A solid dosage form is a complex mixture of multiple solid components. A systematic application of scientific principles to formulation and process design results in an increased level of product and process understanding. This approach enables higher levels of assuring assurance of product quality and performance, more robust manufacturing processes, improved efficiency, and other benefits. This approach is consistent with the basic principle of quality by design (QbD). The goal of product design is to consistently deliver the intended dose of a drug in a bioavailable, safe,...

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