

Salts in Vaccines

Dr. Paul Lohmann®

High value mineral salts

www.lohmann4minerals.com

Salts in Vaccines

Vaccines usually consist of the active ingredient, known as antigen, and several excipients, e.g. amino acids, proteins and Salts. While the antigen triggers the patient's immune response, the excipients stabilize the sensitive active ingredient during processing, storage and application. Therefore, Salts are an essential component of vaccines and play an important role in the final dosage form. They serve either as adjuvants to enhance the pharmacological effect of the active ingredient or as formulation stabilizers, as they act as buffers, preservatives and tonicity agents[1,2].

Requirements for Salts in Vaccines

Since ingredients used in vaccines have to meet the highest quality standards, we offer high-purity Salts manufactured under the strictest conditions. The excipients fulfill IPEC (International Pharmaceutical Excipients Council), GMP and DIN EN ISO 9001 guidelines. Our know-how in production and analysis of Salts as well as our customer-oriented approach enable us to offer Salts with the following parameters and services:

- Multi-compendial (e.g. Ph.Eur., BP, USP/NF, JP)
- Bioburden (TAMC/TYMC) and additional parameters
- Low in Endotoxin grade
- Low in RNase grade
- Heavy metal profile according to ICH Q3D
- Lot-to-lot consistency
- Residual solvent free
- Animal component free (ACF)
- BSE/TSE free
- GMO-free
- Customized packaging

Salts of the highest purity

- Standard harmonized pharmacopoeia Bioburden limits* are TAMC max. 2000 CFU/g and TYMC max. 200 CFU/g
- LAL test** according to Ph.Eur.
- RNase test***

Wide range of applications

Salts perform specific functions in vaccines and can be categorized as follows, depending on their particular function:

- Adjuvants increase the efficacy of vaccines
- Buffering agents keep the pH-value constant
- Tonicity agents keep the vaccine isotonic
- Preservatives prevent degradation of the vaccine
- Stabilizers minimize chemical reactions and prevent segregation of ingredients

* Lower Bioburden limits are possible on request
** Test for bacterial endotoxines (LAL test) is accomplished acc. to Ph.Eur.2.6.14 using product specific validated methods
*** RNase test on request



GMP Certified Manufacturer of Salts

- Consistent
- Traceable
- Reliable

Product Portfolio

Adjuvants

Product	Product no.	CAS no.	Quality	Solubility 20 °C
Phosphate Tricalcium Phosphate	512035001	12167-74-7	Ph.Eur.	– –
Sulfate Potassium Aluminium Sulfate 12-hydrate	511023001	7784-24-9	Ph.Eur.	++

Buffers/pH-Adjusters

Product	Product no.	CAS no.	Quality	Solubility 20 °C
Acetate				
Ammonium Acetate	515005001	631-61-8	chem. pure	++++
Sodium Acetate, anhydrous	511018001	127-09-3	USP	+++
Sodium Acetate 3-hydrate	511016001	6131-90-4	Ph.Eur. | USP; Low in Endotoxins	+++
	511016002		Ph.Eur. | BP | USP	
Potassium Acetate, anhydrous	515002001	127-08-2	Ph.Eur.; Low in Endotoxins	++++
	515002002		USP | BP	
	515002004		Ph.Eur.	
Carbonate				
Sodium Carbonate, anhydrous	505011001	497-19-8	Ph.Eur. | BP | NF	++
Sodium Bicarbonate	519013400	144-55-8	Ph.Eur. | BP	+
Citrate				
Trisodium Citrate 2-hydrate	502009001	68-04-2	Ph.Eur. | USP; Low in Endotoxins	+++
	502009003		Ph.Eur. | USP | BP | ACS	
Organic Acid				
Citric Acid, anhydrous	503001001	77-92-9	Ph.Eur.; Low in Endotoxins	+++
	503001010		Ph.Eur. | USP	
Citric Acid 1-hydrate	503002000	5949-29-1	Ph.Eur. | USP | BP	+++
Phosphate				
Monopotassium Phosphate	505044001	7778-77-0	NF	++
	505044002		Ph.Eur.; Low in Endotoxins	
	505044003		Ph.Eur.	
Dipotassium Hydrogen Phosphate	505043001	7758-11-4	USP | Ph.Eur.	++
	505043004		Ph.Eur.; Low in Endotoxins	
	505043005		Ph.Eur.	
Dipotassium Hydrogen Phosphate 3-hydrate	505053001	16788-57-1	chem. pure	++++
Monosodium Phosphate, anhydrous	503062001	7558-80-7	USP | BP | DPL-BioPharm	+++
	503062003		USP; Low in Endotoxins	
Monosodium Phosphate 1-hydrate	503092001	10049-21-5	USP | BP	++
Monosodium Phosphate 2-hydrate	503032001	13472-35-0	USP | Ph.Eur. | DPL-BioPharm	++
	503032002		USP | Ph.Eur.; Low in Endotoxins	
Disodium Hydrogen Phosphate, anhydrous	503037001	7558-79-4	USP | Ph.Eur.	+
Disodium Hydrogen Phosphate 2-hydrate	503063001	10028-24-7	Ph.Eur.	+
	503063002		USP	
	503063003		Ph.Eur.; Low in Endotoxins	

Buffers/pH-Adjusters

Product	Product no.	CAS no.	Quality	Solubility 20 °C
Phosphate				
Disodium Hydrogen Phosphate 7-hydrate	503048001	7782-85-6	USP	++
Disodium Hydrogen Phosphate 12-hydrate	503031001	10039-32-4	USP | Ph.Eur. | DPL-BioPharm	++
	503031002		Ph.Eur.; Low in Endotoxins	
Succinate				
Sodium Succinate, anhydrous	502080002	150-90-3	NF; Low in Endotoxins	++
Sodium Succinate 6-hydrate	502045001	6106-21-4	NF | chem. pure	++
	502045003		NF; Low in Endotoxins	

Stabilizers/Preservatives/Tonicity Agents

Product	Product no.	CAS no.	Quality	Solubility 20 °C
Acetate				
Potassium Acetate, anhydrous	515002001	127-08-2	Ph.Eur.; Low in Endotoxins	++++
	515002002		USP	
	515002004		Ph.Eur. | BP	
Sodium Acetate, anhydrous	511018001	127-09-3	USP	+++
Sodium Acetate 3-hydrate	511016001	6131-90-4	Ph.Eur. | USP; Low in Endotoxins	+++
	511016002		Ph.Eur. | USP | BP | chem. pure	
Chloride				
Calcium Chloride 2-hydrate	511030301	10035-04-8	Ph.Eur. | USP | DPL-BioPharm	++++
Magnesium Chloride 6-hydrate	522030220	7791-18-6	Ph.Eur. | USP	++++
Potassium Chloride	511038000	7447-40-7	Ph.Eur. | USP | BP	++
	511038005		Ph.Eur. | USP | DPL-BioPharm	
Sodium Chloride	511029300	7647-14-5	Ph.Eur. | USP | JP	+++
Citrate				
Trisodium Citrate 2-hydrate	502009001	68-04-2	Ph.Eur. | USP; Low in Endotoxins	+++
	502009003		Ph.Eur. | USP | BP	
EDTA				
Calcium Disodium EDTA	511085001	62-33-9	Ph.Eur. | USP	+
	511085002		Ph.Eur. | USP; Low in Endotoxins	
Disodium EDTA 2-hydrate	505062001	6381-92-6	Ph.Eur. | USP | JP | ACS; Low in Endotoxins	++
Organic Acid				
Citric Acid 1-hydrate	503002000	5949-29-1	Ph.Eur. | USP | BP	+++
Sulfate				
Ammonium Sulfate	522040002	7783-20-2	Ph.Eur. | NF | ACS | DPL-BioPharm	+++
Magnesium Sulfate 7-hydrate	522014002	7487-88-9	Ph.Eur.; Low in Endotoxins	+++
	522014004		Ph.Eur.	
	522014005		USP	
	522014007		Ph.Eur.; Low in Endotoxins	
	522014008		chem. pure	
	522014009		Ph.Eur. | USP | DPL-BioPharm	

++++ > 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.



High Purity Salts

Over 135 years of Salt development and production have strengthened our outstanding know-how and made us one of the world's leading suppliers of high-quality Salts. Diverse production capabilities allow us to modify specific chemical and physical properties to produce tailor-made Salts and Salt solutions. Transparency as well as highest product quality make us the ideal and reliable partner for Salts used in vaccines.

Committed to our Customers

- Multi-compendial pharma grades
- Custom blends and Salt solutions
- Individual packaging

Salts are an essential component of Biopharma and are used throughout the production process. They are nutrients and buffers in fermentation and cell culture (upstream), processing aids in the isolation and purification of target products (downstream), and excipients in the final formulation of biologics and vaccines (fill/finish). Since Biopharma processes are highly sensitive to impurities and fluctuations, the highest quality of raw materials is of paramount importance.

Please contact us regarding our brochure Innovative Salts for Biopharma!

Our Low in Endotoxin products are manufactured in a GMP-certified facility using low endotoxin process water. Strictest manufacturing controls minimize lot-to-lot variability and thus in both your production process and the final vaccine formulation.

Please see also our brochure Mineral Salts Low in Endotoxins!

References

[1] Kamerzell, TJ., et al. Protein-excipient interactions: Mechanisms and biophysical characterization applied to protein formulation development. Adv. Drug Del. Reviews, 63:1118-1159 (2011).

[2] Kwissa, M.; Kasturi, SP.; Pulendran, B.; The science of adjuvants. Expert Rev. Vaccines, 6(5): 673-684 (2007).

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
- 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, EcoVadis, Sedex)
- High purities can be realized according to specific requirements

Modification

- Physical properties
- Chemical properties
- Packaging
- Labeling

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