

# PETER GREVEN

Your partner for pharmaceutical excipients





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Sustainability and the demand for renewable raw materials are becoming more and more important in many areas. As a middle-sized family owned company, we have always produced additives based on renewable raw materials and can look back to a long experience with these raw materials and associated production technologies.

Oleochemical additives are among the most important excipients in the pharmaceutical industry. We began addressing these requirements many years ago and dedicated our production facility in Venlo (NL) to the manufacture of high-quality, vegetable stearates for pharmaceutical applications.

The complexity of operations requires a continuous process of improvement and customisation. For decades we have embraced this challenge and became the market leader for pharmaceutical stearates in Europe.

Our LIGAMED® product portfolio offers a variety of high-quality additives which are dedicated to the needs and requirements of the pharmaceutical industry. In addition to the special physical and chemical characteristics of our products we focus on the strict adherence to regulatory requirements as well as strong technical service.

Our **LIGAMED**<sup>®</sup> grades cover an extensive range of applications in the pharmaceutical industry:

- · Tableting agent
- Lubricant
- · Flowability agent
- · Separating agent
- Water repellent
- Stability improvement agent
- · Emulsifying agent
- · Gelling agent





# LIGAMED® High Quality Excipients for the Pharmaceutical Industry

Our **LIGAMED**® product line offers outstanding quality and purity. Furthermore it is characterised by the following quality features and product advantages:

- Different product groups are produced on dedicated production lines to avoid cross contamination.
- LIGAMED® grades are produced in accordance with IPEC PQG GMP conditions. The adherence to the strict regulations is supported by our EXCiPACT certificate.
- We comply with all major pharmacopeias: Ph.Eur, USP/NF, JP and ChP.
- Our products are Kosher and Halal certified grades. All LIGAMED® products are produced in accordance with strict Kosher and Halal regulations and offer the respective certifications. These certificates are required for OTC pharmaceutical and nutraceutical preparations in Jewish and Arab cultures. Kosher and Halal certification has also become an important quality standard requested by European formulators.
- The special precipitated production process enables the high specific surface area of our products. Therefore, they are very efficient and the required dosage is low.

- Our LIGAMED® products offer exceptional lubrication, release and separation abilities due to the high percentage of fine particles.
- High batch-to-batch consistency is guaranteed by constant supervision.
- Only the **best vegetable based raw materials** are used for our production.
- Usage of sustainably grown palm oil is important to us.
   Therefore our LIGAMED® products are based on RSPO certified raw materials.

**EXCIPACT** 



HALAL







# Products based on certified sustainable palm oil

As sustainability and the responsible use of natural resources have always been fundamental aspects of our corporate philosophy, we offer different products based on sustainable, RSPO certified fatty acids to support the sustainable palm oil production.

The Roundtable on Sustainable Palm Oil (RSPO), which was founded in 2004, is a non-profit association. It unites stakeholders from seven sectors of the palm oil industry in order to develop and to introduce global standards for sustainable palm oil.

Peter Greven became an official member of the RSPO in 2010. As soon as RSPO Mass Balance (MB) certified fatty acid became available on the market, we started all the internal preparations and processes in order to conclude the RSPO SCCS (Supply Chain Certification System) certification. In September 2013 Peter Greven became the first metal soap producer to receive the RSPO SCCS certificate which officially acknowledged the production and distribution of vegetable stearates and dispersions based on RSPO Mass Balance (MB) certified fatty acid.

In 2016 the existing certification could be extended by RSPO Segregated (SG) which is the next higher certification level. As a consequence, RSPO SG certified products were added to our portfolio.



CERTIFIED

Contains certified sustainable palm oil.

www.rspo.org

RSPO-1106171
RSPO Segregated



RSPO Mass Balance

In 2022 we decided to go one more step towards sustainable and certified products:

We shifted our **LIGAMED**® product range from conventional to RSPO Mass Balance (MB) certified fatty acid. Therefore, all **LIGAMED**® products are only available as certified grades.



## **MAGNESIUM STEARATE**

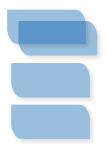
Magnesium Stearate is the most widely used excipient within the pharmaceutical industry: It ranks first on the list of the Top Ten excipients used in solid oral dosage forms.

How does **LIGAMED**® Magnesium Stearate work?

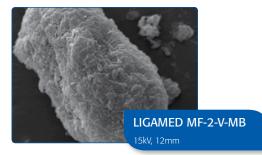


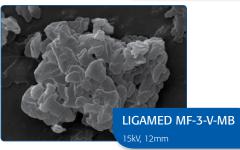
Blending process

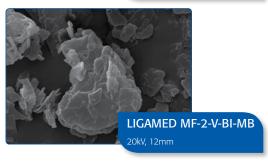
The crystal structure of high quality Magnesium Stearate is often pictured as a deck of cards. Due to the lamella structure Magnesium Stearate offers a very high specific surface area.



During the blending process with active ingredients, carriers or fillers, the "plates" of Magnesium Stearate dismantle from the decks, piece by piece, to coat other particles.









#### LIGAMED MF-2-V-MB

specific surface area: 6–10 m<sup>2</sup>/g, median particle size (D50): 7–11 μm

This is our most widely used excipient for the production of tablets and capsules. Its high specific surface area and fine particles offer a high releasing speed during tablet pressing and consistent physical performance of the tablets such as hardness and dissolution profiles. Due to the exceptional high specific surface area, typical quantity used during formulation is low: 0,2 % to 1 % by tablet weight. In addition to the application as a tableting agent, this product is also used as a flowability agent for powder preblends, offering an efficient and low dosage in capsules.

#### LIGAMED MF-3-V-MB

specific surface area:  $8-12 \text{ m}^2/\text{g}$ , median particle size (D50):  $5-9 \mu\text{m}$ 

This grade is characterised by the same unique properties as LIGAMED MF-2-V-MB but in addition MF-3-V-MB offers an even higher specific surface area and a smaller median particle size. This product is preferred in applications where processing conditions are more critical and very fine excipients or herbal formulations are used.

#### LIGAMED MF-2-V-BI-MB

specific surface area: 6–8 m $^2$ /g, median particle size (D50): 7–11  $\mu$ m

This variation of our LIGAMED MF-2-V-MB offers a tighter specific surface area range in combination with the favourable crystalline structure of LIGAMED MF-2-V-MB. This grade supports a lower dissolution profile and is used in special formulations as tablet coatings, where a low and stable viscosity is required.

#### LIGAMED MF-2-V PREMIUM-MB

For highly complex pharmaceutical applications (e.g. inhalation medicine) we have developed our LIGAMED MF-2-V PREMIUM-MB. This specialty grade has a high quality specification with additional tests for the fatty acid profile, particle size characterization and microbial count.

#### LIGAMED MF BLS-MB

LIGAMED MF BLS-MB extends our existing product portfolio of Magnesium Stearates and is produced according to a special production process. Offering the specific characteristic of being water dispersible, this product is very suitable for the use within water-soluble drugs.





## **CALCIUM STEARATE**

Calcium Stearate possesses characteristics similar to Magnesium Stearate. Likewise it is physiologically safe and is used as a lubricant, flowability agent and water repellent.

#### LIGAMED CPR-2-V-MB

specific surface area: 5–9 m $^2$ /g, median particle size (D50): 5–9  $\mu$ m

Some pharmaceutical formulations include vegetable based Calcium Stearate instead of Magnesium Stearate. LIGAMED CPR-2-V-MB is a perfect choice encompassing all core LIGAMED® pharmaceutical excipient principles. LIGAMED CPR-2-V-MB is also used as a water repellent agent in the production of effervescent tablets. Premature reaction of the effervescent tablet is avoided by preventing unwanted absorption of moisture.

## STEARIC ACID

Some formulations in the pharmaceutical industry are incompatible with Magnesium Stearate. For such formulations, Magnesium Stearate may be substituted by a high quality Stearic Acid.

#### **LIGAMED SA-1-V-MB**

This grade is a very fine quality from vegetable origin Stearic Acid. It is used as a tableting and flowability agent in specific pharmaceutical formulations. LIGAMED SA-1-V-MB is designed to support the high demands of the pharmaceutical industry, it complies with Ph.Eur & USP/NF regulations and is produced by a complex production process.

## Addition LIGAMED® Portfolio

In addition to our **LIGAMED**® product portfolio our brand **PALMSTAR**® also offers selected products that meet the strict requirements of the pharmaceutical industry:

#### PALMSTAR AL PHARMA-MB

PALMSTAR AL PHARMA-MB is one of our Aluminium Stearates with the best gelling performance capabilities. It is very suitable as an emulsion stabilizer and viscosity increasing agent for creams and ointments. Additionally, pharmaceutical applications use it as an anti-caking agent or suspending agent. PALMSTAR AL PHARMA-MB is in accordance with the European pharmacopeia.

#### PALMSTAR ZPR-2-V MI-MB

PALMSTAR ZPR-2-V MI-MB is a Zinc Stearate for pharmaceutical applications. It is used as an alternative lubricant if Magnesium and Calcium Stearate are incompatible with the API. Furthermore it can be used as a hydrophobing agent with antimicrobial properties for creams and as a stabiliser as well as a release agent for pharmaceutical plastics or rubber.

