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Review Article

OSDrC®: A Revolution in Drug Formulation Technology

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Abstract

Conventional dry-coating method can cause problems like non-core, double-core, off-center, inlay, and cooking, caused by the core tablet supply system. Hence, dry coating is not as widely used as normal tablets. One-step dry-coating (OSDrC) technology is an innovative one to solve these problems. OSDrC technology, which does not require a separate manufacturing process for the core, can even use powders with poor compressibility as the core matrix. This system can be assembled onto the turn table of a rotary tableting machine, and can make a dry-coated tablet in a single turn. This manufacturing method does not require the preparation of the core tablets beforehand, allowing the dry-coating to be made in one process. Compared with the controlled release tablet using membrane by the conventional film coating tablets, OSDrC which can be made by OSDrC-system are useful in the simple manufacturing method, the low manufacturing cost and the easy process management. In general, OSDrC could be a platform for full-range of controlled release tablets. Under this scenario, an understanding of this novel technology could be beneficial for the readers. This mini-review aims to highlight the benefits and mechanism of operation of OSDrC systems.

Keywords: OSDrC technology, dry-coated tablets, pellets, layered tablets, core tablets

1.Introduction

The preparation of dry-coated tablets by conventional methods requires the following steps: (i) the powder for the outer layer fills the inside of the die, (ii) the core tablet is placed on the powder from Step 1, (iii) the remaining powder for the outer layer surrounds the core tablet, and (iv) the powder containing the core tablet is compressed. This method necessitates the compression of core tablets in advance, thus increasing manufacturing cost of the tablets. Further, this method can cause problems like non-core, double-core, off-center, inlay, and cooking, caused by the core tablet supply system. Hence, dry coating is not as widely used as normal tablets. To solve the problems associated with conventional dry coating methods, a novel one-step dry-coating (OSDrC) technology has been developed [1] and has brought revolution in tablet manufacturing. Basically, OSDrC® is a registered trademark of Sanwa Kagaku Kenkyusho Co., Ltd., Japan. This technology enables product development scientists to control the release of drugs by altering 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.

Dry-coated tablets consist of a core and an outer layer. The outer layer completely surrounds the core tablet and, therefore, the selection of the materials for the outer layer greatly influences the release pattern, since it depends on the release rate of the drug and the physical properties of the dry-coated tablets. It is practically difficult to produce the dry-coated tablets with side outer layer of 1.5mm or less thickness by the conventional manufacturing method being so far used. The manufacturing method of OSDrC, however, can make it possible to produce [2]. Cellulose derivatives such as hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose (HPMC), carboxymethylcellulose (CMC) or hydroxyethylcellulose (HEC) are frequently used as outer layer materials because they have water soluble, gel forming and swelling characteristics for delayed drug release pattern tablets [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 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. 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.

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. By using pellets in the core instead of powders, drugs that normally must be formulated as capsules can be produced as tablets [4].

This technology will totally revamp current drug formulation design and manufacturing processes. The purpose of this review is to shed light on some important aspects of this technology.

2. Benefits of OSDrC Technology

a) **Better Treatments:** OptiDose enables our pharmaceutical and OTC partners to formulate, development, manufacture, and ultimately bring better treatments to market.

b) **Better drug efficacy and safety:** Optimized pharmacokinetic and pharmacodynamic profiles to deliver more drugs when it's needed targeted drug delivery to deliver more drugs where it's needed.

c) Improved disease management: Better compliance/reduced pill burden and enhanced patient convenience

d) **Enhanced product branding and differentiation:** Tablets with a unique look and feel; OTC or Private Label product orientation; Potential anti-counterfeit protection

e)**Advanced controlled release formulations:** Full range of controlled release formulations (pulsatile release, enteric coating for targeted delivery, delayed release, extended release (XR, SR); multi-release profiles: immediate/extended/enteric/ delayed);

f) **Fixed dose combination formulations:** combination release profiles for up to three active ingredients in a single tablet

g) **Tablets and Cores are produced in a single, solvent-free one step dry coating process operation:** Simplifying manufacturing by eliminating the need for a separate unit operation to produce the core, and the need for solvent handling

h) **Precision quality tablets:** Independently moving variable double punch design facilitates the manufacture of precision quality tablet

i) **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.

j) **Highly accurate core alignment:** Cores are held in place by the lower outer punch until immediately before the final compression, ensuring core alignment.

k) **Mimimized cross interaction between API core layers and/or coating excipients:** The tablet construct reduces surface area contact vs. conventional bi-layer tablets, increasing stability for non-compatible actives for combination tablet formulations.

OSDrC makes it possible to form tablets from ingredients with which it is usually difficult to do so by conventional tabletting methods due to their poor tabletability. Formulators add diluents, including binders, or improve the drug properties by granulation to make a tablet of a drug with low tabletability. This is also the case for a conventional dry-coated tablet with a low tabletability drug in its core. The addition of diluents, however, causes a decrease in the drug content of a tablet. Granulation makes the manufacturing process complicated and increases manufacturing costs. As described above, OSDrC are new dry-coated tablets which can be applied to drugs with low tabletability, as well as to drugs with high tabletability without a time-consuming optimization process [5].

3. Innovative Forms of OSDrC

OSDrC single and multi-core tablets pave the way for new options in tablet formulations.

a) Flexible single or multi-cored tablets: Up to 3 discrete cores in an individual tablet; Flexible core shapes, sizes, and positioning within tablets [6].

b) Dividable tablets with discrete cores: Address FDA 2013 new guidelines for dividable tablets; IR, CR and enteric coated

c)Loosely or Poorly Compressible Encased: Alternative to encapsulation

d) Precision thin layer coating: Alternative to sugar coating

e) Wide variety of tablet shapes and sizes: Round or Oblong; With debossing capabilities

4. Mechanism of OSDrC Technology

The new manufacturing method for DC was executed with the use of upper and lower punches, which had a double structure, a center punch, and an outer punch surrounding the center punch. The OSDrC process consists of three compressions to make the lower-outer layer (indicated as first-outer layer), the core, and the whole tablet, including the upper-outer and side-outer layers (indicated as second-outer layer) [5].

At first, the powder for the first-outer layer fills a space, which is made by the lower-center punch and lower-outer punch, and is pre-compressed by the upper-center punch. Then, while the upper-center punch pushes the pre-compressed first-outer layer, the lower-center punch is slid down. The upper-center punch is then pulled away to make a space, which is filled with the powder for the core. This is then pre-compressed by the upper-center punch. Finally, the lower-outer punch is slid downward and the powder for the second-outer layer fills and surrounds the pre-compressed core/first-outer layer completely. The core/first-outer layer and the second-outer layer complex are then compressed by the upper and lower punches, in which the center punches are unified with the outer punches, respectively. The Mechanism of OSDRC manufacturing method is described in Fig. 1.

At the last compression, the remaining powder was compressed by the upper and lower punches with the pre-compressed complex. The final

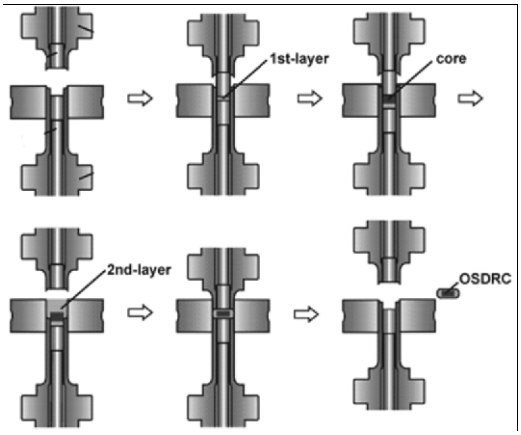

Fig. 1: Sequences of OSDrC system for the manufacturing of tablets [5]

compression employed simultaneous movement of the center and outer punches at a fixed speed of 1 mm/min under pressure (50-200 MPa). The tips of the center and outer punches were adjusted to create a flat face like a normal punch. The quantity of powder for the second-outer layer was adjusted to create the same thickness as that of the first-outer layer. Further, the thickness of both the top and bottom outer layers is tuned to make then about one and a half times as thick as the side outer layer to minimize the effects of drug release from the top and bottom outer layers [5].

This manufacturing method does not require the preparation of the core tablets beforehand, allowing the dry-coating (DC) to be made in one process. Furthermore, this method causes no problems with the core, which are observed for conventional DC; namely, we can produce DC as easily as normal tablets. Different single or multi-core tablet configurations are produced by changing the punches of the rotary tablet machine. The upper and lower punches consisted of the center punches (diameter: 6 mm) and the outer punches (outside diameter: 8 mm) surrounding the center punches.

5.Conclusion

The terms 'unique', 'high-quality', 'reasonable' and 'innovative' are the keywords of this technology. OSDrC technology employs a double punch action that enables dry-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.

Conflicts of interest

The author reports no conflict of interest.

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