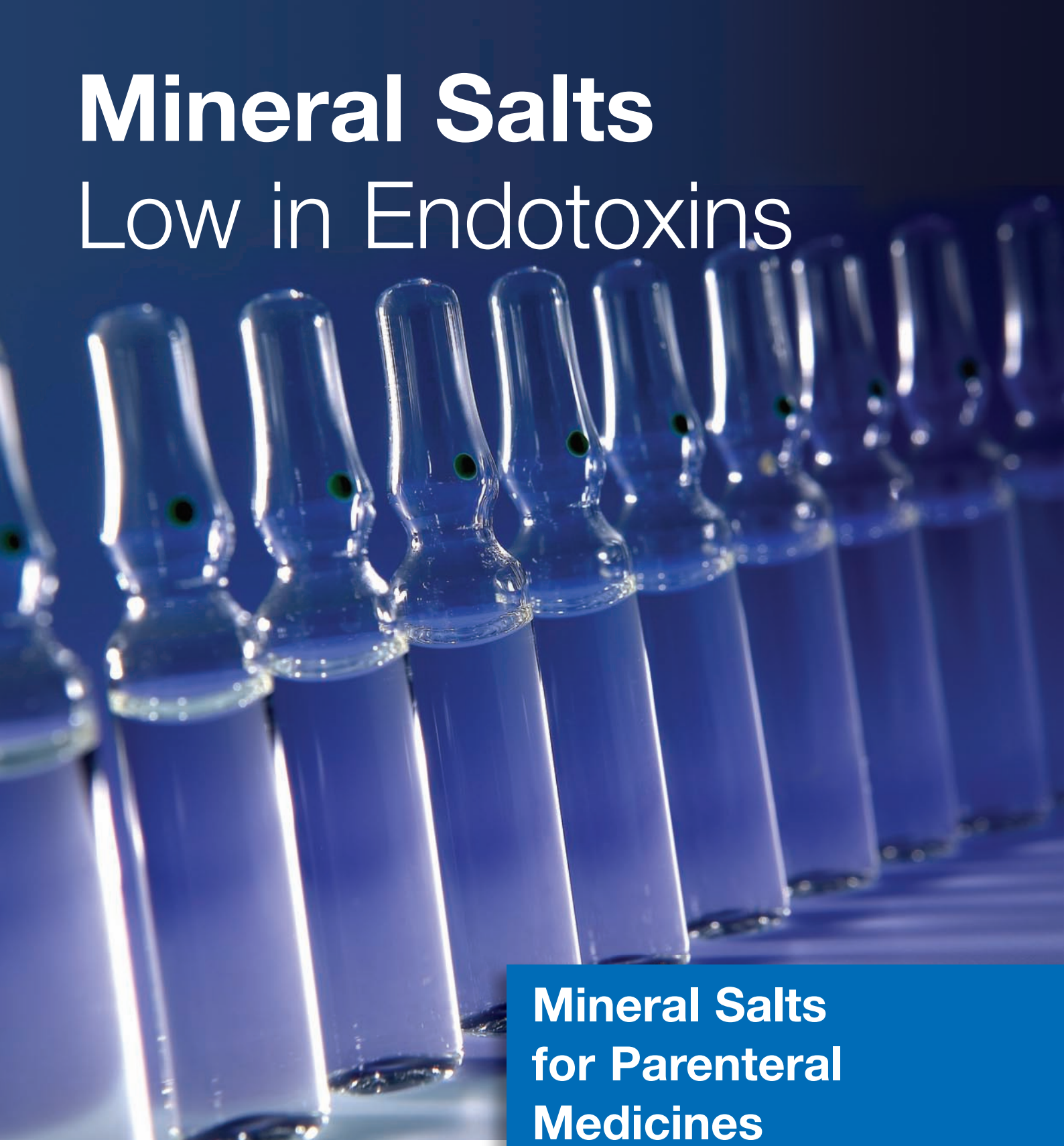
Mineral Salts
Low in Endotoxins



Mineral Salts for Parenteral Medicines

Dr. Paul Lohmann®

High value mineral salts

Low-Endotoxin Products

Endotoxins* or pyrogens are generated, for example, when gram-negative bacteria decompose[1]. Quantities of these lipopolysaccharides as low as 0.1 ng per kilogram of body-weight can cause fever reactions in humans and animals[2] if they get into the bloodstream.

Thus the manufacture of products for parenteral administration requires particular caution: it is subject to special requirements[3] and is regulated by Chapters 2.6.8 and 2.6.14 of the European Pharmacopoeia (Ph.Eur.)[4].

Low-Endotoxin Qualities of Dr. Paul Lohmann® Products

In order to help manufacturers of parenteral products, Dr. Paul Lohmann® offers for several years mineral salts with a very low endotoxin content.

Our low-endotoxin mineral salts are manufactured in purpose-built facilities and/or taking particular precautions, such as the use of low-endotoxin process water, etc.

- Our production sites are GMP and DIN EN ISO 9001:2008 certified.
- We conduct LAL tests** (Method A) according to Ph.Eur. on every single batch.
- This allows customers to seamlessly integrate our products in their process chain.

PRODUCT NO.	PRODUCT	QUALITY****	METAL CONTENT (PER 100 g)	ENDOTOXIN (LAL)**
515001001	Calcium Acetate	Ph.Eur. USP	approx. 24 % Ca	max. 6.0 EU***/g
511019001	Magnesium Acetate 4-hydrate	Ph.Eur.	approx. 11 % Mg	max. 6.0 EU***/g
501064001	Magnesium DL-Aspartate 4-hydrate	DAB	approx. 6 % Mg	max. 6.0 EU***/g
503046014	Magnesium Oxide light	Ph.Eur.	approx. 58 % Mg	max. 6.0 EU***/g
522014002	Magnesium Sulfate	Ph.Eur.	approx. 10 % Mg	max. 6.0 EU***/g
515002001	Potassium Acetate	Ph.Eur.	approx. 40 % K	max. 6.0 EU***/g
501069001	Potassium DL-Aspartate 0.5-hydrate	DAB	approx. 21.5 % K	max. 6.0 EU***/g
511016001	Sodium Acetate 3-hydrate	Ph.Eur. USP	approx. 17 % Na	max. 6.0 EU***/g
502015001	Monosodium Citrate anhydrous	DAC	approx. 10.5 % Na	max. 6.0 EU***/g
502009001	Trisodium Citrate 2-hydrate	Ph.Eur. USP	approx. 23.5 % Na	max. 6.0 EU***/g
512045001	Sodium Glycerophosphate	Ph.Eur.	approx. 15 % Na	max. 6.0 EU***/g
512012114	Sodium Lactate Solution; approx. 52 %; from DL-Lactic Acid	Ph.Eur.	approx. 10.5 % Na	max. 6.0 EU***/g
512012112	Sodium Lactate Solution; approx. 50 %; from L-Lactic Acid	Ph.Eur. USP	approx. 10 % Na	max. 6.0 EU***/g
512012113	Sodium Lactate Solution; approx. 60 %; from L-Lactic Acid	USP	approx. 12.5 % Na	max. 6.0 EU***/g

* Endotoxins are organic molecules with a mass of 10 to 20 kDa. They can exist as larger aggregates with a mass of up to 1000 kDa.
** LAL (Limulus amebocyte lysate) test accomplished according to Method A, as described in Ph.Eur.7.Ed. Every batch produced is tested for this parameter.
*** EU = Endotoxin Unit (equal to IU, International Unit)
**** You can find the versions of the pharmacopoeias in the specifications.

Applications

Low-endotoxin mineral compounds can be used in the following parenteral products:

- Solutions for injection
- Powders for injection
- Solutions for infusion
- Solutions for
  - Dialysis
  - Peritoneal dialysis
  - Haemofiltration
- Ophthalnic preparations

The manufacturer of these finished products is obliged to observe the special regulations specified by the relevant pharmacopoeia and GMP regulations. According to these regulations, once the solutions have been prepared, they must be filtered and sterilised and, if necessary, subjected to pyrogen or endotoxin testing.

Research & Development (R&D)

Every day our R&D department deals with new challenges in application science and technology. That is why we also develop products and procedures in close collaboration with our customers.

Our R&D labs offer a wide variety of possibilities to develop products and applications.

Manufacturing and certification

Our company is GMP (for active substances and excipients) and DIN EN ISO 9001:2008 certified and our products are: Made in Germany.

References

1 http://www.ipa.ruhr-uni-bochum.de/publik/info0103/endotoxin.php, access from July 13, 2010; 11.30 a.m.
2 Salema, V., Pattnaik, P.: Removing endotoxin from biopharmaceutical solutions; Pharmaceutical Technology Europe, 10/2009, pp 36-38
3 Richtlinie 2001/83/EG des europäischen Parlamentes und des Rates vom 6. November 2001 zur Schaffung eines Gemeinschaftskodexes für Humanarzneimittel; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:DE:PDF; access from July 13, 2010; 1 p.m.
4 European Medicines Agency (EMEA): Guideline on the Replacement of Rabbit Pyrogen testing by an Alternative Test for Plasma Derived Medicinal Products; http://www.ema.europa.eu/pdfs/human/bwp/45208107enfin.pdf; access from July 13, 2010; 1.20 p.m.

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