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Enhancing Flow Properties and Preventing Sticking and Picking in Tablet Formulations: Exploring the Efficacy of StarTab[®] as a Multifunctional Additive

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SUMMARY

This study investigates the flow and compression behaviour of four excipients (StarTab[®], MCC, Mannitol, Lactose) when combined with caffeine as a model drug for direct compression. Notably, pure caffeine particles demonstrate high adhesion to punch and die walls. However, the incorporation of StarTab[®] led to improved flow of the pre-blend, along with reductions in detachment stress (DS) and ejection stress (ES) during tableting. Contrarily, blending caffeine with MCC, Mannitol, and Lactose did not result in considerable improvements in flow properties and also did not address sticking and picking issues. The potential of StarTab[®] in enhancing flow properties and addressing sticking issues in pharmaceutical applications is highlighted. These findings contribute to optimizing formulations for efficient tablet production.

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INTRODUCTION

The tablet formulation plays a crucial role in the pharmaceutical industry, where attaining ideal flow properties, tablet compressibility, and preventing defects like sticking and picking in tableting are paramount. Tablet defects can lead to manufacturing difficulties, compromised product quality, and reduced process efficiency. To address these challenges, pharmaceutical companies utilize various excipients, and one particularly noteworthy group is starches. Starches are derived from natural sources like corn, potato, pea or rice, and they possess unique properties that make them highly promising for enhancing flow properties, tablet compressibility, and providing an anti-sticking effect (Chattoraj, S et al. 2018; Builders, P. F et al. 2016). In this study, the application of directly compressible starch (StarTab[®]) as a multifunctional excipient to improve flow, tablet compressibility, and prevent sticking and picking

issues to the punches in the tableting process is demonstrated.

MATERIALS AND METHODS

Caffeine was sourced from Stabilimento Testa Ltd, while StarTab[®] was supplied by Colorcon Ltd. Mannitol was obtained from Roquette, and microcrystalline cellulose (MCC) was provided by IMCD Ltd. Lactose monohydrate was procured from Kerry Group, and magnesium stearate was obtained from Peter Greven. The blends for direct compression were prepared by mixing the ingredients in a Turbula blender for 10 minutes, followed by lubrication with 0.5%w/w magnesium stearate before compaction. To assess the flow properties of the formulation blends, flow analyses were conducted using a GranuDrum[™]. Subsequently, these blends were compressed using 6 mm flat-faced dies at compaction pressures ranging from 350 kg to 950 kg force, utilizing a Gamlen[™] press.

RESULTS AND DISCUSSION

Four tablet formulations were prepared as shown in Table 1 using standard blending and tableting procedures. Formula 1 consisted of a blend of caffeine and StarTab®, a directly compressed starch aimed at improving flow and reducing sticking during tableting. Conversely, formulas 2 to 4 utilized mannitol, lactose, and MCC as the main fillers. All blends were prepared with 25% w/w caffeine loading, allowing for a direct comparison among the fillers.

Table 1. Formulation compositions %w/w

Ingredients	Formula 1	Formula 2	Formula 3	Formula 4
Caffeine	25.0	25.0	25.0	25.0
StarTab®	74.5	0.0	0.0	0.0
Mannitol	0.0	74.5	0.0	0.0
Lactose	0.0	0.0	74.5	0.0
MCC	0.0	0.0	0.0	74.5
Magnesium Stearate	0.5	0.5	0.5	0.5

The average particle size of the caffeine was less than 50 µm, which resulted in poor flow characteristics and cohesiveness.

Cohesive index and flow angle of the caffeine, excipients and four formulations are presented in Table 2. The formula based on StarTab® showed the lowest cohesive index and flow angle, indicating excellent powder flow.

Table 2. Flow behaviour of caffeine, excipients, and formulations

Ingredients	Cohesion index	Flow angle	Flow behaviour
Caffeine	47.35	67.18	Poor
MCC	18.96	50.18	Good
Mannitol	33.12	73.52	Poor
Lactose	6.91	41.72	Excellent
StarTab®	9.51	40.70	Excellent
Formulation 1	23.50	47.55	Excellent
Formulation 2	48.74	57.09	Poor
Formulation 3	36.66	57.29	Passable
Formulation 4	35.78	57.42	Passable

Figure 1 and 2 displays the relationship between detachment (DS) and ejection stress (ES) as a function of compaction pressure. To prevent sticking and picking issues in tableting, it is desirable to have ES and DS values below 1 MPa for an ideal tablet formulation. Notably, only Formula 1, which is based on StarTab®, exhibited low (<1 MPa) DS and ES values, indicating the effectiveness of StarTab® in preventing

sticking and picking in tableting. Interestingly, MCC also demonstrated a DS value of <1 MPa, however ES value exceeded 1 MPa.

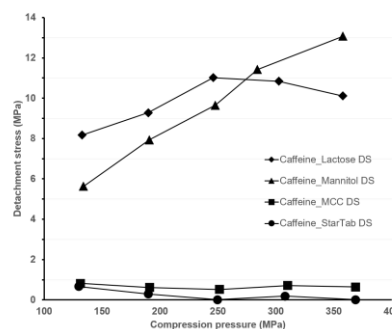


Figure 1. Detachment stress (DS) of caffeine blends

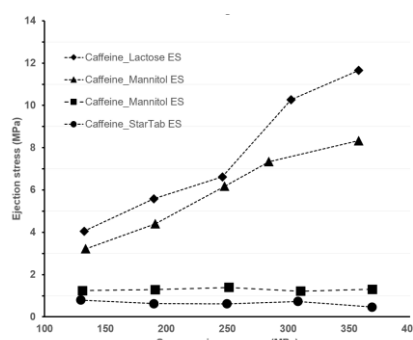


Figure 2. Ejection stress (ES) profile of caffeine blends

CONCLUSIONS

In conclusion, this study highlights the critical influence of the API's morphology and flow behavior on formulation compression and manufacturability. Incorporating StarTab® in poorly flowing formulations enhances flow properties and mitigates tablet sticking issues during direct compression. These findings contribute valuable insights for optimizing tablet formulations and improving pharmaceutical production efficiency. StarTab® shows promise as a versatile excipient to enhance manufacturability and overall formulation performance, paving the way for more effective and reliable medicines.

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