



APIs

Reliable Documentation



Dr. Paul Lohmann®

High value mineral salts

www.lohmann4minerals.com



GMP as the Fundament for APIs

Dr. Paul Lohmann® was one of the first German raw material manufacturers to obtain GMP (Good Manufacturing Practice) certification already in 1994. Since then the company has regularly been inspected by the German health authorities and has maintained this high-level certification although the quality requirements have constantly risen. Based on this solid foundation of quality, Dr. Paul Lohmann® is capable of manufacturing and documenting APIs (Active Pharmaceutical Ingredients).

A broad range of different APIs are manufactured in our GMP certified manufacturing sites in Emmerthal and Lüneburg. These APIs are used in medicines for the following therapeutic areas:

- ◆ Orthopedics
- ◆ Hematology
- ◆ Cardiology
- ◆ Gastroenterology
- ◆ Immunology
- ◆ Nephrology
- ◆ Neurology

More than 90 APIs

Dr. Paul Lohmann® has the world's largest portfolio of Mineral Salts for use as APIs. For the first time our GMP approved products are listed in the official European Inspections data-base (EUDRA GMDP¹). Thus our customers are able to review our registered APIs on a regulatory platform maintained and operated by the EMA (European Medicines Agency).

Regulatory Affairs

Within the Pharma industry, documentation is as important as the product (API) itself. Dr. Paul Lohmann® has established a Regulatory Affairs department to manage API documentation such as CEPs (Certificate of Suitability to the Monographs of the European Pharmacopoeia), ASMFs (Active Substance Master File), DMFs (Drug Master File) and ASEAN-CTDs (Common Technical Document). Our Regulatory Affairs personnel corresponds directly with the worldwide located health authorities after the dossier submission by the MAH (Marketing Authorization Holder). An APIMF is available for Zinc Sulfate 1-hydrate for WHO applications.

We are pleased to develop new APIs and API documentation upon customer request, even for non-monographed substances or specific customer requirements.

Dr. Paul Lohmann's® CEPs

A CEP enables the customer to register a drug in multiple countries in a cost saving and simplified way. Dr. Paul Lohmann® holds 11 CEPs listed at the EDQM (European Directorate for the Quality of Medicines & HealthCare)² and is working to extend this list which underlines the strategic focus of the company. The CEPs are recognized by all signatory states of the European Pharmacopoeia Convention and by the European Union. Canada, Australia, New Zealand, Tunisia and Morocco have also chosen to recognize them.

| Substance | CEP no. |
|-------------------------------|--------------|
| Calcium Acetate | CEP 2011-033 |
| Ferrous Fumarate | CEP 2004-232 |
| Ferrous Gluconate | CEP 2001-444 |
| Ferrous Sulfate, dried | CEP 2007-368 |
| Ferrous Sulfate Heptahydrate | CEP 2007-369 |
| Magnesium Aspartate Dihydrate | CEP 2013-042 |
| Magnesium Carbonate, heavy | CEP 2008-071 |
| Magnesium Carbonate, light | CEP 2010-062 |
| Magnesium Citrate | CEP 2009-017 |
| Magnesium Citrate Nonahydrate | CEP 2011-036 |
| Magnesium Hydroxide | CEP 2013-020 |

GMP approved APIs

ASMF/DMF upon request*

| Product | Product no. | Physical appearance | Quality | CEP |
|---|-------------|---------------------|-----------------------------|-----|
| Calamine | | | | |
| Calamine USP | 515033002 | powder | USP | |
| Calcium | | | | |
| Calcium Acetate, anhydrous | 515001003 | powder | Ph.Eur. USP | ✓ |
| | 515001016 | granules | | |
| Tricalcium Citrate 4-hydrate | 502041001 | powder | USP | |
| | 502041002 | fine powder | | |
| | 502041011 | granules | | |
| Calcium Disodium EDTA | 511085002 | powder | Ph.Eur. – low in endotoxins | |
| Calcium Gluconate 1-hydrate | 503071003 | powder | Ph.Eur. – low in endotoxins | |
| Calcium Hydrogen Phosphate, anhydrous | 512067001 | powder | Ph.Eur. | |
| Copper | | | | |
| Copper(II) Gluconate | 519025002 | fine powder | USP | |
| Copper(II) Sulfate, anhydrous | 511088001 | powder | Ph.Eur. | |
| Iron | | | | |
| Ammonium Ferric Citrate, brown | 503007002 | powder | BP 73 | |
| Ferrous Bisglycinate | 505085002 | powder | | |
| Ferric Sodium EDTA 3-hydrate | 511081002 | powder | BP | |
| Ferrous Fumarate | 505025001 | powder | Ph.Eur. USP | ✓ |
| | 505025005 | fine powder | | |
| | 503073009 | powder | Ph.Eur. | ✓ |
| Ferrous Gluconate 2-hydrate | 503073001 | fine granules | | |
| | 503073008 | granules | | |
| Ferric Polymaltose Complex | 519065001 | powder | chem. pure | |
| Ferric Saccharate | 519001001 | powder | Ph.Helv. | |
| Ferrous Succinate | 501007001 | powder | BP 93 | |
| Ferrous Sulfate, dried | 522005007 | powder | Ph.Eur. USP | ✓ |
| | 522005002 | micronized powder | | |
| | 522005011 | fine powder | Ph.Eur. USP | |
| Ferrous Sulfate 7-hydrate | 522004002 | crystals | Ph.Eur. USP | ✓ |
| Lithium | | | | |
| Trilithium Citrate 4-hydrate | 502056001 | powder | Ph.Eur. | |
| Lithium Sulfate | 502057001 | fine powder | chem. pure | |
| Magnesium | | | | |
| Magnesium Acetate 4-hydrate | 511019004 | crystals | Ph.Eur. | |
| | 511019001 | | Ph.Eur. – low in endotoxins | |
| Magnesium DL-Hydrogen Aspartate 4-hydrate | 501064003 | powder | DAB | |
| | 501064001 | powder | DAB – low in endotoxins | |
| | 501064004 | granules | DAB | |
| Magnesium L-Hydrogen Aspartate 2-hydrate | 501061006 | powder | Ph.Eur. | ✓ |
| | 501061005 | fine granules | | |
| Magnesium Carbonate, heavy | 503036002 | powder | Ph.Eur. USP | ✓ |
| Magnesium Carbonate, light | 503036009 | powder | Ph.Eur. | ✓ |
| Magnesium Hydrogen Citrate | 503033004 | fine granules | DAC 2015 | |
| Trimagnesium Dicitrate, anhydrous | 503043002 | powder | Ph.Eur. USP | ✓ |
| Trimagnesium Dicitrate 9-hydrate | 503042002 | powder | Ph.Eur. USP | ✓ |
| | 503042003 | micronized powder | Ph.Eur. | |
| | 503042005 | granules | Ph.Eur. USP | |
| Trimagnesium Dicitrate 12-hydrate | 503044002 | powder | Ph.Eur. | |
| Magnesium Gluconate | 503074001 | powder | Ph.Eur. | |
| | 503074003 | | | |
| Magnesium Glycerophosphate | 512048003 | powder | Ph.Eur. | |
| Magnesium Hydroxide | 503035007 | powder | Ph.Eur. | ✓ |
| Magnesium Lactate 2-hydrate | 512021008 | powder | Ph.Eur. | |
| | 512021002 | crystalline powder | | |

| Product | Product no. | Physical appearance | Quality | CEP |
|---|---|-------------------------------------|--|-----|
| Magnesium | | | | |
| Magnesium Oxide, light | 503046002 503046007 503046011 503046012 503046013 | powder | Ph.Eur. | |
| Magnesium Oxide, heavy | 503046001 | powder | Ph.Eur. USP | |
| Magnesium Hydrogen Phosphate 3-hydrate | 503057002 | fine powder | DAB | |
| Magnesium Sulfate, anhydrous | 522015001 522015005 522015008 | powder | BP USP heavy, approx. 18 % H ₂ O, purity acc. to BP | |
| Magnesium Sulfate 7-hydrate | 522014002 | powder | Ph.Eur. – low in endotoxins | |
| Manganese | | | | |
| Manganese(II) Gluconate 2-hydrate | 512034001 | powder | Ph.Eur. | |
| Manganese(II) Sulfate 1-hydrate | 512014005 | crystalline powder | Ph.Eur. USP | |
| Potassium | | | | |
| Potassium Acetate | 515002004 515002001 | powder | Ph.Eur. Ph.Eur. – low in endotoxins | |
| Potassium DL-Hydrogen Aspartate 0.5-hydrate | 501069002 501069001 | powder powder | DAB DAB – low in endotoxins | |
| Potassium L-Aspartate | 501067001 | crystalline powder | Ph.Eur. | |
| Tripotassium Citrate 1-hydrate | 502040002 | crystals | Ph.Eur. USP BP JPC 2002 | |
| Potassium Gluconate | 503076001 | fine crystals | USP | |
| Sodium | | | | |
| Sodium Acetate, anhydrous | 511018001 | powder | USP | |
| Sodium Acetate 3-hydrate | 511016002 511016001 | crystals | Ph.Eur. USP Ph.Eur. – low in endotoxins | |
| Sodium Carbonate, anhydrous | 505011001 | powder | Ph.Eur. | |
| Sodium Carbonate 1-hydrate | 505012001 | crystalline powder | Ph.Eur. | |
| Monosodium Citrate, anhydrous | 502015002 502015001 | crystalline powder | DAC 2005 DAC 2005 – low in endotoxins | |
| Disodium Citrate 1.5-hydrate | 502006002 502006001 | powder crystals | BP | |
| Trisodium Citrate, anhydrous | 502010002 502010005 502010010 | crystalline powder fine granules | USP | |
| Trisodium Citrate 2-hydrate | 502009008 502009003 502009001 | fine powder crystals crystals | Ph.Eur. Ph.Eur. Ph.Eur. – low in endotoxins | |
| Sodium Glycerophosphate | 512045001 | crystalline powder | Ph.Eur. | |
| Sodium Lactate (solution) | 512012002 | solution | Ph.Eur., approx. 50 % | |
| Monosodium Phosphate 2-hydrate | 503032002 | fine crystals | Ph.Eur. – low in endotoxins | |
| Sodium Succinate 6-hydrate | 502045001 | crystalline powder | NF | |
| Sodium Sulfate, anhydrous | 522017010 | crystalline powder | Ph.Eur. | |
| Zinc | | | | |
| Zinc Acetate 2-hydrate | 515006001 515006004 | powder crystals | Ph.Eur. Ph.Eur. – low in endotoxins | |
| Zinc Gluconate | 503077004 | fine granules | Ph.Eur. | |
| Zinc Sulfate 1-hydrate | 515059002 | powder | Ph.Eur. | |
| Zinc Sulfate 7-hydrate | 515009001 | crystals | Ph.Eur. | |

*The products above are listed at the EUDRA GMDP database¹. The regulatory fundament for these products is established in order to prepare API documentation. Due to the changing requirements of the different authorities worldwide and the actual GMP Q7 guidelines together with the varying pharmacopeia revisions, the status of API documentation might be different. Depending on the status, a DMF/ASMF is available or needs to be updated/ revised respectively. Therefore, we ask to send inquiries for products as APIs.

Tailor-made Solutions for state-of-the-art Applications

Product Line Low in Endotoxins

Dr. Paul Lohmann® also offers APIs even in low in endotoxin qualities. These APIs are applied in parenteral preparations such as infusions, injections or ophthalmological dosage forms. These highest regulatory and quality requirements are fulfilled by a QbD (Quality by Design approach). A dedicated purpose-built GMP certified plant ensures the production of APIs meeting highest purity requirements.

Please also see our brochure:
[Mineral Salts low in Endotoxins.](#)

References

- ¹ <http://eudragmdp.ema.europa.eu/inspections/view/apiReg/APIRegistrationHome.xhtml>
- ² https://extranet.edqm.eu/publications/recherches_CEP.shtml

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.

Product Modification



Chemical properties

- ◆ Solubility
- ◆ pH value
- ◆ Concentration
- ◆ Assay
- ◆ Color
- ◆ Water content
- ◆ Flowability
- ◆ Purity



Particle size engineering

Bulk density variation

- ◆ Optimized ratio between weight and volume
- ◆ Ultralight to heavy qualities available for specific products



Granules

- ◆ Excellent flowability
- ◆ Reduced dust
- ◆ Minimized material agglomeration

d50=2µm



Micronization

- ◆ Improved dispersion and homogeneity in mixtures
- ◆ Reduced segregation



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

With over 130 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 9001:2015 certified production sites
- ◆ FSSC 22000/ISO 22000 certified
- ◆ Processes according to HACCP
- ◆ Successfully inspected production site in Emmerthal by FDA (U.S. Food and Drug Administration) in the context of 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, Sedex)
- ◆ High purities can be realized according to specific requirements

Modification

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

Dr. Paul Lohmann GmbH & Co. KGaA

Hauptstraße 2
31860 Emmerthal/Germany

T +49 5155 63-0
F +49 5155 63-5818

sales@lohmann4minerals.com
www.lohmann4minerals.com

Dr. Paul Lohmann (Asia) Pte. Ltd.

Singapore
service@lohmann-asia.com
www.lohmann-asia.com

Dr. Paul Lohmann Benelux B.V.

Eindhoven/The Netherlands
benelux@lohmann4minerals.com
www.lohmann4minerals.com

Dr. Paul Lohmann Inc.

New York/USA
info@dpl-us.com
www.dpl-us.com

Dr. Paul Lohmann France SARL

Evry/France
france@lohmann-selsmineraux.fr
www.lohmann-selsmineraux.fr



Dr. Paul Lohmann®

High value mineral salts

www.lohmann4minerals.com