Refining stability and dissolution rate of amorphous drug formulations - DTU Orbit
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Refining stability and dissolution rate of amorphous drug formulations
Introduction: Poor aqueous solubility of active pharmaceutical ingredients (APIs) is one of the main challenges in the
development of new small molecular drugs. Additionally, the proportion of poorly soluble drugs among new chemical
entities is increasing. The transfer of a crystalline drug to its amorphous counterpart is often seen as a potential solution to
increase the solubility. However, amorphous systems are physically unstable. Therefore, pharmaceutical formulations
scientists need to find ways to stabilise amorphous forms. Areas covered: The use of polymer-based solid dispersions is
the most established technique for the stabilisation of amorphous forms, and this review will initially focus on new
developments in this field. Additionally, newly discovered formulation approaches will be investigated, including
approaches based on the physical restriction of crystallisation and crystal growth and on the interaction of APIs with small
molecular compounds rather than polymers. Finally, in situ formation of an amorphous form might be an option to avoid
storage problems altogether. Expert opinion: The diversity of poorly soluble APIs formulated in an amorphous drug
delivery system will require different approaches for their stabilisation. Thus, increased focus on emerging techniques can
be expected and a rational approach to decide the correct formulation is needed.

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