Benefits of multilayer and core tableting

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This article provides a brief summary of the advantages of multilayer and core tableting techniques compared to traditional, single-layer tableting.

Currently, about two-thirds of all prescription drug products are solid dosage forms. Many of these products provide a combination of immediate and extended or delayed release of one or more active pharmaceutical ingredients (APIs). With the increased production of high-potency formulations and specialized solid dose applications in recent years, pharmaceutical companies are increasingly turning to innovative oral drug delivery systems such as multilayer and core tableting technologies.

Multilayer tablets consist of one or more active matrix layers and one or more layers that act as barriers and regulate API release. Core tableting (also called tablet-in-tablet) technology consists of a premade, inner core tablet compressed within a surrounding granulation layer.

Traditional core tableting used a pick-and-place, or vacuum type, method for placing the core tablets into the tablet press die cavity, but this was very unreliable and
often produced finished tablets with misaligned or missing core tablets. Newer core-tableting technology uses a punch-driven, core transfer chain, which is synchronized with the rotation of the tablet press turret to precisely position the inner core tablets in the center of the die cavity every time. The process also uses optical vision technology, in which a camera detects the inner-core tablets for positioning during production. These new developments allow the core to be positioned precisely at the top, bottom, side, or center of the tablet so formulators can more accurately anticipate the dissolution rate of the core coating and the API release.

Multilayer and core tableting technologies can provide drug product manufacturers with multiple formulation, manufacturing, therapeutic, and marketing advantages.

**Formulation advantages**

Perhaps the most prominent advantage of a multilayer and core tableting versus conventional single-layer tableting is that it allows for multiple incompatible APIs within a single tablet. Each API is compressed into a separate matrix separated by an inert barrier layer. This prevents problems such as instability that can occur when the APIs are compressed into a single matrix.

Multilayer and core tableting both work well with extended and delayed API release. Many new formulations require API release into the lower stomach. Multilayer or core tableting can provide a dependable, accurate, delayed-release delivery mechanism for such products.

Multilayer tablets can also contain two or more layers of the same API, with each layer having a different release profile. An extended-release product works by controlling the hydration or swelling rate of the core, which slows down the tablet’s dissolution in a patient’s body. When the tablet enters a patient’s stomach, it swells and increases in volume, causing it to remain in the stomach and release the API over a longer period of time.

**Manufacturing advantages**

Multilayer and core tableting can provide substantial operational and capital cost savings by reducing concurrent manufacturing activities. Because a formulation can include two APIs in a single tablet, only one manufacturing process is required rather than two.

**Therapeutic advantages**

Multilayer and core tablet products can reduce or eliminate the need for patients to take multiple tablets at one time or over time. This is ideal for elderly patients who may have difficulty remembering to take prescribed tablets throughout the day. Also, multilayer and core tableting allow you to create specialty drug products that combine treatments for multiple conditions into a single-dosage form. For example, the proprietary polypill is a multilayer tablet that contains a combination of medications to treat both heart disease and high blood pressure. These types of products can be very beneficial to patients and open up additional opportunities for manufacturers.

**Marketing advantages**

Multilayer tablets offer a unique product appearance, allowing manufacturers to design tablets with a distinct appearance for marketing to consumers or create a new look for an existing product. Manufacturers can also extend product patents by creating combinations or new forms of previously marketed products. By allowing for a multitude of API-matrix combinations, multilayer and core tableting technologies provide manufacturers with a broad range of cost-effective product possibilities that are also convenient and therapeutically beneficial for patients.

**Outsourcing**

In developing drug products that use multilayer and core tableting, you should employ an end-to-end planning approach that can examine a broad spectrum of value-added services and manufacturing capabilities. Such an approach takes a method or service from development through manufacturing, delivering a complete functional solution. Such solutions allow the incorporation of a broad spectrum of value-added services and product development and manufacturing capabilities that small to mid-sized pharmaceutical companies may not have in-house. They also allow the use of comprehensive strategies.

For example, a CMO or CDMO that offers an end-to-end approach will have the ability to work with a company during the initial product development stage, involving clinical trials, and also have the ability to take the drug product through to manufacturing.

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