EFFECTS OF LUBRICANTS ON DIRECT COMPRESSION PARAMETERS

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INTRODUCTION

By the invention of instrumented tablet press (1) the factors which affect tablet properties has been evaluated. The type and concentration of the excipients play big role in the physico-mechanical properties of tablets. One class of functional excipients that is essential in the most tablet formulation is ‘lubricants’. Hexagonal boron nitride (HBN) is an interesting compound with the potential of being used as a tablet lubricant to be incorporated into tablet formulations (2). In our previous studies (2,3) we reported that magnesium stearate (MGST) and a newly introduced lubricant HBN provided the smallest lower punch ejection forces (LPEF) during tableting for wet granulation and direct compression process. In this study binary direct compression mixture of spray dried lactose and microcrystalline cellulose was used to explore the performance of lubricant type and concentration on instrumented tablet press with different parameter ‘lubricant effectiveness’.

MATERIALS AND METHODS

Materials

Microcrystalline cellulose (Avicel pH102) was donated by FMC, Brussels, Belgium. Spray dried lactose (Tabletose 80), Magnesium stearate pure (MGST), Hexagonal boron nitride nanopowder (HBN) (Average particle size 70nm) were purchased from Meggle AG, Wasserburg, Germany, Sigma-Aldrich, St. Louis, USA, Lower Friction, Mississauga, Ontario, Canada, respectively. Compritol (COMP) was donated from Gattefose, Cedex, France. Stearic acid (STAC) and Polyethylene glycol (PEG) were gifts from Deva Research and Development Center (Turkey). Micro Talc was purchased from Mondo Minerals, Amsterdam, Netherlands.

Powder mixtures

A 1:1 mixture of spray dried lactose and microcrystalline cellulose were mixed for 20 min in a laboratory size V-blender. All lubricants were added to these binary mixtures depending on their studied concentrations and mixed further for 3 min.

Tablet Preparation

For lubricant performance, 20 batches of tablets were manufactured using a single-station instrumented tablet press (Korsch EKO, Berlin, Germany) with a 9mm flat faced punch set. Study design is Spray dried lactose/Microcrystalline cellulose 1:1 mixture with one lubricant for a batch with the lubricant concentrations %1, 2, 4 plus %0.5 for MGST and HBN. The target tablet weight is 250 mg. The upper punch compression level which is responsible for tablet hardness and the lower punch diving level which is responsible for tablet weight are kept constant.

Lubricant effectiveness

The quotient of compression force and lower punch ejection force (kN/N) is calculated as a parameter of lubricant effectiveness. A high value indicates good lubrication. The Lubricant effectiveness values from each batch were calculated for mean value of compression force and low punch ejection force (4).

Instrumentation of tablet press

A single-station tablet press was instrumented for monitoring upper and lower punch forces. Compression and ejection forces were monitored, recorded and determined quantitatively during tablet manufacturing.

Figure 1. Events during compression process (5).

(i) Consolidation time: time to reach maximum force. 
(ii) Dwell time: time at maximum force.
(iii) Contact time: time for compression and decompression excluding ejection time.
(iv) Ejection time: time during which ejection occurs.
(v) Residence time: time during which the formed compact is within the die.

RESULTS AND DISCUSSION

Figure 2 summarizes the results for lubricant effectiveness listed in table 2. The best effects were observed for MGST. The second effective lubricant is HBN also in low concentrations. The lubricants effectiveness values decreased in %1 concentration for STAC, COMP, TALC and PEG, respectively. PEG shows minimum value in %1 concentration. By increasing the lubricant concentration all the lubricants became more effective.

Figure 2. Concentration vs. Lubricant effectiveness graph of the lubricants

CONCLUSION

In general all tested lubricants in this study are effective. But their differences can be defined with lubricant effectiveness. With the change of the factors as compression force or tablet weight, lubricant effectiveness value indicates how effective a lubricant works. In this study MGST is found as most effective lubricant in all concentrations. HBN is an alternative for it.

ACKNOWLEDGMENTS

This research was supported by Scientific Research Project Unit of Marmara University (BAPKO; SAG-A-080410-0066)