

Implementation of Quality of Design for the Development of Bilayer Tablet

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Abstract: *Different drug release properties for different drugs contained in each layer of a bilayer tablet are rarely achievable with regular tablets. Additionally, these tablets help avoid physicochemical incompatibilities between medications and excipients. The successful production of such more complicated dosage forms depends on screening the material qualities of APIs and excipients and optimizing the processing parameters of each unit operations of the manufacturing process. In order to meet safety and efficacy regulations, these operations need to be properly monitored and managed to produce a drug product with acceptable quality and performance. Blending, granulation, pre-compression, and main compression are critical stages when formulation qualities and production processes should be tuned to avoid problems like weight variation, segregation, and delamination of particular components. Bilayer tablets, as opposed to ordinary tablets, offer distinct drug release properties for certain medications that are housed in each layer. These tablets also help to avoid physicochemical incompatibilities between drugs and excipients. The successful manufacturing of such more complex dosage forms depends on screening the material attributes of API and excipients and optimizing the processing parameters of individual unit operations of the manufacturing process in order to achieve safon of layers, which is frequently encountered during the production of bilayer tablets. For the quality and performance of the medication product to be acceptable, these processes need to be properly watched over and managed. The main objective of this review is to establish the foundation for implementing the Quality by Design (QbD).*

Keywords: Optimized formulation , Layered manufacturing , Quality by design