

MEDELPHARM

EXTENDED RELEASE FORMULATIONS:
HAVE YOU EVER THOUGHT OF USING MULTI-LAYER
TABLETS OR TAB-IN-TAB?

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01 / What are the different strategies to formulate a modified release tablet?

Many options exist depending on the nature of the Active Pharmaceutical Ingredient (API) and the required release profile: Hydrophilic or lipophilic matrices, osmotic pumps, coated tablets or pellets with pH-sensitive polymers to just name a few.

However, even with only one API, it is still possible to make two different formulations and locate them in two different layers of a tablet. One layer can be immediate release, whereby the second one being an extended release formulation. Delivery systems like Geomatrix™ from the company

Skyepharm (Vectura Group) are based on a 3-layer tablet; here the API is located in the centre layer with a swellable formulation whereby the 2 outer layers are only excipients controlling the surface area and therefore the release rate of drug.

As for other formulation alternatives, Medelpharm offers expertise with a wide experience to accompany your formulation specialists and guide you in making your most challenging formulation and daring ideas a success.

02 / But are you capable of achieving a pulse drug release with multi-layers?

Pulse is generally performed by using the so-called dry coating process, also known as compression-/press-coating or tab-in-tab. The compression process is quite old: The first tablet press patent dates from 1897!

A tablet, named "core" in that case, is positioned onto a powder bed, compressed, then refilled with powder and compressed again to create the shell around the core. Recently new technologies have emerged to position the core

accurately and ensure that it's right in the middle of the outer shell or where your formulation requires it to be.

Rotary press manufacturer Romaco-Kilian even has a tablet press with an output above 110,000 tablet/hour, a real achievement when you consider that it's similar to a 3-layer process.

To ensure a robust process, the STYL'One can produce prototype batches with a "perfectly centered core" as well as batches with an "off center core(s)" to test the impact of accurate positioning in the 3 dimensions XYZ.

03 / Does investigation of all these formulations require a lot of different equipment?

No. That is where the usage of the all-in-one STYL'One Tableting Instrument comes into play. Using the same platform, you can develop single layer tablets, but also bi-layers, tri-layers and tab-in-tab.

Above 3-layer is still possible at the R&D level, however, you will have to find a supplier for a commercial-scale rotary press of which there are not so many.

The flexibility and multipurpose nature of the STYL'One puts no limit to your imagination.

It can clearly be illustrated by the capacity to compress the same tablet three times mimicking what is now realized in same commercial rotary presses for effervescent or other complex formulation.

The same ability to compress 1000 times without ejection can be used for sticking studies while the ability to compress and hold is used in some cosmetic formulations.

04 / Can STYL'One consequently be considered as a Drug Delivery System?

STYL'One is simply a tool. The Swiss army knife for pills if I may casually call it that.

Formulation scientists shall focus on their primary job which is formulation and process development. We believe that a scientist should not be mechanical specialist to operate complex machinery. STYL'One does

not require dedicated personal.

Once trained, it is as simple as riding a bike, previously mastered, you do it by intuition.

Formulators can let their imagination go to create innovative Drug Delivery Systems for new drug applications or to prolong a patent with an extended release form.

05 / What are the benefits of an R&D instrument?

STYL'One is a single-punch tableting instrument allowing the use of very small amount of API.

For tab-in-tab, the press comes with automatic core positioning device. Such instrument makes it easy to evaluate all process parameters and their influence on quality attributes. For example the sensitivity of drug release to core centring, or to total compression force destroying core coating inside the tablet as well

as sensitivity to compression for dissolution can be tested easily.

For bi-layer tablets, the effect of tamping force on the layer adhesion can be assessed in a simple manner. All these tests can be done with a minimal amount of API and very short time which is not easily feasible on other equipment.

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