Solid Solutions for Drug Development Problems

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Solid dispersions are known to pharmaceutical science and industry since the early 1960´s. With the ongoing development of suitable manufacturing technologies and improved knowledge on the characterization and physicochemical backgrounds of solid dispersion systems they meanwhile have made their way from interesting subjects for research labs to attractive development options.

The term “solid dispersion” summarizes several different physicochemical systems that can be classified according to their number of phases and the physicochemical state of active and carrier. Among these systems special cases are crystalline and glassy solid solutions.

Solid solutions combine advantageous properties of solida and liquida. Therefore they are very well suited to overcome typical drug development problems like:

- poor bioavailability due to poor drug solubility
- undefined solid state drug properties due to poor crystallization (partial amorphousness)
- drug substance polymorphism
- poor chemical (solution) stability

Main characteristics of solid solutions providing their ability to solve the above problems are shortly discussed.

In spite of these favourable properties and opportunities solid solutions have often been regarded as metastable systems that can not secure long-term physicochemical stability. However, they meanwhile have proven their ability to provide physicochemical stability with several years of shelf-life. In comparison to the mere metastable amorphous form of a drug, the state of a drug in solid solution systems can be stabilized both kinetically and thermodynamically. These principles of stabilization of solid solution systems are briefly discussed.

As a first basis for a successful solid solution formulation development the test system SOLISCREEN^{TM} has been developed to screen a drug compound´s fit and potential for a solid solution formulation and to give guidance for rational development of a solid solution formulation.