



# LUBRITAB® RBW – Direct Compression Tableting vs. Standard Lubricants

## Aim of the study

The goal of this study was to compare the lubricant functionality of LUBRITAB® RBW (rice bran wax) with that of the lubricants magnesium stearate, sodium stearyl fumarate (PRUV®), and hydrogenated vegetable oil (LUBRITAB®).

The tablet model chosen used microcrystalline cellulose (MCC) and ibuprofen. With respect to tableting issues, ibuprofen is a challenging active ingredient – it is sticky, has a low melting point, exhibits poor flow, and is generally formulated as a high dose active.

Each lubricant was studied at five different levels. A portion of each blend was withdrawn from the blender at five different blending times, and compacted at five separate compression forces. This was done to develop a thorough understanding of their behavior in this tablet model.

## LUBRITAB® RBW

LUBRITAB® RBW (Rice Bran Wax) is an all-natural, gluten-free, plant-based, 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 recommended concentrations of 0.25 – 2% (w/w), and may be used in combination with an anti-adherent.

LUBRITAB® RBW has multiple advantages:

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

## Formulation

The tablet formulation consisted of ibuprofen (USP), EMCOCEL® 90 M (MCC) as binder, and either LUBRITAB® RBW, magnesium stearate (USP), PRUV® SSF or LUBRITAB® HVO as lubricant. The amount of MCC was adjusted to make up for the different lubricant levels used and maintain a consistent blend size and drug concentration.

Formulation	mg/Tablet	Contribution (%)
ibuprofen	400.0	80.00
EMCOCEL® 90 M	95.00 – 99.375	19.00 – 19.875
Lubricant	0.625 – 5.00	0.125 – 1.00
Total	500.0	100.0

## Excipients

LUBRITAB® RBW is a clean label lubricant that is intended for nutraceutical formulations. Magnesium stearate is the most commonly used tableting lubricant. PRUV® SSF is a tablet lubricant specifically designed for formulations in which other lubricants lead to formulation and/or manufacturing challenges. LUBRITAB® HVO is a liquid film lubricant that can also be applied as an auxiliary tablet binder. EMCOCEL® 90 M is a grade of microcrystalline cellulose with good flow and compactibility characteristics.

## Procedure

### Blending

Blends consisting of five separate levels of each lubricant type were prepared, with the lubricant blending time set for up to 60 minutes. After the addition of the lubricant, sieved through a 20-mesh screen, to the ibuprofen-MCC premix in a low shear mixing vessel, and the initiation of blending, a portion of each blend (enough to make a representative number

of tablets) was withdrawn at each of 5 intervals (5, 15, 30, 45 and 60 minutes). Each blend was compacted at five different compression forces, on an instrumented tablet press, using 1/2 inch round, flat-face tooling.

### Equipment

Low Shear Mixer	Glen Mills Turbula
Tablet Press	Piccola Rotary Instrumented Tablet Press
Hardness Tester	Sotax Model HT10 Hardness Tester

### Tablet Characteristics

Tablet Weight	500.0 mg
Tablet Shape	0.5000" round flat faced
Tablet Height	2.7 - 4.3 mm

In all cases, with all lubricants at all conditions, some "filming" of the punches was observed, highlighting the sticky nature of ibuprofen. Punches were cleaned before continuing with each variant. Picking was observed in the blends with magnesium stearate.

Tablet hardness and ejection force were measured for each variant. Ejection force values within each lubricant level and each blending time were generally low (100 - 200 N) and comparable across all four lubricants indicating satisfactory lubricant functionality (Table 1).

Lubricant Concentration	Magnesium Stearate	PRUV® SSF	LUBRITAB® HVO	LUBRITAB® RBW
0.125%	177	166	161	168
0.25%	182	185	164	156
0.50%	168	207	153	171
0.75%	215	191	157	164
1.0%	123	153	105	131

Tab. 1 MCC/Ibuprofen Tablets: Ejection Forces after 5 Minutes

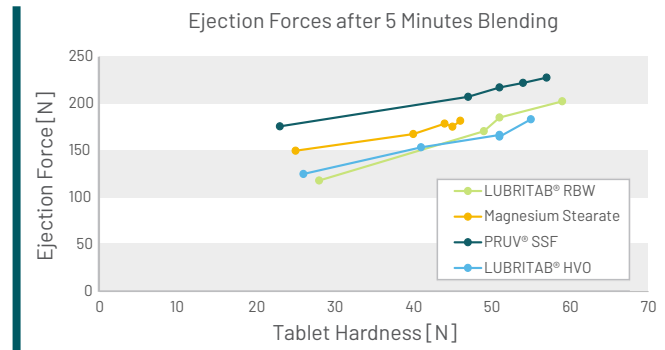


Fig. 1 Effect of Lubricant Choice on the Ejection Forces of MCC/Ibuprofen Tablets after 5 Minutes Blending.

Figure 1 shows similar ejection force and tablet hardness values for LUBRITAB® RBW, magnesium stearate and LUBRITAB® HVO at 0.5% lubricant after 5 minutes of blending, with slightly higher ejection forces (but similar tablet hardness values) with PRUV® SSF. The increase in ejection forces with increased tablet hardness is to be expected as increased compaction force increases die-wall adhesion.

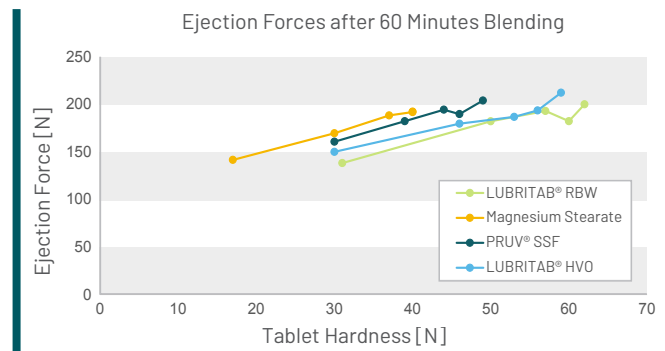


Fig. 2 Effect of Lubricant Choice on the Ejection Forces of MCC/Ibuprofen Tablets after 60 Minutes Blending.

Figure 2 shows similar ejection force and tablet hardness values for LUBRITAB® RBW, PRUV® SSF and LUBRITAB® HVO at 0.5% lubricant after an hour of blending, with similar ejection forces (but lower tablet hardness values) with magnesium stearate, due to decreased inter-particulate cohesion from lubricant over-blending.

Figures 3-6 show three-dimensional contour plots for each lubricant at 15 kN compression force, indicating tablet hardness across lubricant levels and lubricant blending times. When comparing tablet hardness values for the lowest levels of lubricant blended for the shortest time with the highest levels blended for the longest time (see also Figure 7), tablets lubricated magnesium stearate show a substantial drop in tablet hardness (~16 N), while tablets lubricated with PRUV® SSF, LUBRITAB® HVO show a minor drop in tablet hardness (~2-4 N). Tablets lubricated with LUBRITAB® RBW, on the other hand, show a marked increase in tablet hardness (~13 N).

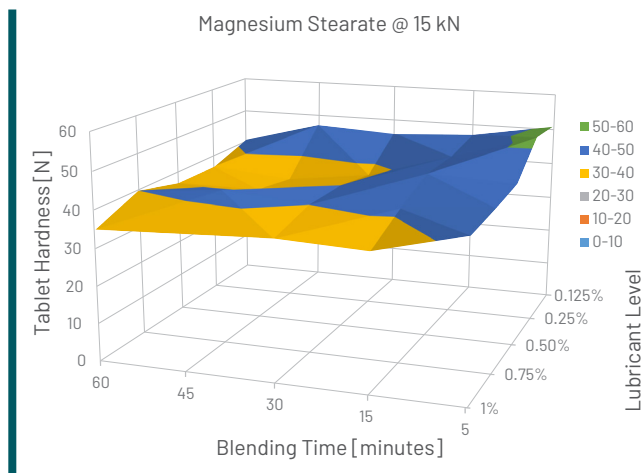


Fig. 3 Effect of Lubricant Level and Blending Time on the Tablet Hardness of MCC/Ibuprofen Tablets Lubricated with Magnesium Stearate.

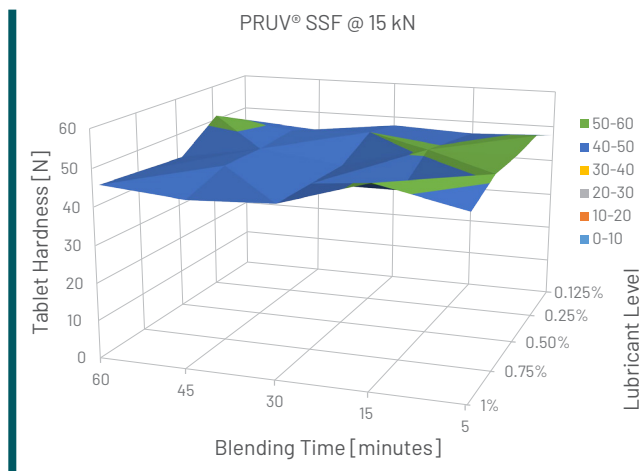


Fig. 4 Effect of Lubricant Level and Blending Time on the Tablet Hardness of MCC/Ibuprofen Tablets Lubricated with PRUV® SSF.

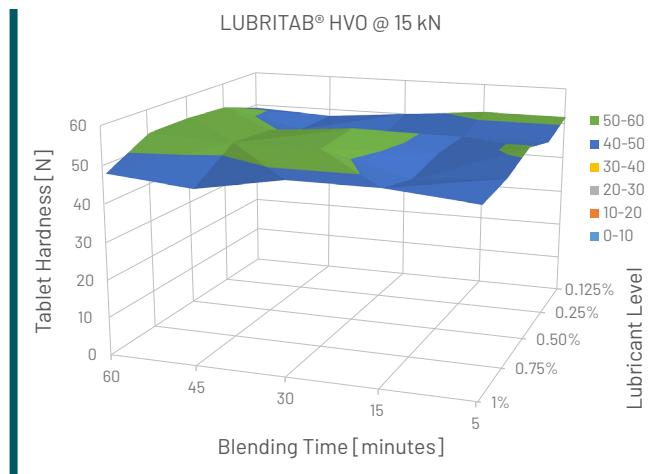


Fig. 5 Effect of Lubricant Level and Blending Time on the Tablet Hardness of MCC/Ibuprofen Tablets Lubricated with LUBRITAB® HVO.

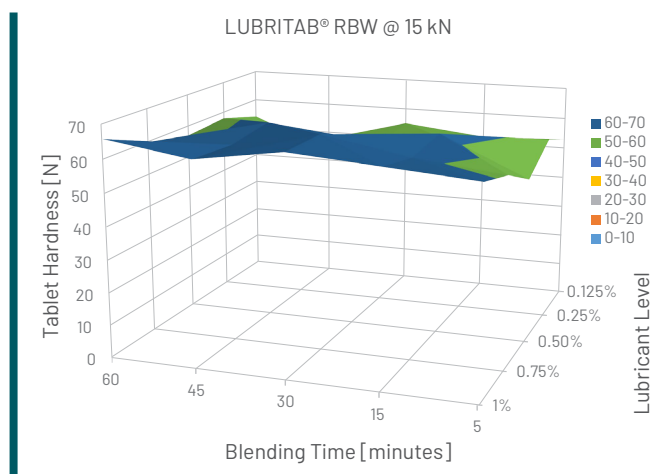


Fig. 6 Effect of Lubricant Level and Blending Time on the Tablet Hardness of MCC/Ibuprofen Tablets Lubricated with LUBRITAB® RBW.

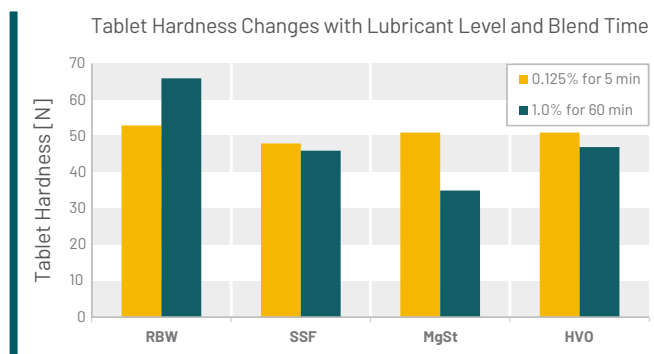


Fig. 7 Effect of Lubricant Level and Blending Time on the Tablet Hardness of MCC/Ibuprofen Tablets at 15 kN Compression Force.



### Conclusion

The main functions of a tablet lubricant are to reduce adhesion of the tablet post compression, minimize ejection forces, and reduce punch face adhesion. An ideal tablet lubricant would achieve these functions without any negative impact on the compaction and disintegration / dissolution of the resulting tablets.

Contrary to what is typical of lubricants, tablets lubricated with LUBRITAB® RBW showed an increase in tablet hardness of with increasing compression forces and blending times. This suggests that LUBRITAB® RBW is acting as a binder to some degree (without negatively impacting ejection forces).

When compared to PRUV® SSF, LUBRITAB® HVO and magnesium stearate, LUBRITAB® RBW demonstrated comparable and in some cases superior die wall lubrication (lower ejection force) and comparable reduction of punch face adhesion, in the ibuprofen tablet model studied.

Find out more about LUBRITAB® RBW on

[https://www.jrspharma.com/pharma\\_en/products/promo/lubritab-rbw.php](https://www.jrspharma.com/pharma_en/products/promo/lubritab-rbw.php)

Key Words: Lubricant, Direct Compression, Clean Label

JRS Products: LUBRITAB® RBW, PRUV® SSF, LUBRITAB® HVO, EMCOCEL® 90 M, EXPLOTAB® SSG

### What Makes LUBRITAB® RBW Special

An ideal tablet lubricant ...	Magnesium Stearate	PRUV® SSF	LUBRITAB® HVO	LUBRITAB® RBW
Facilitates ejection of the tablet from the die (lowers ejection force)	+++	+++	+++	+++
Minimizes adhesion of the tablet ingredients to the punch faces	+++	+++	++	++
No impact on tablet hardness	-	++	++	+++
No impact on disintegration / dissolution	--	++	+	+

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U.S. HEADQUARTERS  
**JRS PHARMA LP**

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