APIs

Reliable Documentation

Dr. Paul Lohmann®

High value mineral salts

www.lohmann-minerals.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 100 GMP registered Mineral Salts

Dr. Paul Lohmann® has the world's largest portfolio of Mineral Salts for use as APIs. For the first time our GMP registered products are listed in the official European Inspections database (EUDRA GMDP[1]). 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 12 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 Pharmacopeia 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 Hydrate	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
Sodium Dihydrogen Phosphate Dihydrate	CEP 2019-228

GMP registered Mineral Salts

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.	✔
	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.	
	512067002	micronized powder		
Copper				
Copper(II) Gluconate	519025002	fine powder	USP	
Copper(II) Sulfate, anhydrous	511088001	powder	Ph.Eur.	
Iron				
Ammonium Ferric Citrate, brown	503007002	powder	DAC 2003	
Ferrous Bisglycinate	505085002	powder		
Ferrous Carbonate, saccharated	519008006	fine powder		
Ferrous Fumarate	505025001	powder	Ph.Eur.	✔
	505025003			
	505025005	fine powder		
Ferrous Gluconate 2-hydrate	503073009	powder	Ph.Eur.	✔
	503073001	fine granules		
	503073002			
	503073008	granules		
Ferrous Oxalate	515019001	powder		
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.	✔
	522005002	micronized powder		
	522005011	fine powder		
Ferrous Sulfate 7-hydrate	522004002	crystals	Ph.Eur.	✔
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		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.	✔
Magnesium Carbonate, light	503036009	powder	Ph.Eur.	✔
Magnesium Hydrogen Citrate	503033004	fine granules	DAC 2015	
	503033009			
	503033007	granules		
Trimagnesium Dicitrate, anhydrous	503043002	powder	Ph.Eur. | USP	✔
	503043010	granules	Ph.Eur.	
Trimagnesium Dicitrate 9-hydrate	503042002	powder	Ph.Eur. | USP	
	503042003	micronized powder	Ph.Eur.	✔
	503042005	granules	Ph.Eur. | USP	
Trimagnesium Dicitrate 12-hydrate	503044001	powder	Ph.Eur.	
Magnesium Gluconate	503074003	powder	Ph.Eur.	
	503074004		Ph.Eur. – Low in Endotoxins	
Magnesium Glycerophosphate	512048003	powder	Ph.Eur.	
Magnesium Hydroxide	503035007	powder	Ph.Eur.	✔

Product	Product no.	Physical appearance	Quality	CEP
Magnesium Lactate 2-hydrate	512021008	powder	Ph.Eur.	
Magnesium Oxide, light	503046002	powder	Ph.Eur.	
	503046007			
	503046011			
	503046012			
Magnesium Oxide, heavy	503046001	powder	Ph.Eur.	
Magnesium Hydrogen Phosphate 3-hydrate	503057002	fine powder	DAB	
Magnesium Sulfate, dried	522015005	powder	USP	
	522015008		heavy, approx. 18 % H_2O, 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.	
Potassium				
Potassium Acetate	515002004	powder	Ph.Eur.	
	515002001		Ph.Eur. – Low in Endotoxins	
Potassium DL-Hydrogen Aspartate 0.5-hydrate	501069002	powder	DAB	
	501069001		DAB – Low in Endotoxins	
Potassium L-Aspartate	501067001	crystalline powder	Ph.Eur.	
Tripotassium Citrate 1-hydrate	502040004	powder	Ph.Eur.	
	502040001	fine crystals		
	502040002	crystals		
Potassium Gluconate	503076001	fine crystals	USP	
Potassium Phosphate	505044002	crystalline powder	Ph.Eur. – Low in Endotoxins	
Dipotassium Phosphate	505043004	powder	Ph.Eur. – Low in Endotoxins	
Sodium				
Sodium Acetate, anhydrous	511018001	powder	USP	
Sodium Acetate 3-hydrate	511016002	crystals	Ph.Eur.	
	511016001		Ph.Eur. – Low in Endotoxins	
Monosodium Citrate, anhydrous	502015002	crystalline powder	DAC 2005	
	502015001		DAC 2005 – Low in Endotoxins	
Disodium Citrate 1.5-hydrate	502006002	powder	BP	
	502006001	crystals		
Trisodium Citrate, anhydrous	502010002	crystalline powder	USP	
	502010005	fine granules		
	502010010			
Trisodium Citrate 2-hydrate	502009008	fine powder	Ph.Eur.	
	502009003	crystals		
	502009001		Ph.Eur. – Low in Endotoxins	
Sodium Glycerophosphate	512045001	crystalline powder	Ph.Eur. – Low in Endotoxins	
Sodium Lactate (solution)	512012112	solution; approx. 50 %	Ph.Eur. – Low in Endotoxins	
	512012113	solution; approx. 60 %	Ph.Eur. – Low in Endotoxins	
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.	
	522017013		Ph.Eur. – Low in Endotoxins	
Zinc				
Zinc Acetate 2-hydrate	515006001	powder	Ph.Eur.	
	515006004	crystals	Ph.Eur. – Low in Endotoxins	
Zinc Citrate	502017001	powder		
Zinc Gluconate NEW	503077004	fine granules	Ph.Eur.	
	503077007		Ph.Eur. – Low in Endotoxins	
Zinc Sulfate 1-hydrate	515059002	powder	Ph.Eur.	
	515059008		USP – WHO APIMF232	
Zinc Sulfate 7-hydrate	515009001	crystals	Ph.Eur.	

*The products above are listed at the EUDRA GMDP database[1]. 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, our API documentation may not always be up to date. Depending on the status, a DMF/ASMF is promptly available or needs to be updated/revised respectively. Therefore, preparation time will be checked and advised upon individual inquiry.

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

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

Micronization

- Improved dispersion and homogeneity in mixtures
- Reduced segregation

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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