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Short communication

Lubrication effect of three novel lubricants in comparison to some commonly used lubricants

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Introduction

Lubricants are important excipients used in manufacturing of tablets. The main function of a lubricant is to reduce the friction between the die wall and tablets during ejection. Secondary aims of lubricant use can be the prevention of sticking and the increase of bulk density. While their main function does not aim at a glidant-effect, some lubricants might also improve powder flow. Hydrophobic lubricants (e.g. Magnesium Stearate or Talc) are commonly used in concentrations between 0.25% and 5% w/w (Li&Wu, 2014). Identifying the ideal lubricant candidate and an appropriate concentration is a challenge due to the impact of the lubricants on the mechanical properties of tablets. Moreover, the lubrication efficiency is affected by the mixing time as well as the particle size grade, surface area and the morphology of the chosen lubricant. In this study, the performance of three novel lubricants, CompactCel LUB (pharma grade, food grade and a bio-vegan grade) was investigated in comparison to nine commonly used lubricant materials**.**

Materials and methods

All materials were used as provided by the manufacturers: Microcrystalline Cellulose MCC 200 (MCC), DC grade Anhydrous Dibasic Calcium Phosphate (DCPA), Croscarmellose Sodium (CCS), Sodium Carboxymethyl Cellulose (CMC), .Five types of Mg-Stearate (MgSt A - E), Calcium stearate (CaSt), Zinc stearate (ZnSt), Glyceryl behenate (GlyBe), Stearic acid (StAc), were used as delivered by the manufacturers. The novel lubricants were of the CompactCel® range of BIOGRUND. Two coconut milk based lubricants (here labeled as: CC FOOD, CC BIO-VEGAN) and a carrier based system containing medium chain triglycerides (CC PHARM). The compositions of tablet mixtures M1 and M2 are shown in Table.1

Table 1: Components of Tableting Mixture

Tablet Mixture	% Material				
	MCC	DCPA	CCS	CMC	MgSt
M1	63	28	2,0	7,0	-
M2	20	77,9	2,0	-	0,1

The components were blended for 10 min. in 10 l drum blender at batch sizes of 5 kg. Pre-lubrication was required for M2 by admixing 0,1 % of Mg-St A for 30 min after mixing the other components as mentioned above. All mixtures were designed to yield moderate to high ejection forces as shown in Figure1. Lubrication was achieved by admixing the lubricants in a Turbula Blender for 3 minutes. For the evaluation of mixing time effects on the tensile strength of lubricants the blending times were prolonged to 9 and 15 minutes. Lubricant concentrations were as follows: MgSt A-E, GlyBe, StAc, CaSt 1% for all mixtures. CC FOOD: in M1=2,5 %, in M2=3% , CC BIO-VEGAN: M1+M2=3% ; CC PHARM: M1=2,5 % , M2=3%

Mixtures were compressed on a RoTab T rotary press using flat-faced 11.28-mm punches. Compaction forces fixed for each mixture individually (M1=10 kN; M2=12, 5 kN; M3=15 kN). Breaking force values were converted to the corresponding tensile strengths (TS) and the lubricant sensitive ratio was calculated using equation 1 where σu is the TS of the unlubricated tablet and σl that of the lubricated compact.

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$$LSR = \frac{\sigma u - \sigma l}{\sigma u} * 100\% \qquad \text{(Equation 1)}$$

Tablet tooling was cleaned and polished after each experimental run and the ejection forces were measured at all times.

Results and discussion

Lubricant sensitivity ratio did not vary significantly after compression at different compaction forces. However, ejection forces mostly increased with increasing force (data not shown here). For all lubricants, the ejection forces were reduced sufficiently to enable a smooth production process of defectless tablets. Mixture 1 contains more plastically deforming MCC and therefore shows lower ejection forces than Mixture 2 that contains brittle and more abrasive DCPA.

	LSR [%]		Ejection Force [N]	
	M1	M2	M1	M2
unlub. Mixture			665	1640
Mg-St-A	33	-5	150	357
Mg-St-B	35	-19	90	348
Mg-St-C	11	-11	38	308
Mg-St-D	41	-17	80	334
Mg-St-E	19	-26	26	303
CaSt	30	-4	119	319
Zn St	19	-10	112	311
GlyBe	-6	-8	111	376
StAc	11	1	175	443
CC FOOD	12	-10	118	451
CC Bio Vegan	13	-31	159	757
CC Pharm.	41	-8	140	400

Fig. 1: Result-Matrix for the lubricant sensitivity ratio and the ejection force of tablet formulations

Figure 1 shows the result matrix for the ejection forces and the lubricant sensitivity ratio. The colour scheme identifies maximum and minimum values in each column. A significant decrease in tensile strength can be observed for all formulations with M1. Especially the use of the commonly used lubricants leads to a loss in tensile strength. Contrary to that, the novel food-grade lubricants of the CompactCel range only bring about minor losses.

Figure 2 shows examples for the dependency among tablet tensile strength and mixing time. The graph outlines that use of stearate type lubricants results in loss of tensile strength at extended mixing times

For mixture M2 the lubricants caused an increase of the tensile strength. This phenomenon has been reported in the literature (Bolhuis, 1995), is not that common and is most likely correlated to the deformation behaviour of the tableting excipients used for that formulation.

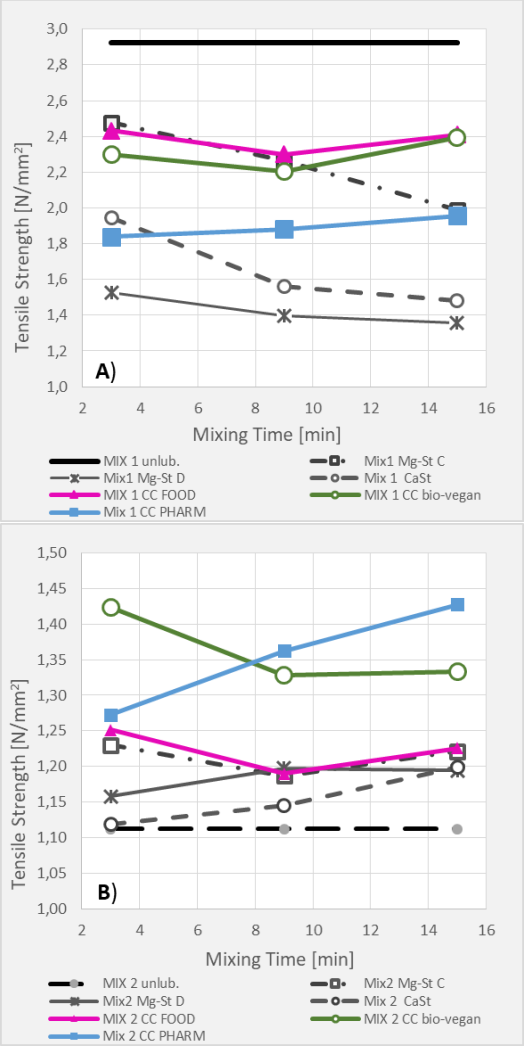

Fig. 2: Examples of tensile strengths of unlubricated and lubricated tablet formulations with mixtures M1 (A) + M2 (B) in correlation to the lubricant mixing time

Conclusion

Choosing the ideal lubricant candidate, its optimal concentration and an appropriate blending time is a challenging task. It is often not regarded that many tableting formulations are prone to over-lubrication at extended mixing times. The novel CompactCel lubricants provide good lubrication properties while their performance does not suffer from mixing time effects.

References

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