VITAMIN C – Tableting with LUBRITAB® RBW Lubricant

Aim of the study

Vitamin C (ascorbic acid) is a popular supplement available over the counter in dosage forms such as tablets, capsules, sprinkles and gummies. From a formulator's perspective, it can be challenging since it is poorly compressible and is very sensitive to moisture. Because of this, it requires effective lubrication to facilitate ejection, but with minimal impact on tablet hardness.

This issue is common among supplements and is the "double-edged sword" of tablet lubrication. This study compared the lubricant functionality of LUBRITAB® RBW (rice bran wax) at several levels with a commonly used lubricant, stearic acid.

Vitamin C

From the therapeutic perspective, Vitamin C is a nutrient necessary for survival. It plays a role in tissue development and repair. It also supports the efficient function of the immune system, wound healing, maintenance of bone and connective tissue health, collagen formation and absorption of iron. Claimed to be one of the safest nutrients, it is touted to be an effective treatment in resistance to and treatment of common cold viruses.

Formulation

The tablet formulation consisted of Vitamin C (ascorbic acid, USP), PROSOLV® SMCC 90 as binder, VIVASOL® croscarmellose sodium as disintegrant, and LUBRITAB® RBW as lubricant. One additional formulation included stearic acid (USP/NF) at 2.0% in place of LUBRITAB® RBW, for comparison.

Formulation	mg/Tablet	Contribution (%)
Vitamin C	500.0	50.00
PROSOLV® SMCC 90	430.0-457.5	43.00-45.75
VIVASOL® Croscarmellose Sodium	40.0	4.0
LUBRITAB® RBW	2.5-30.0	0.25-3.0
Total	1000.0	100.0

Excipients

LUBRITAB® RBW is an all-natural, plant-based, clean label lubricant that is desirable for nutraceutical applications. PROSOLV® SMCC 90 was chosen for its excellent flow and compactibility characteristics, while VIVASOL® CCS is an effective wicking-type disintegrant that will pull water into the tablets to facilitate tablet disintegration and dissolution of the Vitamin C.

Procedure

Blending

Vitamin C was added to a low shear mixing vessel along with PROSOLV® SMCC 90, VIVASOL® CCS, and 20-mesh screened LUBRITAB® RBW. After blending for five minutes, the blends were immediately used for direct compression tableting.

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	1000.0 mg
Tablet Shape	0.325" x 0.675" modified oval
Tablet Height	6.4 - 7.2 mm

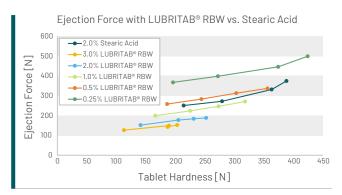


Fig. 1 Effect of Lubricant Choice and Level on the Ejection Force of SMCC/Vitamin C Tablets

Figure 1 shows a rank order performance of LUBRITAB® RBW in ejection force values for Vitamin C formulation. With respect to lubricant level, all but the lowest level (0.25% LUBRITAB® RBW) produced acceptable ejection forces. Surprisingly 2.0% stearic acid was needed to produce an ejection force equivalent to that of only 0.5% LUBRITAB® RBW.

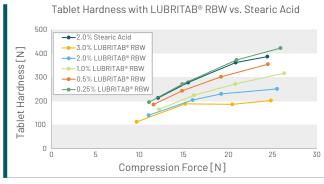


Fig. 2 Effect of Lubricant Choice and Level on the Tablet Hardness of SMCC/Vitamin C Tablets.

Figure 2 shows a rank order performance of LUBRITAB® RBW in tablet hardness values as well. As is common with lubricants, an increase in lubricant level resulted in a decrease in tablet hardness. This reduction in hardness was across a wide range of lubricant level (from 0.25 – 3.0%) and tablets of satisfactory (200 N) hardness were still achievable.

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Tablets formulated with 0.5% LUBRITAB® RBW were almost as hard as those formulated with stearic acid at 2.0%.

It should be noted that while LUBRITAB® RBW has been observed in some cases to act like a binder (actually increasing tablet hardness as the input level is increased), this appears to be dependent on the choice of both API and binder.

With Vitamin C and PROSOLV® SMCC 90 there was some picking observed on the tablets made with 2-3% LUBRITAB® RBW, particularly at the lowest compaction levels. This suggests that when there are formulations containing very sticky actives, the additive effect of the adhesive characteristics of LUBRITAB® RBW may need to be moderated with the addition of an anti-adherent.

Conclusion

LUBRITAB® RBW was found to be well-suited for the production of Vitamin C tablets by direct compression. The tablets showed sufficiently low ejection forces at lubricant levels equal to or greater than 0.5% LUBRITAB® RBW, and reasonable tablet hardness at all lubricant levels.

In the case of Vitamin C, the recommended level of LUBRITAB® RBW to optimize both tablet hardness and ejection forces is 0.5-1.0%.

Find out more about LUBRITAB® RBW on

https://www.jrspharma.com/pharma_en/products/promo/lubritab-rbw.php

Key Words: Vitamin C, Direct Compression, Health Supplement

JRS Products: LUBRITAB® RBW, PROSOLV® SMCC 90, VIVASOL® CCS

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