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The use of SANS in optimising pharmaceutical formulation

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Nanosuspensions are sub-micron-sized colloidal dispersions of nano-sized drug particles stabilised by surfactant and/or polymer. Nanosuspensions are of considerable interest as a means of solving the problems of poor water solubility and low bioavailability exhibited by many drugs, and which pose significant challenges for the preparation of a medicine for patient use. Despite the fact that there are an increasing number of commercially available nanosuspensions, it is still not possible to make a rational selection of the stabilising polymer/surfactant. To gain this understanding we have performed small-angle neutron scattering (SANS) measurements in combination with isotopic substitution of the aqueous solvent on a range of drug nanosuspensions wet-bead milled in the presence of a number of different hydrophilic polymers of varying molecular weight and, in some instances, in the presence of surfactant. The layer thickness and amount of the absorbed polymer was determined to be insensitive to the molecular weight of the various polymers indicating that the adsorbed layer was lying relatively flat on the various drug particle surfaces. In contrast, however, SANS studies revealed that the amount adsorbed and the thickness of the polymer layer was dependent on both the nature of the hydrophilic polymer and the nature of the drug. The insensitivity of the adsorbed polymer layer to polymer molecular weight has important implications for the production of nanoparticles, suggesting that lower molecular weight polymers should be used when preparing nanoparticles by wet-bead milling, since nanoparticle formation is then more rapid but with no likely consequence as regards the physical stability of the resultant nanoparticles.

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