An attempt to calculate in silico disintegration time of tablets containing mefenamic acid, a low water-soluble drug

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Based on a Quality by Design (QbD) approach, it is important to follow International Conference on Harmonization (ICH) guidance Q8 (R2) recommendations to explore the design space. The application of an experimental design is, however, not sufficient because of the fact that it is necessary to take into account the effects of percolation theory. For this purpose, an adequate software needs to be applied, capable of detecting percolation thresholds as a function of the distribution of the functional powder particles. Formulation-computer aided design (F-CAD), originally designed to calculate in silico the drug dissolution profiles of a tablet formulation is, for example, a suitable software for this purpose. The study shows that F-CAD can calculate a good estimate of the disintegration time of a tablet formulation consisting of mefenamic acid. More important, F-CAD is capable of replacing expensive laboratory work by performing in silico experiments for the exploration of the formulation design space according to ICH guidance Q8 (R2). As a consequence, a similar workflow existing as best practice in the automotive and aircraft industry can be adopted by the pharmaceutical industry: The drug delivery vehicle can be first fully designed and tested in silico, which will improve the quality of the marketed formulation and save time and money. (c) 2013 Wiley Periodicals, Inc. and the American Pharmacists Association J Pharm Sci 102:2166-2178, 2013
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