

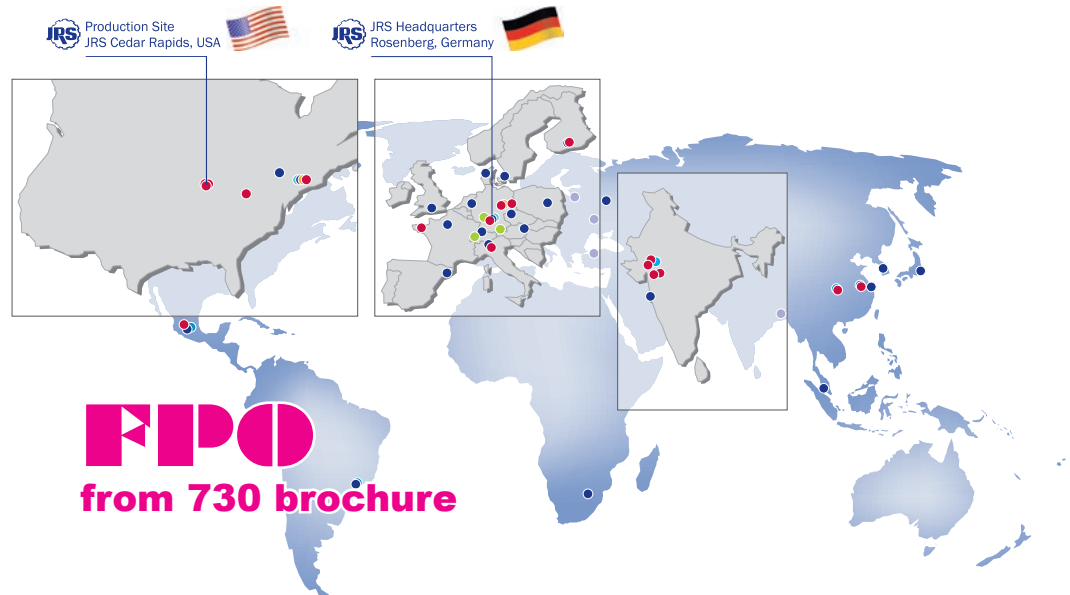


Fibers for Life.

Global Network

GMP 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

NEW PROSOLV® 730
Directly Compressible Carrier for Lipophilic Ingredients

BINDERS

VIVAPUR®, EMCOCEL®
Microcrystalline Cellulose

EMDEX®
Dextrates

VIVAPHARM® Povidones
Povidone and Copovidone

FUNCTIONAL FILLERS

ARBOCEL®
Powdered Cellulose

EMCOMPRESS®
Calcium Phosphates

COMPACTROL®
Calcium Sulfate Dihydrate

DISINTEGRANTS

VIVASTAR®, EXPLOTAB®
Sodium Starch Glycolate, Sodium Carboxymethyl Starch

VIVASOL®
Croscarmellose Sodium

EMCOSOY®
Soy Polysaccharides

VIVAPHARM® Crospovidone
Polyvinylpyrrolidone, crosslinked

LUBRICANTS

PRUV®
Sodium Stearyl Fumarate

LUBRITAB®
Hydrogenated Vegetable Oil, Hydrogenated Oil

LUBRI-PREZ™
Magnesium Stearate

THICKENERS • STABILIZERS • GELLING AGENTS

VIVAPUR® MCG
Microcrystalline Cellulose and Carboxymethylcellulose Sodium

VIVAPHARM® Alginates
Calcium Alginate

VIVAPHARM® Alginates
Sodium Alginate

VIVAPHARM® Alginates
Alginic Acid

VIVAPHARM® Pectins

COATINGS

VIVACOAT®
Ready-to-Use Coating System

VIVACOAT® protect
Ready-to-Use High Functional Coating System

VIVAPHARM® HPMC
Hypromellose

VIVAPHARM® PVA
Polyvinyl Alcohol

CARRIERS

VIVAPUR® MCC SPHERES
Microcrystalline Cellulose Pellets

VIVAPHARM® Sugar Spheres
Sugar Pellets, Non-GMO

BIOPHARMA SERVICES



JRS PHARMA LP

2981 Route 22, Patterson, NY 12563
Phone: (845) 878-3414 info@jrspharma.com

LUBRITAB® RBW

Rice Bran Wax



The Clean Label
Lubricant for
Tablet and Capsule
Formulations

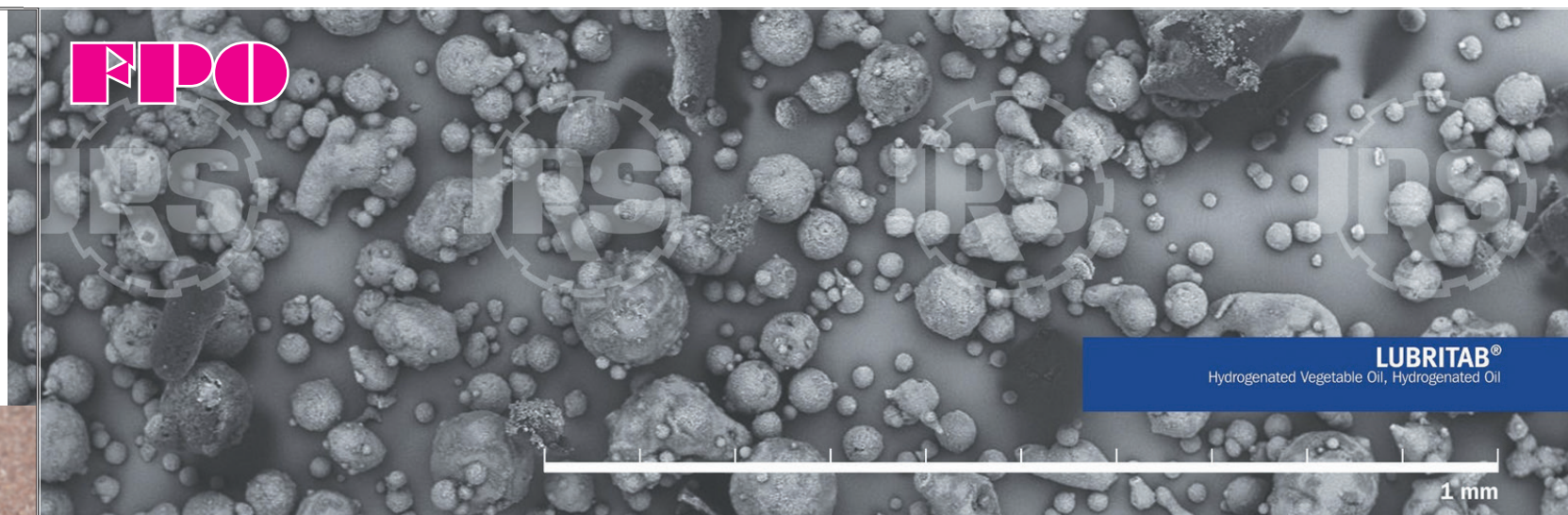
All Natural Tablet & Capsule Lubricant

- Sustainably sourced
- Comparable use level to standard lubricants
- Robust tablets
- Low risk of overblending
- Low impact on tablet disintegration
- Inert for improved API stability



Fibers for Life.

JRS PHARMA LP



Introducing LUBRITAB® RBW

LUBRITAB® RBW (Rice Bran Wax) is the all-natural, gluten-free, plant-based, vegan, clean label lubricant that is suitable for nutraceutical applications.

Derived from the bran layer found in rice grains, LUBRITAB® RBW serves as a lubricant in tablet and capsule formulations at concentrations of 0.25 – 2% (w/w), and may be used in combination with an anti-adherent.

LUBRITAB® RBW has multiple advantages for nutraceutical formulations:

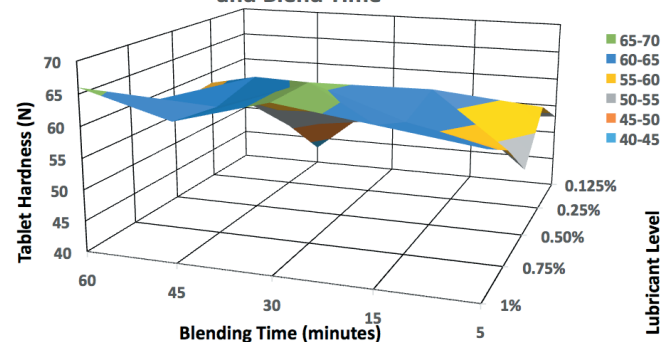
- The only clean label lubricant
- Sustainably sourced
- Comparable use level to standard lubricants
- Robust tablets
- Low risk of overblending
- Low impact on tablet disintegration
- Inert for improved API stability

Characteristics of LUBRITAB® RBW

- Off-white waxy powder
- Less hydrophobic than magnesium stearate
- Chemically inert
- Low melting point

Characteristics	Specifications
Melting point	75 – 80 °C
Acid Value	Max. 20
<u>Saponification Value</u>	75 – 120
Iodine Value	Max. 20
Elemental impurities (ICP-MS)	Cadmium < 1 ppm Arsenic < 1 ppm Lead < 2 ppm Mercury < 1 ppm

Tablet Hardness with LUBRITAB(R) RBW Level and Blend Time





How Does LUBRITAB® RBW Work?

LUBRITAB® RBW is a liquid film lubricant that melts and re-solidifies during the compaction process, thus enhancing the bonding capacity of the tablet matrix, resulting in a more robust tablet.

LUBRITAB® RBW serves as a lubricant in tablet and capsule formulations, and is suitable for use in direct compression and continuous manufacturing, as well as in wet or dry granulation formulations. It may be used in combination with an anti-adherent when used at higher levels.

What Makes LUBRITAB® RBW Special?

An ideal tablet lubricant ...	Magnesium Stearate	LUBRITAB® RBW
Facilitates ejection of the tablet from the die (lowers ejection force)	+++	+++
Minimizes adhesion of the tablet ingredients to the punch faces	+++	++
Does not negatively impact tablet hardness	-	+++
Does not negatively impact disintegration / dissolution	-	+

Clean label with sustainable sourcing

LUBRITAB® RBW was developed from rice, a natural plant source, offering friendly nutritional products labeling. Rice bran wax has applications in cosmetics, foods, industrial coatings, and agrochemical products. **LUBRITAB® RBW** is an excellent alternative to magnesium stearate in nutritional applications.

Since **LUBRITAB® RBW** is an edible vegetable product, it is low in ash content and meets global heavy metals standards. Additionally, it's compatible with vegetarian diets and vegan lifestyles.

LUBRITAB® RBW is free of:

- carbohydrates
- gluten
- proteins and amino acids
- starches and starch derivatives
- additives
- preservatives



Functional Features

Comparable use level to standard lubricants

LUBRITAB® RBW demonstrates equivalent reduction of ejection forces compared to the most widely used tableting lubricant, magnesium stearate (Table 1), reducing wear on tableting equipment.

	Magnesium Stearate	LUBRITAB® RBW
Lubricant Concentration	Ejection Force [N]	
0.125%	177	168
0.25%	182	156
0.50%	207	171
0.75%	215	164
1.0%	123	131

Table 1. MCC/Ibuprofen Tablets: Ejection Forces after 5 Minutes of Blending Time

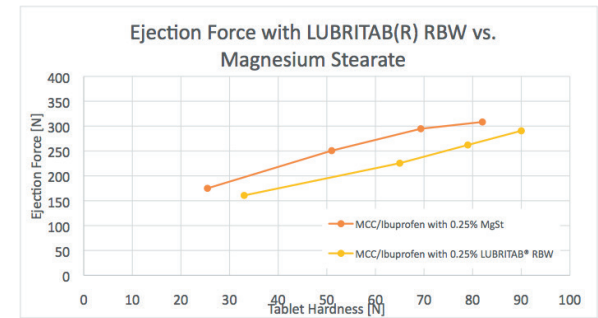


Figure 1. Effect of Lubricant Choice on the Ejection Force of MCC/Ibuprofen Tablets

Robust Tablets

Tablets made with LUBRITAB® RBW (vs. magnesium stearate) are mechanically more robust, with higher tablet hardness (Figure 2) and lower friability (Figure 3), leading to enhanced production yields and shortened formulation and scale-up time. Adding more lubricant does not negatively impact tablet hardness (Figure 4) – need more, use more..

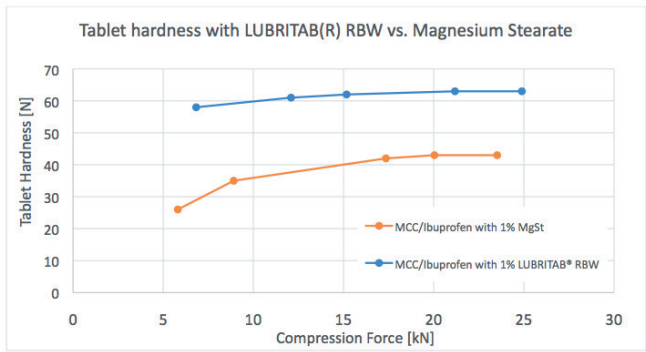


Figure 2. Effect of Lubricant Choice on the Tablet Crushing Strength of MCC/Ibuprofen Tablets

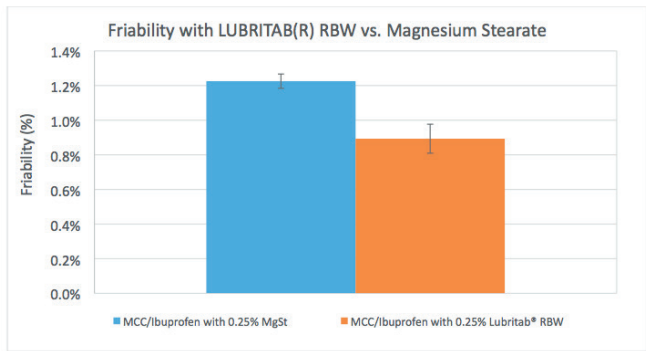


Figure 3. Effect of Lubricant Choice on the Friability of MCC/Ibuprofen Tablets

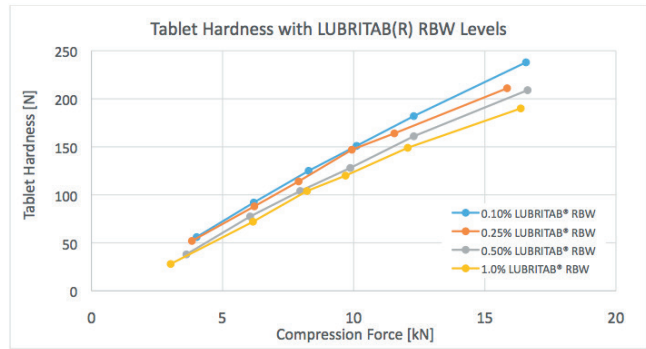


Figure 4. Effect of LUBRITAB® RBW Level on the Tablet Hardness of MCC/DCP Placebo Tablets

Benefits

- Harder tablets and lower friability compared to mag. stearate
- Increased range of lubricant level for troublesome formulations



Low risk of overblending

Formulations with magnesium stearate are extremely sensitive to blending times. Even a slight overblending can lead to a dramatic drop in the mechanical strength of the resulting tablets.

By contrast, blending time has little effect on tablet strength in formulations made with **LUBRITAB® RBW** (Figures 5, 6). No loss in functionality due to overblending results in improved manufacturing flexibility, formula robustness, and reduced chance of lost batches.

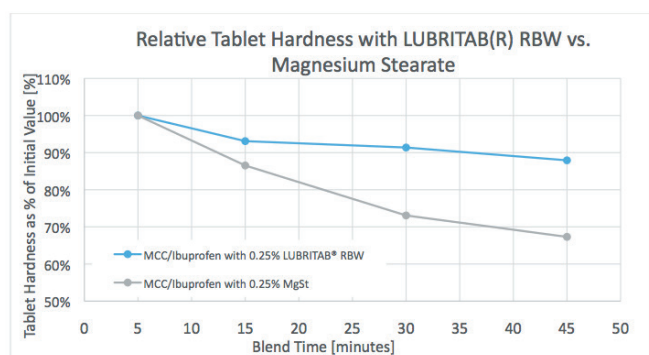


Figure 5. Effect of Blending Time and Lubricant Choice on the Tablet Crushing Strength of MCC/Ibuprofen Tablets

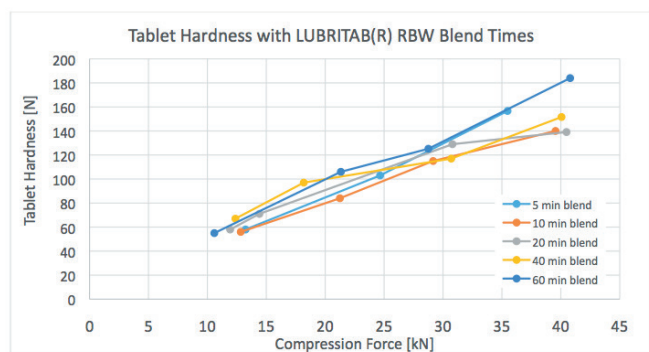


Figure 6. Effect of Blending Time on the Tablet Hardness of DCP Placebo Tablets with 2.0% LUBRITAB® RBW

Low impact on tablet disintegration

The disintegration of tablets can be negatively impacted by the presence of magnesium stearate due to its high hydrophobicity. This new lubricant is less hydrophobic than magnesium stearate, with better water penetration into the tablet matrix.

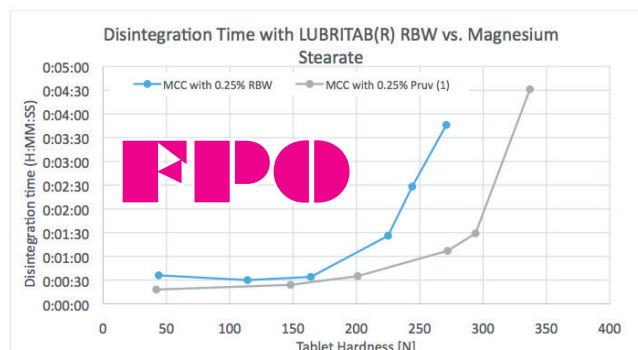


Figure 7. Effect of Lubricant Choice on the Disintegration of MCC Placebo Tablets

Benefits

- Less sensitivity to blending time
- Good tablet mechanical integrity
- Enhanced production yields
- Easier formulation scale-up

Functional Features (continued)

Inert for improved API stability

LUBRITAB® RBW helps to avoid API incompatibilities as it is generally unreactive towards APIs, while magnesium stearate is reactive and can cause API degradation. With few exceptions, **LUBRITAB® RBW** can be applied to any formulation for lubrication, particularly those in which API stability or tablet taste is compromised due to magnesium stearate.

Magnesium stearate is known to interact with APIs of various types (iron salts, some vitamins, alkaloid salts, strong organic acid salt formers, APIs containing carbonyl, carboxyl or sulfonyl groups).

LUBRITAB® RBW is preferred for vitamins	LUBRITAB® RBW is preferred for metal salts
Vitamin B1 (thiamine)	Iron salts
Vitamin E (tocopherol)	Potassium salts

API Stability Example: Aspirin

A study examined the lubricant-API stability of **LUBRITAB® RBW**, in comparison with magnesium stearate. Aspirin was chosen as a model API for the study. Magnesium stearate is known to interact unfavorably with aspirin. Aspirin also has a known tendency to convert to salicylic acid in the presence of moisture.

Aspirin and lubricant were ground together at a 1:1 ratio by weight with a glass mortar and pestle, then portioned into three vials which were labeled for room temperature storage or for storage closed or open in a stability chamber at 40°C and 75% RH. Near-IR (NIR) spectra were obtained periodically over two months of storage under these three different conditions.

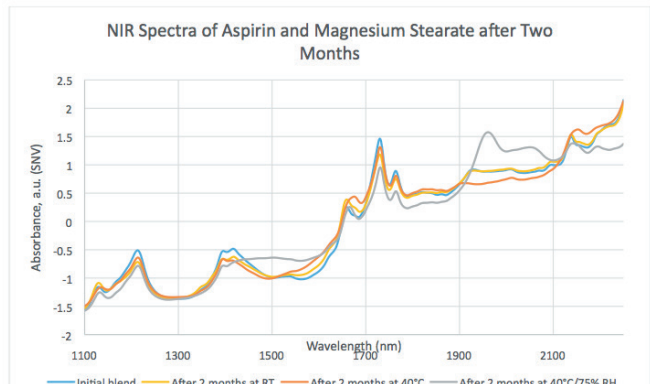


Figure 8. Effect of Different Storage Conditions on the NIR Spectra of Aspirin-Magnesium Stearate Blends.

API Stability Example: Aspirin (continued)

The aspirin-magnesium stearate blend was stable to room temperature storage for two months, but was not stable in heated storage at 40°C and showed even more changes after hot, humid storage at 40°C/75% RH (Figure 8).

The observed shifts in the aspirin peaks may indicate Mg2+-aspirin complexation and/or salicylic acid formation. In contrast, the new peaks in the 1400-1500 nm and 1900-2100 nm regions are likely due to moisture inclusion.

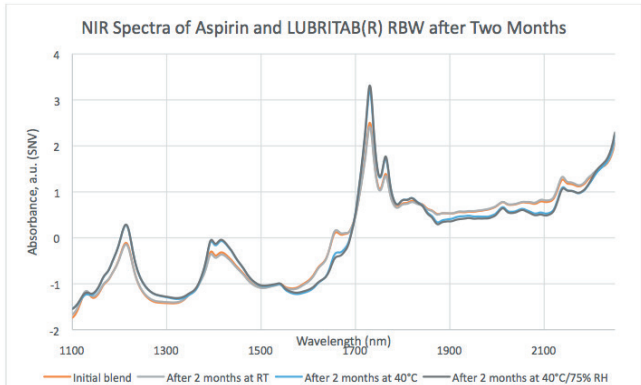


Figure 9. Effect of Different Storage Conditions on the NIR Spectra of Aspirin-LUBRITAB® RBW Blends.

The aspirin-LUBRITAB® RBW blend was stable to room temperature storage for two months (Figure 9). While the blend showed no signs of complexation or moisture inclusion after heated storage or hot, humid storage for two months, aspirin content appeared to decline.

Overall, there was no indication of interaction between **LUBRITAB® RBW** and aspirin under any of the tested storage conditions. However, the aspirin itself was not stable to hot and/or humid storage.

Regulatory and Packaging

Regulatory Information

LUBRITAB® RBW helps to avoid API incompatibilities as it is generally unreactive towards APIs, while magnesium stearate is reactive and can cause API degradation. With few exceptions, **LUBRITAB® RBW** can be applied to any formulation for lubrication, particularly those in which API stability or tablet taste is compromised due to magnesium stearate.

Magnesium stearate is known to interact with APIs of various types (iron salts, some vitamins, alkaloid salts, strong organic acid salt formers, APIs containing carbonyl, carboxyl or sulfonyl groups).

- Oryza Sativa (Rice) Bran Wax
 - GRAS status <take out if keep Food Reg. Status section below>
 - cGMP Production
 - Non-Animal Origin
 - BSE/TSE-free
 - Complies with general chapters for residual solvents (USP <467>)
 - Elemental Impurity statement available
 - Re-evaluation date: <X> years
- <Check finalized PRI to confirm.>

Food Regulatory Status

State	Oryza Sativa (Rice) Bran Wax
USA	GRAS

Packaging, Samples, and Storage

Storage

Store in original, well-closed containers protected from excessive heat and moisture.

Packaging

25 kg drum or 4 kg pail <note: may be 3.5 kg, will have final in next 2 weeks>

Pallet

125 kg (5 x 25 kg drums), stackable(?) <note: spec sheet says 4 drums/pallet, email said 5 drums>

144 kg (36 x 4 kg pails)

Sample Sizes

100 g plastic container

