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# Physiologically-relevant solubility and permeability screens in bioavailability and bioequivalence studies

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Throughout the drug development process, solubility and permeability testing have multifunctional role: at the early clinical development phases, at the formulation development phase, at the post-approval phase as well as at the generics approval phase (when biowaivering is considered). The biopharmaceutical classification system (BCS) is adopted by FDA where dissolution testing serve as a QC tool to ensure lot-to-lot consistency, compliance with the agreed-upon regulatory specification criteria and to facilitate the generics development at reduced cost without jeopardizing public safety. Nevertheless, some questions regarding the current BCS arise about: 1) the physiological relevance of the current dissolution media and/or the pH and if these were modified 2) the biowaivers umbrella if it can embrace drug classes other than Class I (only BCS class currently included) and 3) resemblance of in vivo situation in the small intestine at the fasted and fed state. Data and experience will be presented to highlight and tackle these issues with focus on physiologically relevant solubility and permeability in vitro screens and their ability to solve some of the above mentioned questions.

## Biography

Noha M. Zaki had her Ph.D. graduation in 2006 from Ain Shams University, Egypt. She has performed experimental solubility and permeability studies in Uppsala University, Sweden and continued postdoctoral research in Manchester University, School of Pharmacy, UK. She has published more than 8 papers in reputed, peer-reviewed journals and was awarded ACDIMA award for best research article year 2008.