Physiologically-Relevant Dissolution Media for BCS Class II Drugs: Towards Accurately Predicting the *In Vivo* Performance

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Abstract

Oral route of administration remains the most preferred route. However, this route suffers from poor bioavailability particularly for poorly soluble drugs. The *in vitro* dissolution test is a quality control tool that is used to predict the *in vivo* performance of drugs. Dissolution is a rate-limiting step for Biopharmaceutical Classification System class II drugs, which are characterized by low solubility and high permeability. In this thesis, carvedilol, a BCS class II weak base, was used as a model drug. A series of dissolution tests using non-physiologically- and physiologically-relevant media were conducted to enable development of a universal dissolution medium for BCS class II. Dissolution media of pH and surface tension values that matched those of physiological GI fluids were used. Dissolution media of varying buffer capacity, ionic strength, and osmolality were also used to study the rate of drug release.