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Self-emulsifying pellets: Formulation, properties and drug release patterns

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A major challenge in the formulation of poorly water soluble drugs belonging to class II or IV of the Biopharmaceutics Classification System (BCS) is the improvement of their solubility. One solution to this problem is the formulation of Self-Emulsifying Drug Delivery Systems (SEDDS) consisting of a lipid and a non-ionic surfactant. After arrival in the GI tract, the SEDDS spontaneously emulsify to small, nano-size droplets, which present the drug at the absorption site of the epithelium, thus enhancing its permeability and bioavailability. Relationships between characteristics of emulsions like oil/surfactant ratio, viscosity, solubility of the drug in the SEDDS with the size distribution, shape, reconstitution ability and drug release from the produced pellets may exist, allowing prediction of pellet properties and *in vitro* release performance from emulsion characteristics. As a result of migration during drying, two phases of drug release, a burst initial and a terminal slow release phase are distinguished. Furthermore, control release and enhancement of drug loading is feasible by using adsorbents together with microcrystalline cellulose as the base of pellets. Data of different formulations of several drugs with logP in the range 2-4 will be presented demonstrating the potential of self-emulsifying pellets to monitor *in vitro* release. Presently, there is a vast number of published scientific papers on this topic, but only few marketed products, indicating that the potential of this method has not yet been exploited by industry.