

OSDrC[®] OptiDose[™] : A Revolution in Drug Formulation Technology

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ABSTRACT

OSDrC[®] OptiDose[™] concept is an innovative first of its kind tablet-in-tablet manufacturing process. This technology opens the door to new world of pharmaceutical tablet manufacturing. The rotary tablet machine, with its variable double-punch configuration, supports single-step manufacturing of broad range of tablet options such as, controlled release, divided core, bi-layer and pulsatile release tablets. This technology allows accurate and flexible positioning of any number of cores and permits commercial-scale production of cored tablet without misaligned cores. This innovative technology can also replace conventional sugar and film-coated tablets. No doubt, it is a revolution in tableting technology.

Keywords: OSDrC, Variable double-punch, Solvent free coating, Divided core, Controlled release.

INTRODUCTION

Coatings are an essential part in the formulation of solid pharmaceutical dosage forms to achieve superior aesthetic quality (e.g., colour, texture, mouth feel, and taste masking), physical and chemical protection for the drugs in the dosage forms, and modification of drug release characteristics. Coating technique mostly used in pharmaceutical industry is film coating. Most film coats are applied as aqueous- or organic-based polymer solutions. But soon solvent free coating techniques had emerged as an alternative of film coating technology for solid pharmaceutical dosage forms for last two decades, in which coating materials are directly coated onto solid dosage forms without using any solvent and then cured by various methods to form a coat (1). It reduces the cost by eliminating the tedious and expensive processes of solvent disposal/treatment. Moreover, the technology can significantly reduce the processing time because there is no drying and evaporation step and thus can provide an alternative technology to coat temperature-sensitive drugs (2). Recently with the advancement of science and technology, a novel one-

step dry coated tablet manufacturing method (OSDrC-system) has been introduced. The OSDrC-system is capable of producing compression-coated tablets in one process without previous core tablet preparation. The common manufacturing problems for compression-coated tablets, such as central positioning of the core in the compression-coated tablets and misalignment of core in coat, could be overcome by this method.

OSDrC[®] is a registered trademark of Sanwa Kagaku Kenkyusho Co., Ltd, Japan. Precise OSDrC[®] positioning technology enables product development scientists to control the release of the API by altering the thickness of the outer coating. The ability to precisely position multiple cores allows the creation of tablet products with a variety of pulsatile drug release profiles (3).

OSDrC[®] technology also makes it possible to manufacture divided tablets with separate cores in a one-step operation, a feat not possible with current technology. For example, OSDrC[®] divided enteric coated tablets are among the world's first dividable enteric coated tablets. Because the core remains fully encased in the coating even when the tablet is divided, the intended release profile remains unaffected by dividing the tablet (4). OSDrC[®] technology can also produce cored tablets with extremely thin coats in a one-step process. OSDrC[®] tablets can therefore replace sugar- and film-coated tablets, substantially reducing manufacturing stages and production costs (3).

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OSDrC® tablets do not have to be round. The shape of the core, coating thickness, and tablet configuration can be varied simply by changing the punches. OSDrC® technology, which does not require a separate manufacturing process for the core, can even use powders with poor compressibility as the core matrix. As it is possible to directly encase core pharmaceutical powders with the outer coating, these powders can be used in oral rapid disintegration tablets (5). By using pellets in the core instead of powders, drugs that normally must be formulated as capsules can be produced as tablets. This technology will totally revamp current drug formulation design and manufacturing processes. Thus, the purpose of this article is to highlight in brief some important aspects of this technology.

One-Step Manufacture of Cored Tablets with Variable Double-Punch Technology

OSDrC® technology is an innovative new pharmaceutical manufacturing technology that produces precise tablets of nearly any shape using a variable double-punch configuration. This rotary tableting machine 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 longer any need for a separate stage to deliver the core. Because the core is held in place by the lower outer punch until immediately before the final compression, misalignment does not occur and tablets with uniform thickness of outer-layer is obtained, which was difficult to achieve with conventional dry-coated tablets (6,7). OptiDose™ is an innovative flexible core tableting technology that enables the formulation and manufacturing of single or multi-cored tablets with differentiated controlled release functionality and a range of unique dose forms including fixed dose combination tablets. The OSDrC® OptiDose™ (one step dry coating) tableting process simplifies manufacturing by forming the tablet and core in a solvent free, dry compression single process operation (8). The innovative variable double punch and independent cam movement provide the

flexibility to produce cores of various shapes, sizes and positions within a tablet. OSDrC® OptiDose™ is a fully developed technology and is commercially proven in Japan for cardiovascular and type II diabetes products. Catalent has exclusively partnered with Sanwa Kagaku Kenkyusho Co. Ltd., to bring this innovative technology to the global market.

Innovative Technology: How it Works?

The manufacturing method for OSDrC® OptiDose™ is different from conventional methods in that dry-coated tablets can be made with only one process. One of the major advantages of OSDrC® is that we can expect to produce dry coated tablets, which always contain the core tablet exactly in the center of the whole tablet. The schematic sequence of the OSDRC manufacturing method is shown in figure 3. This OSDRC manufacturing method is developed by a rotary type tableting machine using a single set of punches and die. Every upper and lower punch in the OSDRC system has a double structure as shown in Figure 1. Each punch consists of a center punch and an outer punch (6). The OSDrC-system employs three compression processes. The first compression forms lower outer layer (indicated as the first-outer layer), the second compression to builds up the first-outer layer/core complex and the third compression shapes the whole tablet, including both the upper-outer and side-outer layers (indicated as the second-outer layer).

In the first step to form the first-outer layer, the lower-center punch is slid down to fill up the space made by the lower-center punch with the powder for the first-outer layer (Polymer). Then, the powder is pre-compressed by the upper-center punch. While the upper-center punch is pushing down the pre-compressed first-outer layer to downward, the lower-center punch slid down at the same time. After pre-compression, the upper-center punch is pull up to create a space, which was to be filled up with the drug powder for the core. Drug powder is then subjected to pre-compression by the upper-center punch, this form complex of first outer layer with core powder. While

the upper-center punch is pre-compression, the lower-outer punch is sliding down, that create the space over the pre-compressed complex of the first-outer/core, and which is fill up with the remaining powder (Polymer) to build up the second-outer layer. At the last compression, the remaining powder is compress by the upper and lower punches with the pre-compressed complex. The final compression employs simultaneous movement of the center and outer punches at a fixed speed of 1mm/min under constant pressures. The tips of the center and outer punches are adjusted to create a flat face like a normal punch. The quantity of powder for the second-outer layer is adjusted to create the same thickness as that of the 1st-outer layer (9).

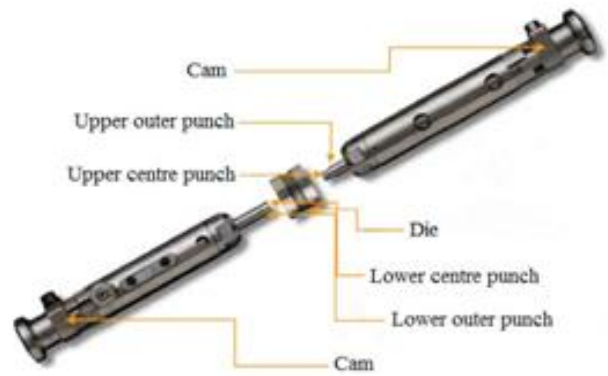


Figure 1: Variable double-punch configuration



Figure 2: OSDrC® OptiDose™ tablets

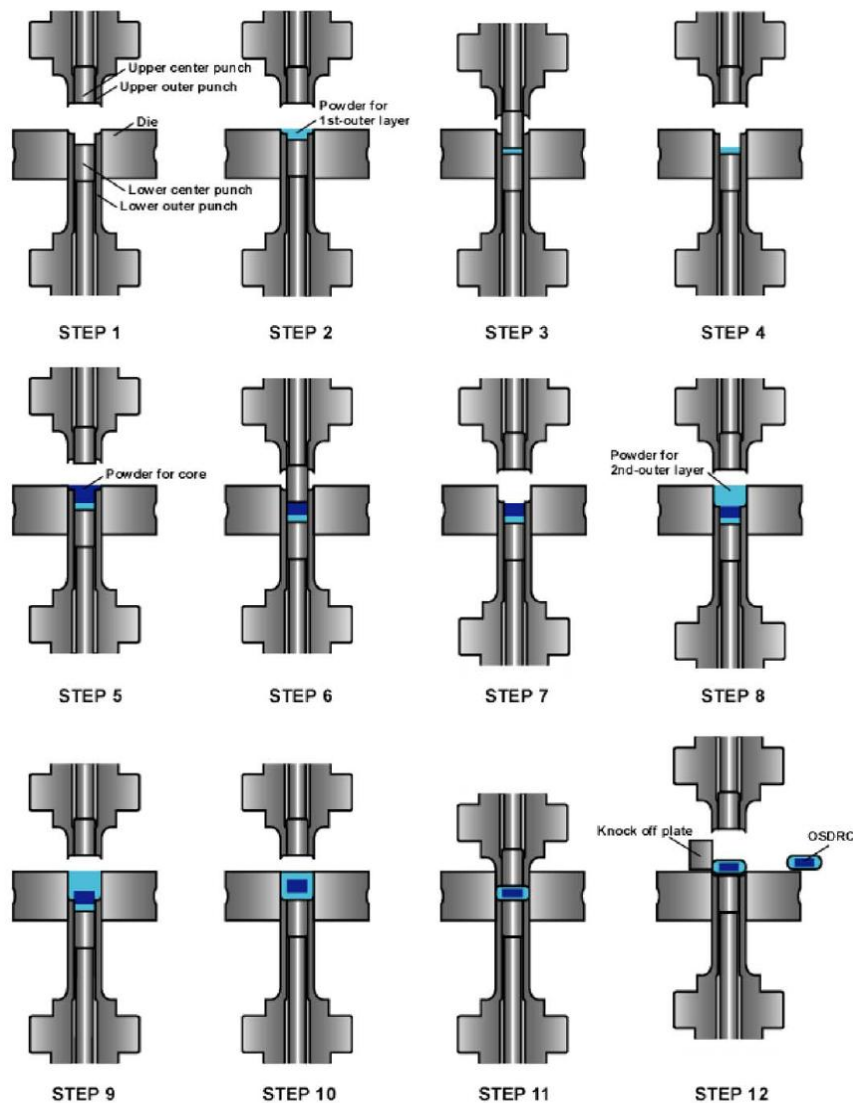


Figure 3: Steps of OSDrC manufacturing method

Technology Attributes

The patented, variable double punch configuration and cam function allow complex and independent movement of inner and outer, upper and lower punches. This enables formulation and manufacturing of tablets across the range of OptiDose combination and controlled release dosage forms. Different single or multi-core tablet configurations are produced by changing the punches of the rotary tablet machine.

- **Punches can be customized to meet desired tablet configurations**

Enabling flexibility in core shapes, sizes, and positioning of up to 3 active cores within a tablet.

- **Tablets and Cores are produced in a single, solvent-free one step dry coating process operation**

Simplified manufacturing by eliminating the need for a separate unit operation to produce the core, and the need for solvent handling.

- **Independently moving variable double punch design facilitates the manufacture of precision quality tablets**

- **Superb weight control of layer quantities**

The tablets and cores are produced in a single stage while the punches make one rotation on the turntable, producing precise coatings of nearly any thickness and tablet shape utilizing the innovative cam movement design and variable double punch configuration.

- **Highly accurate core alignment**

Cores are held in place by the lower outer punch until immediately before the final compression, ensuring core alignment.

- **Minimized cross interaction between API core layers and/or coating excipients**

The tablet construct reduces surface area contact compared to conventional bilayer tablets, thereby increasing stability for non-compatible API's for combination tablet formulations.

- **Controlled release**

OSDrC® OptiDose™ makes it possible to control API release by altering the thickness of the outer layer. Capability to precisely position multiple cores allows the manufacturing of tablet product with variety of pulsatile drug delivery profiles.

- **Divided core**

OSDrC® technology also makes it possible to manufacture divided tablets with separate cores in a one-step operation, a feat not possible with current technology. Because the core remains fully encased in the coating even when the tablet is divided, the intended release profile remains unaffected by dividing the tablet.

- **Pellet core**

By using pellets in the core instead of powders, drugs that normally must be formulated as capsules can be produced as tablets.

- **Variable core**

The shape of the core, coating thickness, and tablet configuration can be varied simply by changing the punches. Up to three discrete cores in an individual tablet can be placed.

- **Cored tablets with poorly compressible cores**

By using this technology there is no need of separate manufacturing of core tablet even using of powders with poor compressibility as the core matrix. As it is possible to directly encase core pharmaceutical ingredients with the outer covering, these ingredients can be used in oral rapid disintegration tablets.

CONCLUSION

The terms "unique", "high-quality", "reasonable" and "innovative" are the keywords of this technology. The common manufacturing problems for compression-coated tablets, such as central positioning of the core in the compression-coated tablets and absence of core in coat, could be overcome by applying one-step dry coated tablet (OSDrC) method. OSDrC-technology employs a double punch action that enables dry-

Delivery Capabilities of OSDrC® OptiDose™

coated tablets to be assembled in a single run. This makes possible a completely new type of formulation process and new types of pharmaceutical products never before seen. No doubt, it is a revolution in tableting technology.

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