	512045001	Ph.Eur.	approx. 15 % Na	max. 6 EU**/g
Gluconates				
Calcium Gluconate 1-hydrate	503071003	Ph.Eur.	approx. 9 % Ca	max. 167 EU**/g
Magnesium Gluconate	503074004	Ph.Eur.	approx. 5.5 % Mg	max. 167 EU**/g
Zinc Gluconate	NEW 503077007	Ph.Eur.	approx. 14 % Zn	max. 25 EU/g
Lactates				
Sodium Lactate Solution; approx. 50%; from L-Lactic Acid	512012112	Ph.Eur.	approx. 10 % Na	max. 6 EU**/g
Sodium Lactate Solution; approx. 60%; from L-Lactic Acid	512012113	Ph.Eur. USP-NF	approx. 12.5 % Na	max. 6 EU**/g
Phosphates				
Monopotassium Phosphate	505044002	Ph.Eur.	approx. 28.5 % K approx. 22.8 % P	max. 50 EU**/g
Dipotassium Hydrogen Phosphate	505043004	Ph.Eur.	approx. 45 % K; approx. 18 % P	max. 3 EU**/g
Monosodium Phosphate, anhydrous	503062002	USP-NF	approx. 19 % Na approx. 25.5 % P	max. 30 EU**/g
Monosodium Phosphate 2-hydrate	503032002	Ph.Eur. USP-NF	approx. 15 % Na	max. 6 EU**/g
Disodium Hydrogen Phosphate 2-hydrate	503063003	Ph.Eur.	approx. 26 % Na approx. 17 % P	max. 20 EU**/g
Disodium Hydrogen Phosphate 7-hydrate	503048002	USP-NF	approx. 17 % Na approx. 12 % P	max. 5 EU**/g
Disodium Hydrogen Phosphate 12-hydrate	503031002	Ph.Eur.	approx. 13 % Na approx. 8.5 % P	max. 6 EU**/g
Succinates				
Sodium Succinate, anhydrous	502080002	NF	approx. 28 % Na	max. 6 EU**/g
Sodium Succinate 6-hydrate	502045003	NF	approx. 17 % Na	max. 6 EU**/g
Sulfates				
Magnesium Sulfate 7-hydrate	522014002	Ph.Eur.	approx. 10 % Mg	max. 6 EU**/g
Sodium Sulfate, anhydrous	522017013	Ph.Eur.	approx. 32 % Na	max. 6 EU**/g

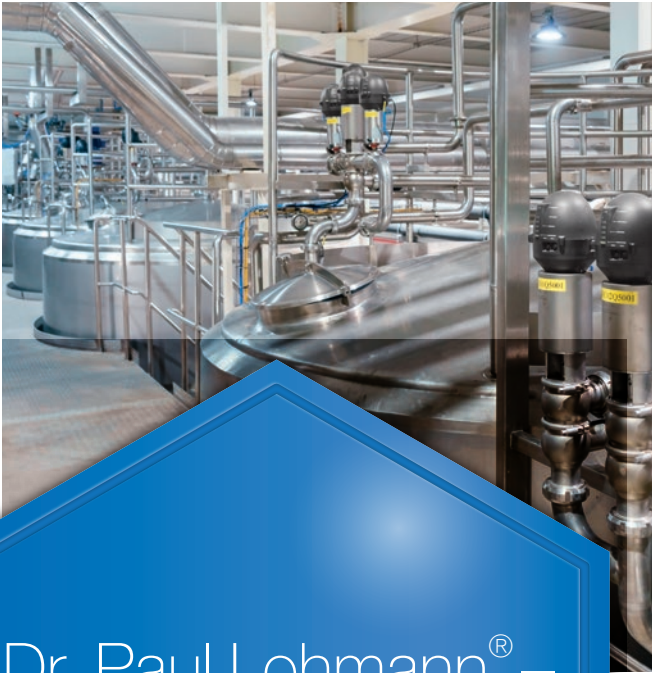
Additional products can be developed or lower endotoxin limits (LAL) can be met upon customer request.

* Test for bacterial endotoxines (LAL test) is accomplished acc. to Ph.Eur.2.6.14 using product specific validated methods.

** EU = Endotoxin Unit (equal to IU, International Unit)

*** You can find the versions of the pharmacopoeias in the specifications.

german manufacturer
since 1886



Dr. Paul Lohmann® – Your Partner for high value Mineral Salts

With over 135 years of producing Mineral Salts that meet the highest quality standards we have been established as the leading global supplier to the pharmaceutical, biopharmaceutical, nutritional supplement, food and personal care industries.

Our Expertise

- ◆ GMP and DIN EN ISO 9001 certified production sites
- ◆ FSSC 22000/ISO 22000 certified
- ◆ Processes according to HACCP
- ◆ Compliance and commitment with the FSMA (food safety modernization act)
- ◆ Tailor-made and innovative solutions according to customer requirements
- ◆ Highly qualified experts in R&D lab and application technology with long-term experience and a wide variety of possibilities to develop new products and applications
- ◆ Joint product and application development together with our customers
- ◆ Our manufactured products are exclusively Made in Germany
- ◆ A wide range of more than 400 different Mineral Salts
- ◆ Products in compliance with the most relevant pharmacopoeias (Ph.Eur., USP, BP), food codices (FCC, E-numbers, etc.) and customer specific requirements
- ◆ Regulatory documentation (CEP, ASMF, etc.)
- ◆ REACH compliance on request
- ◆ Wide range of production equipment
- ◆ Social and environmental standards (DIN EN ISO 50001, EcoVadis, Sedex)
- ◆ High purities can be realized according to specific requirements

Modification

- ◆ Physical properties
- ◆ Chemical properties
- ◆ Packaging
- ◆ Labeling

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