



Innovative Salts for Biopharma



Dr. Paul Lohmann[®]

High value mineral salts

www.lohmann-minerals.com

Biopharmaceutical Industry



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 as well as excipients in the final formulation. 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.

- ◆ GMP manufacturer of organic and inorganic Salts
- ◆ Dedicated **DPL-BioPharm** grade for upstream, downstream and fill/finish
- ◆ Low in Endotoxin grades
- ◆ Innovative physical and chemical product modifications

Dr. Paul Lohmann® is your partner for innovative product solutions for maximizing the full potential of your fermentation, downstream and fill/finish 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:

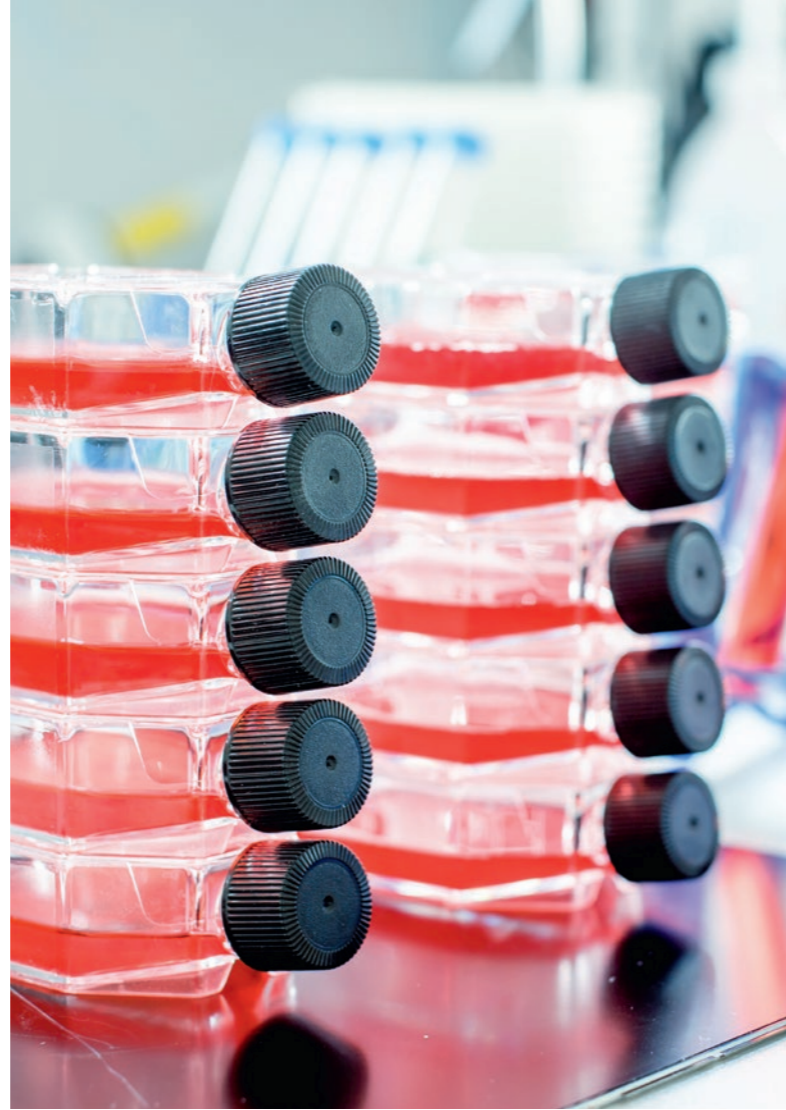
- ◆ Low in Endotoxin grade
- ◆ Extended impurity profile
- ◆ Additional bioburden parameters
- ◆ Optimized solubility
- ◆ Complete customized salts
- ◆ Innovative physical and chemical product modifications

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
- ◆ Innovative new product development (e.g. amino acid salts)
- ◆ Cell culture and buffering blends (e.g. Phosphate and Citrate 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.

Three Areas – Upstream, Downstream and Fill/Finish – 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.

Fill/Finish

Salts and other organic and inorganic chemicals constitute fundamental excipients in the final formulation of biologics and vaccines. These excipients act as chelators, buffer and adjuvants in vaccines or stabilize the drug substance for instance. Since biologics and vaccines are administered via parenteral injection, the purity of the excipients are of utmost importance.

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.

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

DPL-BioPharm Salts for Upstream*

Product	Product no.	Assay	Bioburden	Low in Endotoxins**	Solubility 20 °C	pH (5 %)	Physical appearance	Function
Calcium								
Calcium Chloride 2-hydrate	511030001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 7	crystalline powder	◆ Osmotic balance support ¹ ◆ Membrane potential regulation ¹
Copper								
Copper(II) Sulfate 5-hydrate	511008001	min. 98.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		+++	approx. 4	crystals	◆ Enzymatic co-factor ² ◆ Cell growth support ³
EDTA								
Disodium EDTA 2-hydrate	505062001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 4.5	crystalline powder	◆ Metal chelator ³ ◆ Sequestrant ³
Iron								
Ferric Ammonium Citrate, brown	503007001	min. 16.5 % Fe	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 7	powder	◆ Iron transporter (Chelator) ⁴ ◆ Enzymatic co-factor ²
Ferric Choline Citrate	505054002	min. 10.2 % Fe	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 3	powder	◆ Iron transporter (Chelator) ⁴ ◆ Enzymatic co-factor ²
Ferric Citrate	503005007	min. 16.5 % Fe	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 2	powder	◆ Iron transporter (Chelator) ⁴ ◆ Enzymatic co-factor ²
Ferric Pyrophosphate, soluble	503012004	min. 10.5 % Fe	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		+	approx. 6	powder	◆ Enzymatic co-factor ²
Ferrous Sulfate 7-hydrate	522004002	min. 99.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 3.5	crystals	◆ Enzymatic co-factor ²
Magnesium								
Magnesium Sulfate, dried	522015005	min. 99.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 7	powder	◆ Cellular and enzymatic regulation ⁵
Magnesium Sulfate 7-hydrate	522014009 522014002	min. 99.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+++	approx. 6.5	crystalline powder	◆ Cellular and enzymatic regulation ⁵
Manganese								
Manganese(II) Sulfate 1-hydrate	512014005	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		+++	approx. 5	crystalline powder	◆ Enzymatic co-factor ²
Potassium								
Potassium Chloride	511038005	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 5	fine crystals	◆ Osmotic balance support ⁶
Monopotassium Phosphate	505044003 505044002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 4	crystalline powder	◆ Cell culture buffer ³
Dipotassium Hydrogen Phosphate	505043001 505043004	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++++	approx. 9	powder	◆ Cell culture buffer ³
Dipotassium Hydrogen Phosphate 3-hydrate	505053001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 9.2	crystals	◆ Cell culture buffer ³
Sodium								
Sodium Carbonate, anhydrous	505011001	min. 99.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 11	powder	◆ Cell culture buffer ²
Sodium β-Glycerophosphate 5-hydrate	512054003	min. 97 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 9	crystalline powder	◆ Osmotic balance support ⁶ ◆ Cell culture buffer ³
Monosodium Phosphate, anhydrous	503062001 503062002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+++	approx. 4	powder	◆ Cell culture buffer ³
Monosodium Phosphate 1-hydrate	503092001	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 4	powder	◆ Cell culture buffer ³
Monosodium Phosphate 2-hydrate	503032001 503032002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+++	approx. 4	powder fine crystals	◆ Cell culture buffer ³
Disodium Phosphate, anhydrous	503037001	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 9	powder	◆ Cell culture buffer ³
Disodium Hydrogen Phosphate 2-hydrate	503063002 503063003	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+	approx. 9	powder	◆ Cell culture buffer ³
Disodium Hydrogen Phosphate 7-hydrate	503048001 503048002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 9	crystals	◆ Cell culture buffer ³
Disodium Hydrogen Phosphate 12-hydrate	503031001 503031002	min. 98.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 9	crystals	◆ Cell culture buffer ³
Sodium Succinate 6-hydrate	502045001 502045003	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 8	crystalline powder	◆ Cell culture buffer ³ ◆ Cell growth support ³
Zinc								
Zinc Sulfate 7-hydrate	515009001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		+++	approx. 5	crystals	◆ Enzymatic co-factor ² ◆ Cell growth support ³
Amino acid salts								
L-Aspartic acid Sodium Salt	501072002	min. 98.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 6	crystalline powder	◆ Diagnostics; analysis of diffusion and osmotic coefficients of amino acids ⁷
Glutamic Acid Sodium Salt 1-hydrate	501035001	min. 99 %	TAMC max. 100 CFU/g TYMC max. 100 CFU/g		+++	approx. 7	powder	◆ Essential cell nutrition ⁸
L-Tyrosine Disodium Salt 2-hydrate	519086001	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		+++	approx. 11	powder	◆ Essential cell nutrition ⁸

* Customized qualities upon request (DPL-BioPharm upgrade)

** DPL-BioPharm upgrade

++++ > 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.

DPL-BioPharm Salts for Downstream & Fill/Finish*

Product	Product no.	Assay	Bioburden	Low in Endotoxins**	Solubility 20 °C	pH (5 %)	Physical appearance	Function
Acetates								
Ammonium Acetate	515005001	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 6.5	crystals	◆ Buffer ⁹
Potassium Acetate, anhydrous	515002004 515002001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++++	approx. 8	powder	◆ Buffer ¹⁰
Sodium Acetate, anhydrous	511018001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		+++	approx. 8 (3 %)	powder	◆ Buffer for purification and formulation ^{3,11}
Sodium Acetate 3-hydrate	511016002 511016001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+++	approx. 8	crystals	◆ Buffer for purification and formulation ^{3,11}
Carbonates								
Sodium Carbonate, anhydrous	505011001	min. 99.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 11	powder	◆ Buffer ¹²
Chloride								
Calcium Chloride 2-hydrate	511030001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 7	crystalline powder	◆ Ionic strength adjustment ³ ◆ Protein precipitation ¹³
Magnesium Chloride 6-hydrate	522030220	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 5.5	crystals	◆ Ionic strength adjustment ³ ◆ Stabilizer ¹⁴
Potassium Chloride	511038005	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 5	fine crystals	◆ Ionic strength adjustment ³ ◆ Protein precipitation ¹³
Sodium Chloride	511029300	min. 99 %	TAMC max. 10 CFU/g TYMC max. 10 CFU/g		+++	approx. 7	fine crystals	◆ Ionic strength adjustment ³ ◆ Protein precipitation ¹³
Citrates								
Trisodium Citrate 2-hydrate	502009003 502009001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g TAMC max. 100 CFU/g TYMC max. 100 CFU/g	✓	+++	approx. 8	crystals	◆ Buffer for purification and formulation ³
EDTA								
Calcium Disodium EDTA	511085003 511085002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+	approx. 7 (pH 20%)	powder	◆ Metal chelator ³ ◆ Sequestrant ³
Disodium EDTA 2-hydrate	505062001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 4.5	crystalline powder	◆ Metal chelator ³ ◆ Sequestrant ³
Phosphates								
Monopotassium Phosphate	505044003 505044002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 4	crystalline powder	◆ Buffer for purification and formulation ^{10,11}
Dipotassium Hydrogen Phosphate	505043001 505043004	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++++	approx. 9	crystals	◆ Buffer for purification and formulation ^{10,11}
Dipotassium Hydrogen Phosphate 3-hydrate	505053001	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++++	approx. 9.2	crystals	◆ Buffer for purification and formulation ^{10,11}
Monosodium Phosphate, anhydrous	503062001 503062002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+++	approx. 4	powder	◆ Buffer for purification and formulation ^{10,11}
Monosodium Phosphate 1-hydrate	503092001	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 4	powder	◆ Buffer for purification and formulation ^{10,11}
Monosodium Phosphate 2-hydrate	503032001 503032002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+++	approx. 4	powder fine crystals	◆ Buffer for purification and formulation ^{10,11}
Disodium Hydrogen Phosphate, anhydrous	503037001	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g		++	approx. 9	powder	◆ Buffer for purification and formulation ^{10,11}
Disodium Hydrogen Phosphate 2-hydrate	503063002 503063003	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	+	approx. 9	powder	◆ Buffer for purification and formulation ^{10,11}
Disodium Hydrogen Phosphate 7-hydrate	503048001 503048002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 9	crystals	◆ Buffer for purification and formulation ^{10,11}
Disodium Phosphate 12-hydrate	503031001 503031002	min. 98.5 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 9	crystals	◆ Buffer for purification and formulation ^{10,11}
Succinates								
Sodium Succinate, anhydrous	502080002	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 8	powder	◆ Buffer for purification and formulation ^{10,11}
Sodium Succinate 6-hydrate	502045001 502045003	min. 98 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 8	crystals crystalline powder	◆ Buffer for purification and formulation ^{10,11}
Sulfates								
Ammonium Sulfate	522040002	min. 99 %	TAMC max. 1000 CFU/g TYMC max. 10 CFU/g		+++	approx. 5.5	crystals	◆ Ionic strength adjustment ³ ◆ Protein precipitation ¹³
Magnesium Sulfate 7-hydrate	522014009 522014002	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g TAMC max. 1000 CFU/g TYMC max. 100 CFU/g	✓	+++	approx. 7.5	crystalline powder	◆ Stabilizer ¹⁵
Sodium Sulfate, anhydrous	522017002 522017013	min. 99 %	TAMC max. 2000 CFU/g TYMC max. 200 CFU/g	✓	++	approx. 5	crystalline powder	◆ Ionic strength adjustment ³ ◆ Protein precipitation ¹³

* Customized qualities upon request (DPL-BioPharm upgrade)

** DPL-BioPharm upgrade

++++ > 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 135 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, downstream and fill/finish processes.



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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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