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Influence of the Punch Head Design on the Physical Quality of Tablets Produced in a Rotary Press

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ABSTRACT

This study aims to investigate the influence of tablet punch head design on compaction and the resultant tablet mechanical properties. Tablets were prepared using flat-face punches with different head flat and head radius configurations, on a rotary tablet press with compression rolls of different diameters. The results showed that tablets produced using punches with head flats consistently displayed higher tensile strengths and lower capping tendencies. Exclusion of the head flat in the punch head geometry caused the compacts to undergo a state of continual deformation during the compaction cycle, possibly with increasing elasticity without the opportunity for more prolonged stress relaxation. Extension of head flat diameter produced small increments in dwell time and this could bring about significant improvements to the tablet mechanical quality. Changes to the punch head radius were found only to affect the compression profiles marginally, but this only produced insignificant differences in the tablet mechanical properties. A smaller compression roll allowed greater plastic flow during the dwell phase, but this was insufficient to effectively counteract the adverse effects due to increased strain rate during the consolidation phase, leading to deterioration of tablet mechanical quality.
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Introduction

The tablet dosage form is the most widely used drug delivery system, and thus, tableting remains an important unit operation in the pharmaceutical industry. Improvements to the process of tablet manufacture are always keenly sought, so as to ensure that good quality tablets are made. As compaction is a critical process that determines tablet physical and mechanical properties, densification of material confined in a die by axially applied forces supplied by punches during the compaction cycle is an important process. Tablet compression tooling design is one such factor that affects the compaction process significantly. Understanding the basic physics of tablet compression will provide the knowledge on how to produce good-quality tablets and trouble shoot or identify causative factors when problems occur.

Standardization of tablet compression tooling, adhering to the American tablet specifications manual and European standards, offers economic and procedural advantages such as interchangeability between tablet presses.[1] However, in some cases, minor modifications may be required to optimize tableting performance. New tooling technologies continue to be introduced with more innovative tool modifications in an effort to improve manufacturing efficiency of tablet press by increasing turret speed, product yield, and tooling lifespan, among others.

Tablet punches have undergone many changes to their design specifications over the years to improve the tablet compression process, product quality, and durability of the tooling. The punch heads are clearly one of the most reworked areas on the tablet tooling.[2] The head flat (HF) and head radius (HR) are design features of the punch head that can potentially be modified by tooling manufacturers to prolong tool life and improve compaction efficiency so as to enhance the physical properties of tablets. Punch HF refers to the flat portion of the punch head that makes contact with the compression roll and determines the dwell time for compression. HR refers to the radius of the curved surface on the top of the head that blends the middle section of the head to the HF. This radius makes initial contact with the compression roll and allows for a smoother transition of each moving punch head into the compression cycle. Modifications to the punch head configuration affect the compression parameters, such as dwell time, contact time, and compression profile, consequently affecting the tablet mechanical properties (Fig. 1). However, the information on the impact of such geometrical changes to the punch head on the compaction

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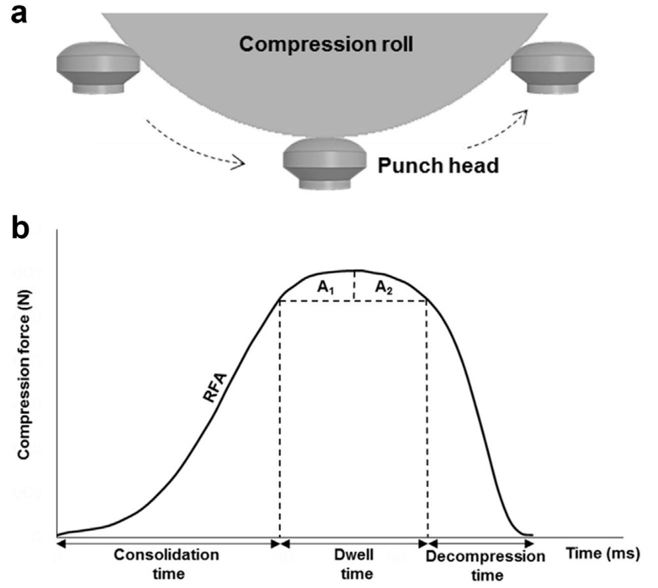

Figure 1. Schematic diagrams depicting the motion of punch head in relation with compression roll (a) and the graphical representation of compression profile with the associated compression parameters (b).

process and resultant tablet mechanical properties is not well documented. Reported studies largely focused on the effect of compression parameters on tablet properties. In most studies, the compression parameters were often modified by adjustments to the compression kinematics, such as tableting or turret speed, rather than via tooling geometrical modifications.[3-5] Furthermore, discrepancies in the results for tablet physicomechanical properties have been reported in the literature, mainly due to the large number of varied methods used for compaction studies, formulation-dependent outcomes and tableting conditions that were very often not representative of the actual factory manufacturing.[6-10] These limitations restrict the extrapolation of such data to predicting the effect of punch head geometrical modifications on compression parameters and the resultant tablet properties.

Apart from the punch head geometry, the size of the compression roll also affects tablet compaction.[11] The compression roll diameter controls the rate and duration of compression force application as the punches diametrically converge into the die (Fig. 1a). It has been reported that punches with standard specifications traveling around the turret that contact compression rolls of different size will lead to significantly different compression parameters. In view of this, the tableting performance of punches with different head designs could also significantly be affected by differences in the compression roll size.

The objective of this study was to investigate the influence of punch head designs on the rotary compression process and properties of tablets produced. The influence of compression roll was also studied. The findings will provide a more comprehensive understanding on the advantages and limitations of changing punch head geometry with respect to tablet properties and aid in making processing considerations for a successful tableting program. The findings could also facilitate the design of better compression tools.

Experimental

Materials

Lactose (Tablettose 80; Meggle Pharma, Wasserburg, Germany) granules for direct compression, paracetamol (Rhodadap Dense Powder; Rhodia Wuxi Pharmaceutical, Jiangsu, China), potato starch (Roquette, Lestram, France), and magnesium stearate (M125; Productos Metalest, Zaragoza, Spain) were used in the tablet formulation.

Preparation of Paracetamol Granules

Granules containing paracetamol and potato starch (77.9:22.1) were produced using a high shear processor (UltimaPro 10L; GEA Collette, Wommelgam, Belgium). A 15.2%, wt/wt starch paste was prepared by adding potato starch to water and the paste later used as the binder. Dry mixing of paracetamol powder and potato starch (19.9%, wt/wt) in the high shear processor was carried out for 2 min at an impeller speed of 450 rpm before starch paste addition and mixture wet massed for an additional 5 min with the impeller and chopper speeds set at 450 and 2800 rpm, respectively. The moistened granules produced were passed through a cone mill with square-hole screen of aperture size 6350 μm (Comil 197S; Idex-Quadro Engineering, Waterloo, Canada) and impeller speed of 1240 rpm. Granules were dried in a fluidized bed drier (Strea-1; GEA-Aeromatic, Bubendorf, Switzerland) with inlet air temperature of 45°C, and drying was terminated when product temperature reached 40°C. The dried granules were re-granulated through the cone mill with round-hole screen of aperture size 1143 μm and impeller speed 1350 rpm.

Compression Behavior of Tableting Feed Components

The compression behaviors of the paracetamol–starch and lactose granules were studied using the Heckel plot and stress relaxation test. A universal testing machine (Autograph AG-10KNE; Shimadzu, Kyoto, Japan) with a 10-mm diameter flat-faced punch was used for both tests. Compacts weighing 325 mg were formed at a compression speed of 10 mm/min. Compressed densities of the granules compacted at each specified compression pressure were calculated. The true density of the granules was determined using a helium pycnometer (Pentapycnometer; Quantachrome Instruments, Boynton Beach, FL). Porosity (ε) values of the compacts were calculated using Equation 1. The Heckel equation (Eq. 2) was used to characterize densification behavior of the granules.

$$\varepsilon = 1 - \frac{\text{Compressed density}}{\text{True density}} \quad (1)$$

$$\ln \frac{1}{\varepsilon} = kP + A \quad (2)$$

where k and A are constants. To determine the viscoelastic behavior of the granules, the stress relaxation test was carried out. Compacts were formed at the specified force levels, and the punch was paused at the position where it achieved the maximal stated force.[12,13] The reduction in force of the upper punch in relation with time due to relaxation of the compressed material was monitored for 500 ms.

Tablet Preparation

Lactose and paracetamol–starch granules were first well mixed and then with 1%, wt/wt magnesium stearate before tableting. Tablets were produced at compression forces ranging between 6 and 9 kN (pressures, 76.4-114.6 MPa), using a rotary tablet press (R190FT; GEA-Courtoy, Halle, Belgium) with 10-mm flat-face bevel-edge punches. Five different types of punches that could be classified into 2 main punch HF configurations—with and without an HF—were used for this study. The specifications of the punch head designs are given in Figure 2. The punches differed mainly in terms of their HF and radial head (RH) specifications. Three punches with

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