Characterizations of Tablets Manufactured by One-Step Dry Coating (OSDrC®) OptiDose™ Technology
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ABSTRACT SUMMARY
The QTFm tablets manufactured on the commercial scale One-Step Dry Coating (OSDrC®) OptiDose™ and Carver presses were characterized and compared. The dissolution profile of sustained release tablets produced manually by the Carver press was similar to those manufactured on the commercial scale press, suggesting that single-punched tablets can be utilized as predictive tools during developmental work.

INTRODUCTION
OSDrC® OptiDose™ drug delivery technology is an innovative new manufacturing technology that allows the production of rapid, commercial scale manufacturing of tablet in a tablet dosage forms. This rotary tableting machinery has 54 double punches and three feeders. Because the tablets are produced in a single step while the punches make one rotation on a turntable, there is no need for a separate stage to deliver the core. OSDrC® OptiDose™ technology is also versatile. In addition to the conventional round tablet in a tablet, various punch designs of this technology allow the manufacturing of more complicated dosage forms, such as a pulsatile drug delivery system¹, dividable core tablets², and encased beads/pellets system³.

Unlike conventional tablet presses, a smaller, development-size tablet press is not available for the OSDrC® OptiDose™ technology, partially due to the complex motion of the inner and outer punches that limits the minimum distance to be traveled. Single tablets can be manually manufactured using a customized punch and a hydraulic press (e.g., Carver Press). These tablets can be useful for generating prototypes and developmental studies. Therefore, the objectives of this study are: (a) to characterize the properties of tablets manufactured on the commercial scale and Carver presses, (b) to determine if a Carver press can be a viable tool for developmental work.

EXPERIMENTAL METHODS
OSDrC® OptiDose™ technology uses the double-punch configuration to accurately place cores within a tablet. The commercial scale tablets were manufactured on a tri-layer, one-step dry coating tablet press (Model PAVG, Kikusui Seisakusho Ltd.), also known as the OSDrC® OptiDose™ press, with 9-mm inner and 11-mm outer cores. The turret speed was set either at 5 or 10 rpm. The first two layers received a pre-compression force of 0.5 kN, and the final compression force was altered either at 10, 15, or 20 kN. The fill weights for each of the first, second, and third layers were 160 mg, 190 mg, and 210 mg, respectively. The single tablets were produced with a customized punch, with 8-mm inner and 10-mm outer cores, specifically designed for the Carver press. Using the same amount of pre-weighed blends, the first two layers were compressed lightly by hand. Subsequent to the addition of the third layer, the tablets were produced by applying a final compression force of 10, 15, or 20 kN.

In order to produce a prototype of a sustained release tablet, two blends of active pharmaceutical ingredient (API) QTFm, with different release profiles were prepared. The composition of the first and third layers was the same. The dissolution, disintegration, content uniformity, and physical attributes, such as weight, hardness, and thickness, were evaluated. Dissolution was performed under sink condition in USP I (basket) at 100 rpm in vessels containing 900 mL of 0.1N hydrochloric acid (37°C). At specific time points, 10 mL samples were withdrawn, filtered, and analyzed by UV Spectrophotometer.

RESULTS AND DISCUSSION
The dissolution profiles of QTFm tablets manufactured on the OSDrC® OptiDose™ press
at turret speed of 5 and 10 rpm are presented in Figure 1 and 2, respectively. At the lower turret speed of 5 rpm the increase in the compression force did not seem to alter the dissolution rate. However, at the higher turret speed of 10 rpm the applied compression force slightly affected the dissolution profile. As the compression force increased, the tablet hardness increases and the dissolution rate decreases.

Figure 1. The dissolution profiles of QTFm tablets manufactured on the OSDrC® OptiDose™ press at a constant turret speed of 5 rpm and various compression forces.

![Dissolution Profile of OSDrC® OptiDose™ Press Tablets](image)

Figure 2. The dissolution profiles of QTFm tablets manufactured on the OSDrC® OptiDose™ press at a constant turret speed of 10 rpm and various compression forces.

Figure 3. The dissolution profiles of QTFm tablets manufactured on the OSDrC® OptiDose™ and Carver presses at a constant compression force of 10 kN.

![Dissolution Profile of OSDrC® OptiDose™ versus Carver Press Tablets](image)

CONCLUSION

Sustained release QTFm OSDrC® OptiDose™ tablets were manufactured on commercial scale and Carver presses. For products that were manufactured on the commercial scale, the compression force did not alter the dissolution profile at turret speed of 5 rpm. When speed was increased to 10 rpm, the dissolution rate was decreased as the compression force increased. The dissolution profile of tablets produced with Carver press was similar to those manufactured on the commercial scale press at turret speed of 5 and 10 rpm.

REFERENCES