

Abstract:

Biopharmaceutical classification system is a scientific framework for classifying a drug substance into the groups based on its aqueous solubility and intestinal permeability. When combined with the in vitro dissolution characteristics of the drug product, then there are three major factors: solubility, intestinal permeability and dissolution rate. All these three factors correspond closely with the rate and extent of oral drug absorption from IR solid oral-dosage forms.

This work presents the overview about the BCS from two major points of view, from the site of the World health organization (WHO) and U.S. Food and drug administration (FDA), while the FDA guideline for biowaiver is fully cited in Czech language. Also reflection of in vitro in vivo correlations in IR drugs development according to BCS is mentioned.

Further, the thesis is analyzing the bioequivalence studies of Czech pharmaceutical company Zentiva, k. s. in context of BCS and compares the results with data obtained from the Canadian CRO Anapharm, which is a contract partner of many pharmaceutical companies being engaged in a clinical research and bioequivalence studies.

Keywords:

Biopharmaceutical classification system, solubility, permeability, dissolution, in vivo/in vitro correlations, Caco-2 cells, bioequivalence, IR drug formulations, biowaiver.

