

Excipients



Dr. Paul Lohmann®

High value mineral salts

www.lohmann-minerals.com



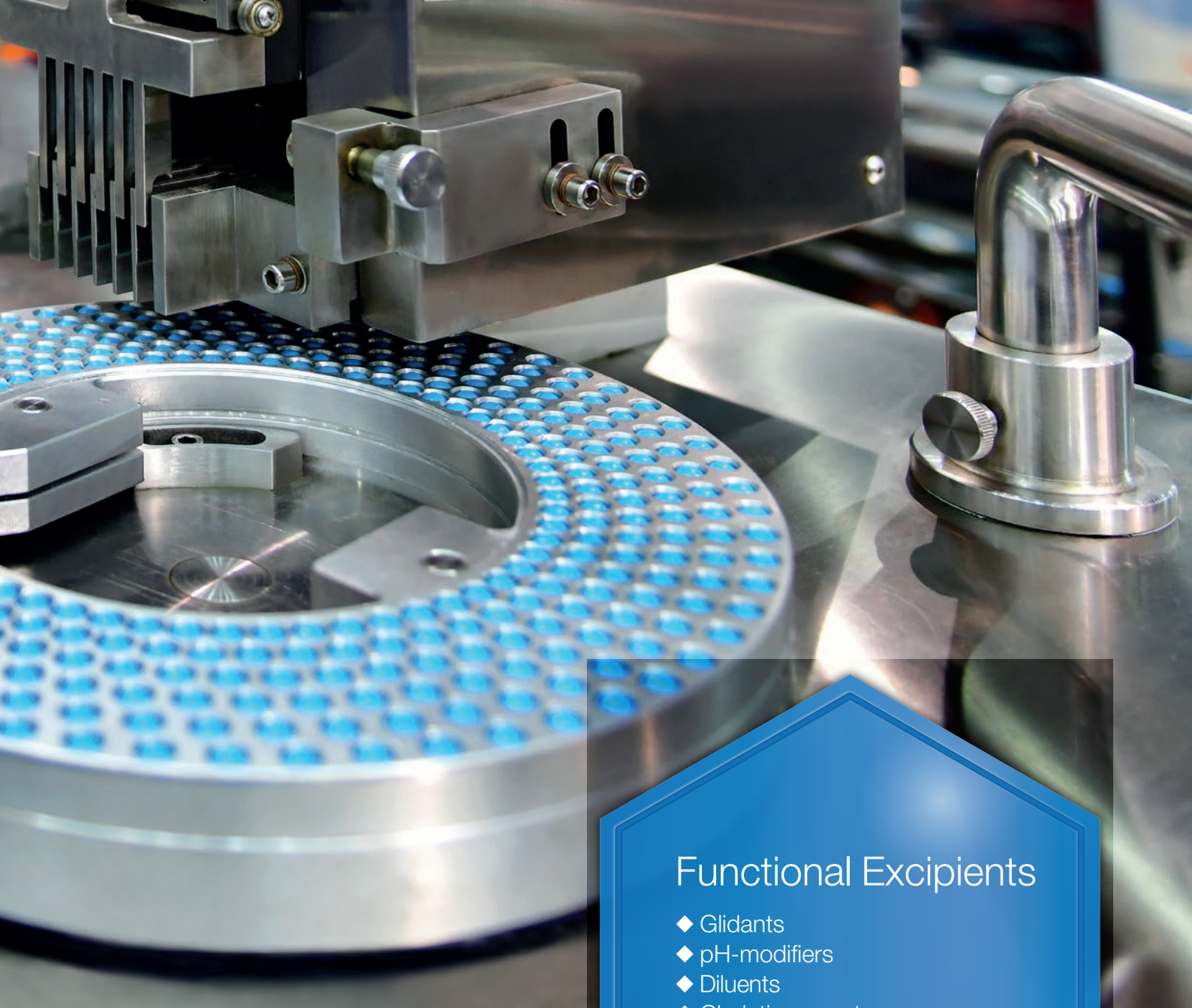
Minerals as Excipients

The major component of ingredients in pharmaceutical products in terms of volume is not the active ingredient itself, it is the excipient. Excipients assist in the administration of an 'active' substance that typically may not be easily administered or absorbed by the patient.

Mineral Salts as excipients are of specific importance, since they largely determine the structure of solid dosage forms and stabilize the chemical properties in liquid pharmaceutical forms.

Excipients have well-defined functions, which significantly influence the processability, stability and control the release of the drug product.

Therefore, the selection of excipients is crucial to ensure that the drug substance is stable and has desired pharmacokinetic properties, adhering to strict standards and regulations.



Functional Excipients

- ◆ Glidants
- ◆ pH-modifiers
- ◆ Diluents
- ◆ Chelating agents
- ◆ Anti-microbial preservatives
- ◆ Whitening agents

Produced for Functionality

Excipients fall into several broad processing categories for functionalities. Bulking agents make the dosage form larger in size, so that it becomes easier to manufacture and for patients to handle. Binders, which are also used in our granules for direct compression (DC), are utilized to facilitate the granulation process to make powders easier to compress. Glidants help the powders flow finally from the hopper to the capsule or tablet cavity and minimize friction and cohesion between particles. Lubricants are often used in combination with glidants to reduce the stickiness of powders or granules to the dies or punches during compression.

A pH-adjuster modifies the pH-value in order to stabilize the drug substance in parenteral dosage forms or optimize the taste and disintegration in oral effervescent tablets. A whitening agent/white color pigment is often used to obtain white tablets.

Due to the chemical nature of Mineral Salts, Dr. Paul Lohmann® products are often used for functionalities beyond the above mentioned examples. Since Dr. Paul Lohmann® Mineral Salts are an integral component of pharmaceutical drugs, its excipients fulfill IPEC (International Pharmaceutical Excipients Council) and ISO 9001 guidelines.

Minerals as Excipients

The following reference tables are based on USP 43 – NF 38¹. The grouping of excipients by functional category is intended to summarize commonly identified purposes that these Mineral Salts as excipients serve in drug product formulations.

Antimicrobial Preservative

Typical dosage form: oral liquids

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Calcium Acetate	515001001	powder	Ph.Eur.; Low in Endotoxins	+
	515001002	powder	FCC USP	
	515001003	powder	Ph.Eur. BP ACS	
	515001004	fine powder	USP	
	515001005	fine granules	USP FCC	
	515001009	granules	USP FCC	
	515001012	granules	Ph.Eur. USP BP	
Calcium Lactate	512001000	granular powder	Ph.Eur. USP FCC	+
	512001100	granules	Ph.Eur.	
Sodium Acetate, anhydrous	511018001	powder	USP FCC	+
	511018002	free flowing powder	E 262(i); with 0.2 % anti-caking agent	
	511018006	granules	USP	+
Sodium Acetate 3-hydrate	511016001	crystals	Ph.Eur. USP; Low in Endotoxins	++
	511016002		Ph.Eur. USP FCC	
Sodium Benzoate	502044002	micronized powder	Ph.Eur. FCC NF	+
Sodium L-Lactate	512012002	solution; approx. 50 %	Ph.Eur. USP	solution
	512012112		Ph.Eur.; Low in Endotoxins	
	512012005		Ph.Eur. USP	
	512012113	solution; approx. 60 %	Ph.Eur. USP; Low in Endotoxins	
	512012006	solution; approx. 70 %	Ph.Eur. USP	
Sodium Propionate	502023002	crystals	Ph.Eur. FCC NF	+
	502023005	granules	Ph.Eur. FCC	
Zinc Oxide	515007800	powder	Ph.Eur. USP	--

Antioxidant

Typical dosage form: oral liquids

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Citric Acid 1-hydrate	503002020	powder	Ph.Eur. USP	++
	503002030	fine powder		
	503002010	crystals		
Magnesium L-Ascorbate 2-hydrate ²	501046201	granular powder	nutritional supplements chem. pure	++
Zinc L-Ascorbate ²	501048001	powder	nutritional supplements chem. pure	++

Chelating and/or complexing Agent

Typical dosage form: oral liquids

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Ammonium Oxalate 1-hydrate ³	515018001	crystals	Erg.B.6 chem. pure	++
Diammonium Tartrate ³	502066001	crystals	chem. pure	++
Calcium Disodium EDTA	511085001		Ph.Eur. USP	+
	511085002	powder	Ph.Eur. USP; Low in Endotoxins	
Calcium Oxalate 1-hydrate ³	515061001	powder	chem. pure	--
Calcium Tartrate ³	503072001	powder	chem. pure	--
Citric Acid 1-hydrate	503002020	powder	Ph.Eur. USP	++
	503002030	fine powder		
	503002010	crystals		
Copper(II) Oxalate ³	515028001	powder	chem. pure	-
Ferrous Oxalate 2-hydrate ³	515019001	powder	Ph.Franc. chem. pure	--
	515019390	fine powder	chem. pure	
Ferric Ammonium Oxalate 3-hydrate ³	515020001	fine crystals	chem. pure	+
Ferric Tartrate 1-hydrate ³	503034001	granules	chem. pure	--
Magnesium Oxalate 2-hydrate ³	515029001	powder	chem. pure	--
Dipotassium Oxalate 1-hydrate ³	515016001	fine powder	chem. pure	+
	515016002	crystals	Erg.B.6 chem. pure	
Dipotassium Tartrate 0.5-hydrate ³	502060001	crystals	DAC 2004 E 336	
Potassium Sodium Tartate 4-hydrate ³	502061001	powder	Ph.Eur. USP FCC E 337	+
	502061002	free flowing powder		
Disodium Oxalate ³	515063004	fine powder	chem. pure	+
Monosodium Tartrate, anhydrous ³	502077002	powder	chem. pure	
Monosodium Tartrate 1-hydrate ³	502076002	fine crystals	chem. pure	
Disodium Tartate 2-hydrate ³	502062003	crystals	USP 34/NF29 Erg.B.6 FCC E 335	+
Zinc Oxalate 2-hydrate ³	515081001	powder	chem. pure	--

*Bulk densities are exemplarily displayed for standard qualities. The data may vary between test methods. We offer a wide range of bulk densities and customized bulk densities are available upon request.

+++ > 100 g/l

+ 10 – 100 g/l

- 1 – 10 g/l

-- < 1 g/l

The solubility specified here was measured in water.
The solubility is influenced by many factors in the application.

Coating Agent

Typical dosage form: tablets and capsules

Product	Product no.	Physical appearance	Quality	Bulk density (g/l)*
Calcium Carbonate, heavy	512006210	powder	Ph.Eur. USP FCC	approx. 1000
	512006003	micronized powder		
Calcium Carbonate DC 97GA	512006018	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 750
Calcium Carbonate DC 90M	512006009	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 750
Calcium Carbonate DC 95M	512006006	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Carbonate DC 90S	512006004	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Carbonate DC 95S	512006005	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Carbonate DC 97P	512006008	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000

Diluent

Typical dosage form: tablets and capsules

Product	Product no.	Physical appearance	Quality	Bulk density (g/l)*
Calcium Carbonate, heavy	515001001	powder	Ph.Eur. USP FCC	approx. 1000
	512006003	micronized powder		
Calcium Carbonate DC 97GA	512006018	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 750
Calcium Carbonate DC 90M	512006009	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 750
Calcium Carbonate DC 95M	512006006	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Carbonate DC 90S	512006004	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Carbonate DC 95S	512006005	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Carbonate DC 97P	512006008	granules, directly compressible	complies with the limits of Ph.Eur., USP, BP, E 170	approx. 1000
Calcium Hydrogen Phosphate, anhydrous	512067001	powder	Ph.Eur. USP	approx. 1000
	512067002	micronized powder	Ph.Eur.	
Calcium Hydrogen Phosphate 2-hydrate	512017001	powder	Ph.Eur.; low in aluminium	approx. 670
	512017120		Ph.Eur.	
	512017004		USP	
	512017170		complies with the limits of: Ph.Eur. USP FCC	
Tricalcium Phosphate, light	512035010	powder	Ph.Eur. FCC	approx. 460
	512035001		analyzed acc. to: Ph.Eur. FCC NF	
Tricalcium Phosphate, heavy	512035200	powder	FCC	
Sodium Sulfate, anhydrous ⁴	522017002	powder	Ph.Eur. USP FCC	approx. 1600
	522017005	fine powder	Ph.Eur.	
	522017013	powder	Ph.Eur.; Low in Endotoxins	
Sodium Sulfate 10-hydrate ⁴	522019001	crystals	Ph.Eur. USP FCC	
	522019002	free flowing crystals	Ph.Eur.	

Emollient

Typical dosage form: semi solids, topicals, and suppositories

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Trisodium Citrate, anhydrous ⁴	502010002	crystalline powder	USP FCC JPE	+
	502010004	fine powder	USP FCC	
	502010005	fine granules	USP	
Trisodium Citrate 2-hydrate ⁴	502009007	fine granules	Ph.Eur. USP FCC	+
	502009008			
	502009001	crystals	Ph.Eur. USP; Low in Endotoxins	
	502009003		Ph.Eur. USP FCC JP ACS	
	502009005	fine crystals	Ph.Eur. USP FCC	
Zinc Acetate 2-hydrate	515006002	fine powder	Ph.Eur.	+
	515006001	crystalline powder	Ph.Eur. USP	
	515006004	crystals	Ph.Eur.; Low in Endotoxins	

Emulsifying Agent

Typical dosage form: oral liquids

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Magnesium Oxide, light	503046011	powder; bulk density < 150 g/l	Ph.Eur. USP FCC	--
	503046007	powder; bulk density approx. 130 g/l		
Magnesium Oxide, heavy	503046001	powder; bulk density approx. 500 g/l	Ph.Eur. USP FCC	--

Glidant and/or anticaking Agent

Typical dosage form: tablets and capsules

Product	Product no.	Physical appearance	Quality	Bulk density (g/l)*
Tricalcium Phosphate, light	512035010	powder	Ph.Eur. FCC	variable
	512035001		Ph.Eur. FCC NF low in aluminium	
Magnesium Carbonate, light ⁵	503036012	powder	Ph.Eur. USP FCC	< 150
Magnesium Oxide, light	503046011	powder	Ph.Eur. USP FCC	< 150
	503046007			approx. 130
Magnesium Oxide, heavy	503046001	powder	Ph.Eur. USP FCC	approx. 500
Magnesium Trisilicate DC 90S	515040004	granules, directly compressible	Ph.Eur. USP	approx. 450

Lubricant

Typical dosage form: tablets and capsules

Product	Product no.	Physical appearance	Quality	Bulk density (g/l)*
Magnesium Stearate	515037000	powder	Ph.Eur. USP NF	
Sodium Benzoate	502044002	micronized powder	Ph.Eur. FCC NF	
Zinc Stearate	515038200	powder	analyzed acc. to: Ph.Eur.	

*Bulk densities are exemplarily displayed for standard qualities. The data may vary between test methods. We offer a wide range of bulk densities and customized bulk densities are available upon request.

++ > 100 g/l

+ 10 – 100 g/l

- 1 – 10 g/l

-- < 1 g/l

The solubility specified here was measured in water.
The solubility is influenced by many factors in the application.

pH-Modifier (Acidifying/Alkalizing Agent/Buffering Agent)

Typical dosage form: oral liquids

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Calcium Carbonate, heavy	512006210	powder	Ph.Eur. USP	--
	512006003	micronized powder		
Tricalcium Phosphate, light	512035010	powder	Ph.Eur.	--
	512035001		Ph.Eur. FCC NF; low in aluminium	
Monopotassium Citrate, anhydrous	502037001	powder	E 332(i)	-
Tripotassium Citrate, anhydrous	502038001	powder	Ph.Eur.	+
Tripotassium Citrate 1-hydrate	502040004	powder	Ph.Eur. USP FCC	++
	502040005	free flowing powder	E 332(ii); with 0.8 % anti-caking agent	
	502040001	fine crystals	Ph.Eur. USP	++
	502040002	crystals	Ph.Eur. USP FCC JPC	
Monopotassium Phosphate	505044001	powder	Ph.Eur. NF	+
Dipotassium Phosphate	505043001	powder	Ph.Eur. USP	++
	505043004		Ph.Eur.; Low in Endotoxins	++
Sodium Acetate, anhydrous	511018001	powder	USP FCC	+
	511018002	free flowing powder	E 262(i); with 0.2 % anti-caking agent	
	511018006	granules	USP	+
Sodium Acetate 3-hydrate	511016002	crystals	Ph.Eur. USP FCC	+
	511016001		Ph.Eur. USP; Low in Endotoxins	++
Sodium Bicarbonate	519013400	powder	complies with the limits of Ph.Eur.	-
	519013001	micronized powder	Ph.Eur.	
Sodium Carbonate, anhydrous	505011007	powder	Ph.Eur.; suitable for effervescent tablets	-
	505011002	fine powder	Ph.Eur. NF	
	505011001	fine granules	Ph.Eur. FCC NF JP	
Sodium Carbonate 1-hydrate	505012002	powder	Ph.Eur.	-
	505012001	crystalline powder	Ph.Eur. FCC NF	
Sodium Carbonate 10-hydrate	505010001	crystals	Ph.Eur. FCC JP	+
Monosodium Citrate, anhydrous	502015009	powder	DAC	-
	502015007	micronized powder		
	502015005	fine powder		
	502015001	crystalline powder		
	502015002	crystals		
Disodium Citrate 1.5-hydrate	502006002	powder	BP	+
	502006005	fine powder		
	502006001	crystals		
Trisodium Citrate, anhydrous	502010004	fine powder	USP FCC	+
	502010002	crystalline powder	FCC USP JPE	
	502010005	fine granules	USP	
Trisodium Citrate 2-hydrate	502009007	fine powder	Ph.Eur. USP FCC	+
	502009008			
	502009003		Ph.Eur. USP FCC JP ACS	
	502009001	crystals	Ph.Eur. USP; Low in Endotoxins	
Trisodium Citrate 5.5-hydrate	502009005	fine crystals	Ph.Eur. USP FCC	
	502003001	crystals	USP Erg.B.6	+

pH-Modifier (Acidifying/Alkalizing Agent/Buffering Agent)

Typical dosage form: oral liquids

Product	Product no.	Physical appearance	Quality	Solubility 20 °C
Sodium L-Lactate	512012002	solution; approx. 50 %	Ph.Eur. USP	solution
	512012005	solution; approx. 60 %		
	512012006	solution; approx. 70 %		
	512012112	solution; approx. 50 %	Ph.Eur.; Low in Endotoxins	
	512012113	solution; approx. 60 %	Ph.Eur. USP; Low in Endotoxins	
Monosodium Phosphate, anhydrous	503062001	powder	USP FCC BP	+
Monosodium Phosphate 2-hydrate	503032001	powder	Ph.Eur. USP	+
	503032002	fine crystals	Ph.Eur.; Low in Endotoxins	
Disodium Phosphate, anhydrous	503037001	powder	complies with the limits of Ph.Eur.	-
Disodium Phosphate 2-hydrate	503063001	fine powder	Ph.Eur.	-
	503063010	crystals	Ph.Eur. USP	
Disodium Phosphate 12-hydrate	503031001	crystals	Ph.Eur. USP	+
	503031002		Ph.Eur.; Low in Endotoxins	
Sodium Succinate 6-hydrate	502045001	crystalline powder	NF	++
	502045003		NF; Low in Endotoxins	
Disodium Succinate, anhydrous	502080002	powder	NF	++

Wet Binder

Typical dosage form: tablets and capsules

Product	Product no.	Physical appearance	Quality	Bulk density (g/l)*
Calcium Carbonate, heavy	512006210	powder	Ph.Eur. USP FCC	approx. 1000
	512006003	micronized powder		
Calcium Hydroxide	512036002	powder	FCC	approx. 400

Whitening Agent – TiO₂-Replacement

Typical dosage form: tablets

Product	Product no.	Physical appearance	Quality	Bulk density (g/l)*
Calcium Carbonate	512006212	powder	LomaWhite Ph.Eur. USP E 170 FCC food supplement	approx. 800
	512006003	micronized powder		
Calcium Citrate 4-hydrate	502041006	micronized powder	LomaWhite UPS E 333 FCC food supplement	
Magnesium Carbonate	503036022	powder	LomaWhite Ph.Eur. USP E 504 FCC food supplement	approx. 300

*Bulk densities are exemplarily displayed for standard qualities. The data may vary between test methods. We offer a wide range of bulk densities and customized bulk densities are available upon request.

++ > 100 g/l

+ 10 – 100 g/l

- 1 – 10 g/l

-- < 1 g/l

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The solubility is influenced by many factors in the application.



Product Modification



Modification of chemical properties

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



Particle size engineering

Granules

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

Granules for Direct Compression

- ◆ Optimum tablet compression characteristics
- ◆ Improved dosage
- ◆ Only small amounts of binders necessary

Micronization

- ◆ Improved dispersion behavior in a liquid or semi-solid matrix, resulting in improved homogeneity
- ◆ Reduced sedimentation
- ◆ Improved mouthfeel
- ◆ Modification of particle size distribution

Bulk density variation

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

Solutions

- ◆ Energy and resource efficient
- ◆ Organic solvent-free – water based
- ◆ Easier processing

Reduced process complexity

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

There is an ongoing trend in the industry to reduce process complexity. Therefore, we offer product lines which address this actual trend.

Product line Low in Endotoxins

Dr. Paul Lohmann® offers excipients even in Low in Endotoxins pharmaceutical grades which are applied in parenteral preparations such as infusions or injections. These highly sensitive routes of administration require highest purity standards, which are fulfilled by our Quality by Design (QbD) approach. A dedicated purpose built GMP certified plant ensures the production of excipients meeting highest purity. Biopharmaceuticals, vaccines and blood plasma derived medicines utilize Phosphates and Citrates as excipients to achieve the required pH-value or EDTAs to stabilize the drug substance. Dr. Paul Lohmann® Low in Endotoxin Mineral Salt excipients enable a seamless integration into the production process and reduce process complexity.

Please also see our brochure:
[Mineral Salts Low in Endotoxins!](#)

References

- ¹ USP 43 – NF 38; 2020 (United States Pharmacopoeia 43 – National Formulary 38); U.S. Pharmacopeial convention
- ² Frei et al.; 1989; Proc. Natl. Acad. Sci., 86, 6377-6381
- ³ Cantar et al.; 2015; Water Res., 79, 66-75
- ⁴ Rowe et al. 2012, Handbook of Pharmaceutical Excipients; Natural Health Ingredients Database (Health Canada)
- ⁵ internal application tests

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.

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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