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Advances in Pharmaceutical Formulation and Processing

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A significant number of new chemical entities under development are poorly water-soluble drugs generally characterized by an insufficient and low bioavailability [1,2]. Currently, >40% of the new drug candidates are speculated to be highly lipophilic and thus poorly bioavailable [3]. Typical methods to produce solid dispersions include the fusion method, hot melt extrusion, spray drying, freeze drying and supercritical fluid precipitation [4]. The most common difficulty encountered in producing such dispersions is stabilisation of amorphous drugs, which prevents them from recrystallization during storage [5,6]. Therefore, research in this area is now focussed on the physical stabilization of the amorphous form of drugs in solid dispersions as a function of several factors: (i) investigations on mixing at the molecular level, miscibility of the drug with the polymer is directly related to the stabilization of an amorphous drug against crystallization; (ii) investigations on configurational thermodynamics, the polymeric carrier generally increases the glass transition temperature (Tg) of the glass solution compared to the pure amorphous drug, lowers the mobility of drug molecules and kinetically acts as a crystallization inhibitor; (iii) investigations on the intermolecular drug-polymer interactions for the stabilization of the drug in solid dispersions [7]. The aim of much of this research is to create a predictive design space for solid dispersions rather than relying on empirical approaches, which is still prevalent in industry.

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