Innovative Salts for Biopharma

Dr. Paul Lohmann®

High value mineral salts

www.lohmann4minerals.com

Biopharmaceutical Industry

- GMP manufacturer of organic and inorganic salts
- Dedicated **DPL-BioPharm** grade for upstream and downstream
- Low in endotoxin grades
- Innovative physical and chemical product modifications

Biopharmaceutical production processes demand the highest raw material standards. These raw materials are used in both upstream and downstream processes such as culture media, buffer solutions and other process aids. Biologics require a very different approach compared to chemically manufactured drugs.

Raw materials for processes such as fermentation, harvest, purification and formulation must meet the highest standards of quality and consistency. Cell lines are highly sensitive, and unpredictable metal impurities or endotoxin levels in cell culture media raw materials can severely impact cell proliferation and function.

Dr. Paul Lohmann® is your partner for innovative product solutions for maximizing the full potential of your cell lines and downstream processes to achieve your unique biopharmaceutical needs.

DPL-BioPharm Salts designated for your Needs

Based on our profound experience with biopharma customers and in depth market research we have developed **DPL-BioPharm**. This quality combines a constant and high product quality including following parameters:

- Multi-compendial (e.g. Ph.Eur., BP, USP/NF)
- Bioburden (TAMC, TYMC)
- Heavy metal profile according to ICH Q3D
- Optimized for biopharmaceutical applications
- Highest purity
- Constant production processes
- Residual solvent free
- Animal component free (ACF)
- BSE/TSE free
- Non-GMO
- Customized packaging

Additionally you may profit from upgrades of the **DPL-BioPharm** grade:

- Low in endotoxin grade
- Specified heavy metal analysis
- Extended impurity profile
- Additional bioburden parameters
- Optimized solubility
- Complete customized salts
- Innovative physical and chemical product modifications

Our **DPL-BioPharm** salts fulfill your biopharmaceutical demands:

- Specially developed product specifications
- Flexible customized upgrade quality
- Reliable, constant high product quality
- Expert support in product modification (chemical and physical parameters, e.g. solubility, pH-value, particle size distribution) to solve your challenges
- Innovative new product development
- Cell culture and buffering blends

Our core expertise lies both in the production and in the analysis of salts. We use an extensive arsenal of instruments to design and monitor the chemical and physical properties of our products.

Two Areas – Upstream and Downstream—one Aim

Finding the right salt and solution for your biopharmaceutical applications

Upstream

In upstream processing, salts provide essential nutrients for mammalian cells, bacteria and yeast to promote growth and API production including stimulatory and metabolic effects within the cell. Dr. Paul Lohmann® offers a broad portfolio of salts with the targeted cell nutrients i.e. Cu, Fe, Mg, Mn, Zn, etc. with various anions to influence productivity. **DPL-BioPharm** salts are of exceeding purity to meet the highest demands.

Downstream

In addition to the crucial role they play as an upstream additive, salts are also used as process aids. Buffers influence process robustness, yield and quality. Each biopharmaceutical production process brings its own set of unique challenges. Our outstanding expertise in product modifications will guide you through numerous options for functional optimization for your processes via our **DPL-BioPharm** salts.

DPL-BioPharm Salts for Upstream*

Product	Assay	Bioburden	Low in endotoxin**
Calcium Calcium Chloride 2-hydrate	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Copper Copper(II) Sulfate 5-hydrate	min. 98.5 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Iron Ferric Ammonium Citrate, brown	min. 16.5 % Fe	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Ferric Choline Citrate	min. 10.9 % Fe		
Ferric Citrate	min. 18 % Fe		
Ferrous Sulfate 7-hydrate	min. 99.5 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Magnesium Magnesium Sulfate dried	min. 99.5 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Magnesium Sulfate 7-hydrate	min. 99.5 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Manganese Manganese(II) Sulfate 1-hydrate	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Potassium Potassium Chloride	min. 99 %		
Sodium Sodium β-Glycerophosphate 5-hydrate	min. 97 %		
Monosodium Phosphate anhydrous	min. 98 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Disodium Phosphate anhydrous	min. 98 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Disodium L-tyrosinate 2-hydrate	min. 98 %		
Zinc Zinc Sulfate 7-hydrate	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	

DPL-BioPharm Salts for Downstream*

Product	Assay	Bioburden	Low in endotoxin**
Acetates Ammonium Acetate	min. 98 %		
Potassium Acetate anhydrous	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Sodium Acetate anhydrous	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Sodium Acetate 3-hydrate	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Carbonates Sodium Carbonate anhydrous	min. 99.5 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	
Citrates Trisodium Citrate 2-hydrate	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Phosphates Monopotassium Phosphate	min. 98 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Dipotassium Phosphate	min. 98 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Monosodium Phosphate 2-hydrate	min. 98 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Disodium Phosphate 12-hydrate	min. 98.5 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔
Sulfates Ammonium Sulfate	min. 99 %	TAMC max. 1000 CFU/g | TYMC max. 10 CFU/g	
Sodium Sulfate anhydrous	min. 99 %	TAMC max. 2000 CFU/g | TYMC max. 200 CFU/g	✔

* Customized qualities upon request (DPL-BioPharm upgrade)

** DPL-BioPharm upgrade

Solubility 20 °C	pH (5 %)	Physical appearance	Function
++++	approx. 7	crystalline powder	◆ Osmotic balance support[1] ◆ Membrane potential regulation[1]
+++	approx. 4	crystals	◆ Enzymatic co-factor[2] ◆ Cell growth support[3]
++++	approx. 7	powder	◆ Iron transporter (Chelator)[4] ◆ Enzymatic co-factor[2]
++	approx. 3	powder	◆ Iron transporter (Chelator)[4] ◆ Enzymatic co-factor[2]
++	approx. 2	powder	◆ Iron transporter (Chelator)[4] ◆ Enzymatic co-factor[2]
++	approx. 3.5	crystals	◆ Enzymatic co-factor[2]
++	approx. 7	powder	◆ Cellular and enzymatic regulation[5]
+++	approx. 6.5	crystalline powder	◆ Cellular and enzymatic regulation[5]
+++	approx. 5	crystalline powder	◆ Enzymatic co-factor[2]
++	approx. 5	fine crystals	◆ Osmotic balance support[6]
++	approx. 9	crystalline powder	◆ Osmotic balance support[6] ◆ Cell culture buffer[7]
+++	approx. 4	powder	◆ Osmotic balance support[6] ◆ Cell culture buffer[2]
++	approx. 9	powder	◆ Osmotic balance support[6] ◆ Cell culture buffer[2]
+++	approx. 11	powder	◆ Essential cell nutrition[8]
+++	approx. 5	crystals	◆ Enzymatic co-factor[2] ◆ Cell growth support[3]

Solubility 20 °C	pH (5 %)	Physical appearance	Function
++++	approx. 6.5	crystals	◆ Buffer[9]
++++	approx. 8	powder	◆ Buffer[12]
+++	approx. 8 (3 %)	powder	◆ Buffer for purification and formulation[10,11]
+++	approx. 8	crystals	◆ Buffer for purification and formulation[10,11]
++	approx. 11	powder	◆ Buffer[14]
+++	approx. 8	crystals	◆ Buffer for purification and formulation[11,13]
++	approx. 4	crystalline powder	◆ Buffer for purification and formulation[11,12]
++++	approx. 9	powder	◆ Buffer for purification and formulation[11,12]
+++	approx. 4	powder	◆ Buffer for purification and formulation[11,13]
++	approx. 9	crystals	◆ Buffer for purification and formulation[11,13]
+++	approx. 5.5	crystals	◆ Protein precipitation[15] ◆ Ionic strength adjustment[16]
++	approx. 5	crystalline powder	◆ Protein precipitation[15] ◆ Ionic strength adjustment[16]

++++ > 1000 g/l +++ 300 – 1000 g/l ++ 100 – 300 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.

Committed to our Customers

More than 130 years of salt development and production strengthened our outstanding expertise, turning us into a globally leading supplier of high-quality salts. Diverse production options enable us to modify specific chemical and physical properties creating tailor-made salts for your specific requirements. Moreover, we offer the technology in providing cell culture media and buffering blends. Our consistent high quality minimizes lot-to-lot variation in your production process. Contamination, such as heavy metals are known to interfere and even inactivate your APIs (e.g. antibodies). Our defined heavy metal content control enables constant production conditions in upstream and downstream processes.

A new dedicated GMP certified manufacturing facility qualifies us for exclusive production of salts low in endotoxins—our full commitment to the biopharmaceutical industry. These **DPL-BioPharm** salts minimize endotoxin contamination throughout your biopharmaceutical production.

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

With over 130 years of producing mineral salts that meet the highest quality standards, we have established ourselves 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
- 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 for customer requests
- R&D lab with large experience and a wide variety of possibilities to develop new products and applications
- Joint product and application development together with our customers
- Own products are exclusively Made in Germany since 1886
- High social responsibility as a family-owned business
- A wide range of more than 400 various 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 methods
- Processes according to HACCP
- Social and environmental standards (DIN EN ISO 50001, Sedex)
- High purities can be realized under certified requirements

Modification

- Physical properties
- Chemical properties
- Packaging
- Labeling

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