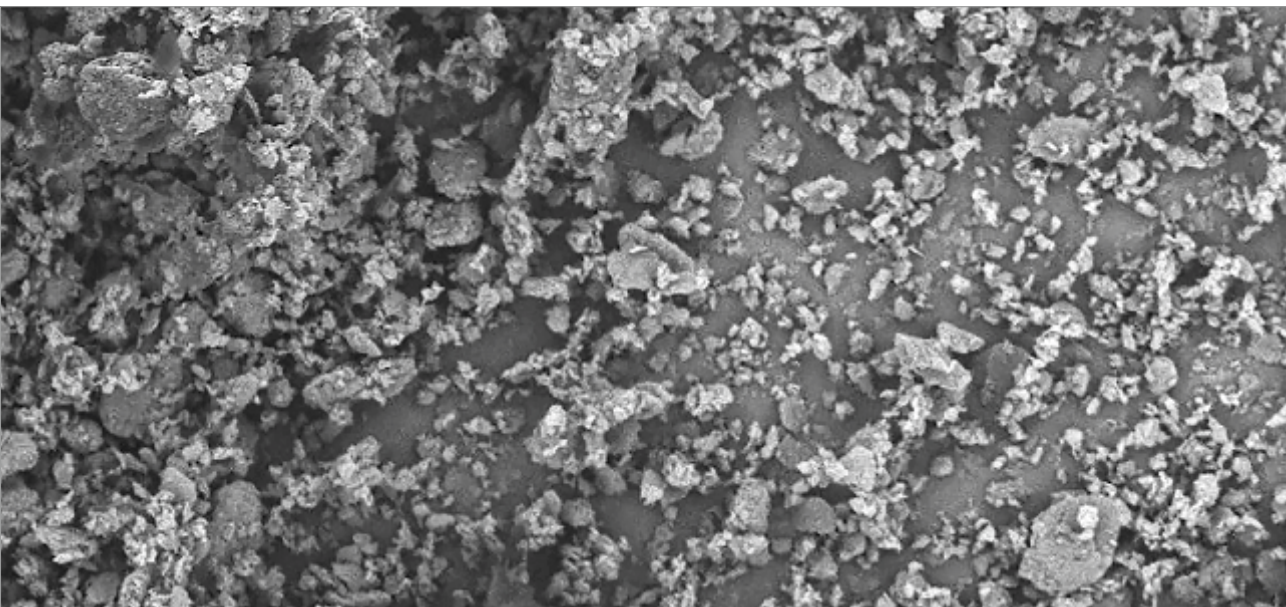


LUBRI-PREZ

Magnesium Stearate



The Most Widely Used Lubricant



LUBRI-PREZ

Magnesium Stearate

Introduction to LUBRI-PREZ

Introduction

Lubricants play a critical role in the development process of tableting and capsule filling. For decades, magnesium stearate has been the most commonly used lubricant in pharmaceutical and nutraceutical tablet formulations, offering both functionality and cost-efficiency.

As a leader in excipient manufacturing, JRS PHARMA offers high-quality tablet lubricants, including LUBRITAB® (Hydrogenated Vegetable Oil) and PRUV® (Sodium Stearyl Fumarate). To further meet customers' needs, JRS PHARMA's extensive tableting excipient portfolio is now further extended to include LUBRI-PREZ Magnesium Stearate.

Grades

Name of Grade	PSD Air Jet Sieve	PSD Malvern	Specific Surface Area	Stearic Acid
LUBRI-PREZ 2	Max. 1 % retained on 200#	D ₅₀ between 7.0 µm and 11.0 µm	6-10 m ² /g	Min. 60 %
LUBRI-PREZ 4	Max. 5 % retained on 200#	D ₅₀ typically between 5.0 and 9.0 µm	5-15 m ² /g	Min. 40 %

Tab 1 Grades of LUBRI-PREZ

LUBRI-PREZ is plant-derived and complies with major pharmacopeias (USP/NF, Ph. Eur.) as well as regulations for nutraceutical applications (FCC, E470b).

It is manufactured based on a stringent set of specifications at the EXCiPACT™ certified site of JRS PHARMA's joint venture partner, Sudeep Pharma, in Gujarat, India.

Functionality

The functionality of LUBRI-PREZ was tested in comparison with established brands of magnesium stearate on the markets.

EMCOMPRESS® Premium	Dibasic Calcium Phosphate Dihydrate	69.5 %
VIVAPUR® 102	Microcrystalline Cellulose	29.5 %
LUBRI-PREZ 2 LUBRI-PREZ 4 Competitor A Competitor B	Magnesium Stearate	1.0 %

Tab 2 Test Formulation. Magnesium Stearate was Blended with the Other Ingredients for Three Minutes. The Blend was Used for Direct-Compression Tableting.

Lubrication Efficiency

The main role of lubricants is the reduction of punch adhesion and die-wall friction. Measurement of the ejection force is a very significant parameter for the characterization of the lubrication efficiency.

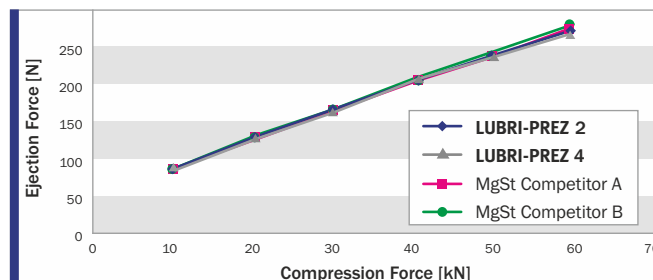


Fig. 1 Ejection Force as Function of Compression Force

Comparison of the ejection forces revealed the exact same lubrication efficiency for the four grades of magnesium stearate tested.



Picture by courtesy of Syntegon Technology GmbH

Effect on Tablet Hardness

A common side-effect of magnesium stearate is the tendency to occupy binding sites in the powder blend, thereby reducing the overall tableability and tablet hardness. This effect is aggravated by prolonged blending times.

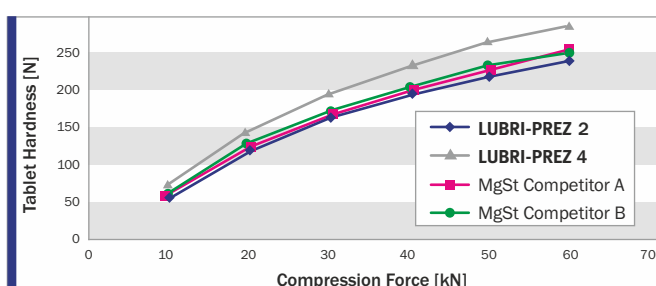


Fig. 2 Tablet Hardness with **LUBRI-PREZ** Compared to Other Products in the Market.

Figure 2 shows the compaction profiles for the four tested grades. **LUBRI-PREZ** exhibited equivalent behaviour as the two grades used for comparison.

Effect on Disintegration Time

Due to its hydrophobic nature, magnesium stearate also affects the ingress of water into the tablet matrix. As a result, the use of magnesium stearate as a lubricant may lead to longer disintegration times.

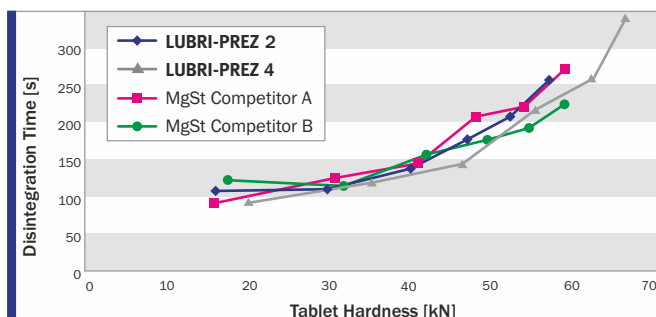


Fig. 3 Disintegration Time with **LUBRI-PREZ** Compared to Other Products in the Market.

All four formulations showed a moderate increase in disintegration time with increasing tablet hardness. Only minor differences were observed between the four different grades of magnesium stearate.

Conclusion

LUBRI-PREZ was found to be functionally equivalent to the tested countertypes. Consistent performance in this regard is ensured by relevant powder parameters as listed in the technical advantages section below.

Technical Advantages of **LUBRI-PREZ**

- Tightly specified PSD
- Clearly defined specific surface area
- Specified, reproducible bulk density

Regulatory

- Complies with Ph. Eur., USP/NF, E470b and FCC
- GRAS listed
- Available certificates:
 - Kosher
 - Halal
 - EXCiPACT™
 - ISO 9001

Packaging and Samples

25 kg paper bag with HDPE liner

500 kg container pallet

Available sample sizes:

100 g / 400 g aluminum bags

Disclaimer:

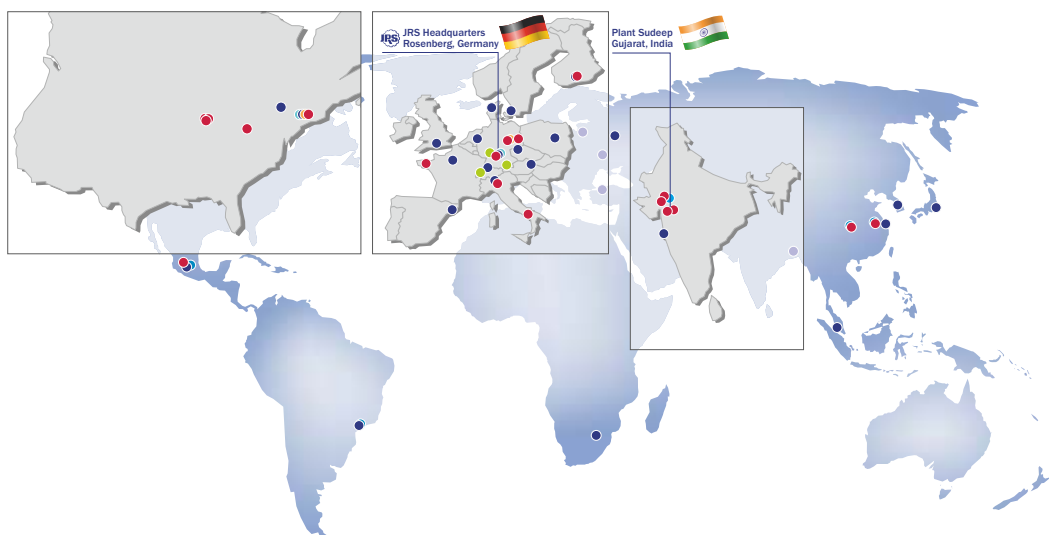
The information provided in this brochure is based on thorough research and is believed to be completely reliable. Application suggestions are given to assist our customers, but are for guidance only. Circumstances in which our material is used vary and are beyond our control. Therefore, we cannot assume any responsibility for risks or liabilities, which may result from the use of this technical advice.

The Global Excipient Maker

Global Network

Dedicated Manufacturing and Service Sites

- Excipients
- Coatings
- Biopharma Services
- JRS Sales Companies (Additionally, dedicated representatives in almost every country.)
- Technical Competence Centers
- Application Labs



HIGH FUNCTIONALITY EXCIPIENTS

- PROSOLV® SMCC**
Silicified Microcrystalline Cellulose
- PROSOLV® EASYtab SP**
Microcrystalline Cellulose, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Sodium Stearyl Fumarate
- PROSOLV® EASYtab NUTRA**
All-in-one Composite for Nutraceutical Applications
- PROSOLV® ODT G2**
Microcrystalline Cellulose, Colloidal Silicon Dioxide, Mannitol, Fructose, Crospovidone

DISINTEGRANTS

- VIVASTAR®, EXPLOTAB®**
Sodium Starch Glycolate, Sodium Carboxymethyl Starch
- VIVASOL®**
Croscarmellose Sodium
- EMCOSOY®**
Soy Polysaccharides
- VIVAPHARM® Crospovidone**
Polyvinylpyrrolidone, crosslinked

COATINGS

- VIVACOAT®**
Ready-to-Use Coating System
- VIVACOAT® protect**
Ready-to-Use High Functional Coating System
- VIVAPHARM® HPMC**
Hypromellose
- VIVAPHARM® PVA**
Polyvinyl Alcohol

BINDERS

- VIVAPUR®, EMCOCEL®**
Microcrystalline Cellulose
- EMDEX®**
Dextrates
- VIVAPHARM® Povidones**
Povidone and Copovidone

LUBRICANTS

- PRUV®**
Sodium Stearyl Fumarate
- LUBRITAB®**
Hydrogenated Vegetable Oil, Hydrogenated Oil
- LUBRI-PREZ**
Magnesium Stearate

CARRIERS

- VIVAPUR® MCC SPHERES**
Microcrystalline Cellulose Pellets
- VIVAPHARM® Sugar Spheres**
Sugar Pellets, Non-GMO

FUNCTIONAL FILLERS

- ARBOCEL®**
Powdered Cellulose
- EMCOMPRESS®**
Calcium Phosphates
- COMPACTROL®**
Calcium Sulfate Dihydrate

THICKENERS • STABILIZERS • GELLING AGENTS

- VIVAPUR® MCG**
Microcrystalline Cellulose and Carboxymethylcellulose Sodium
- VIVAPHARM® Alginates**
Calcium Alginate
- VIVAPHARM® Alginates**
Sodium Alginate
- VIVAPHARM® Alginates**
Alginate Acid
- VIVAPHARM® Pectins**

BIOPHARMA SERVICES