Think tank

vitex

Formulation design - Tablets

All formulas have a limit as to how fast they can be compressed. It is important to remember that formulas are designed to be suitable for the equipment to which they will be manufactured in. Even the best equipment cannot overcome this limitation.

Critical attributes of the final blend:

- Good flow
- Good compressibility
- Acceptable moisture content
- Uniform particle size
- Properly eject after compression

Critical attributes of the tablet:

- Appropriate hardness
- Disintegration <30 min
- Consistent weight
- Consistent thickness
- Friability <1 %

As well as:

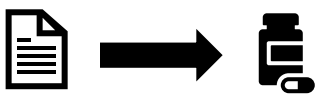
- Consistency in colour and taste if applicable

Author:
Innovation
Department

April 2019
Vitex Pharmaceuticals Pty Ltd
www.vitexpharma.com

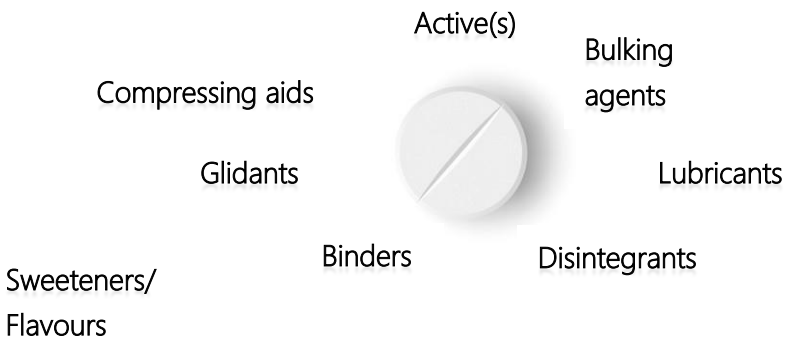
The health and wellbeing industry continues to show immense growth, with research showing that in Australia, 7 out of 10 people use complementary medicines as a preferred option for addressing health issues and preventive care. With competition being stronger than ever, brands are under constant pressure from consumers to produce novel products with new and improved formulas. While this ensures brands offer the best possible product to consumers, this often leads to formulas containing too much active ingredient (AI) than what is at times, possible to manufacture. It is easy to forget that just as important are the excipients that make up the tablet and the processing methods employed by contract manufacturers to ensure a quality product that is stable for the duration of the assigned shelf life.

So, what should be considered for a formula to be successful on the manufacturing floor?



Tablets

The success of the tablet dosage form relies mostly on the properties of the final blend. Characteristics of the AI(s) and the processing methods employed will determine the success or failure of a formula. Unless the AI is directly compressible, it is rare to develop a formula without excipients and even then, it may still require some excipients to enhance the hardness, disintegration, appearance, colour, taste and the overall performance of the tablet. Each excipient serves a function and they all contribute to the success of the finished product. Because different AI(s) will have different physical and chemical characteristics, the correct processing method must also be selected and ensure that the final blend will have good flow, good compressibility, uniform particle size and homogenous consistency.



Once the desired weight is achieved in conjunction with appropriate hardness, disintegration and dissolution, the formulation can be deemed to be appropriate for downstream processing such as film coating, if required. Determination of a formulations' success an be made upon completion of a stability study where all results are within specification, supporting the product shelf life.