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Pharmaceutical Scale up for Solid Dosage Forms

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Abstract : Scale-up is defined as the process of increasing batch size. Scale-up of a process viewed as a procedure for applying the same process to different output volumes. There is a subtle difference between these two definitions: batch size enlargement does not always translate into a size increase of the processing volume. In mixing applications, scale-up is indeed concerned with increasing the linear dimensions from the laboratory to the plant size. On the other hand, processes exist (e.g., tableting) where the term 'scale-up' simply means enlarging the output by increasing the speed. To complete the picture, one should point out special procedures where an increase of the scale is counterproductive and 'scale-down' is required to improve the quality of the product. In moving from Research and Development (R&D) to production scale, it is sometimes essential to have an intermediate batch scale. This is achieved at the so-called pilot scale, which is defined as the manufacturing of drug product by a procedure fully representative of and simulating that used for full manufacturing scale. This scale also makes it possible to produce enough products for clinical testing and to manufacture samples for marketing. However, inserting an intermediate step between R&D and production scales does not, in itself, guarantee a smooth transition. A well-defined process may generate a perfect product both in the laboratory and the pilot plant and then fail quality assurance tests in production.

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