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Biowaivers: An economical feasible methodology for generics

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During drug approval process, bioequivalence studies can be officially waived under specific conditions which are known as a biowaiver. Bio equivalency assessment is an essential step during the registration of a new drug product and reformulation of an already present dosage form. The bioequivalence studies require the involvement of human subjects which represents several constrains for its performance. In vitro testing namely solubility, permeability and dissolution evaluation represents an efficient widely accepted avenue for pharmaceutical products qualification for biowaivers. Drugs are classified based on their solubility and permeability into four classes which represent the scientific bases for the biopharmaceutics classification system (BCS). On the basis of the solubility and gastrointestinal permeability of drug substance, BCS has been widely implemented for waiving bioequivalence studies. Thus, biowaivers-based BCS currently is a vital, economical and feasible tool for generic products legal approval. The present article reviews the benefits of biowaivers, the criteria and requirements for its conductance and the current state in the market.

Biography

Ahmad Badr is a senior pharmacy student at Beirut Arab University. His expected year of graduation is 2019. He is currently a board member in the Quality Assurance Unit and the president of the Students Advising Academic Team. Ahmad is one who started the Lebanese Pharmacy Students Association in his faculty and signified its impact He is an ex-board member in LPSA, used to be the secretary and the head of public health events in Lebanon.He is the organizer of the LPSA's first webinar, and currently the chairperson of the 3rd Lebanese Pharmaceutical Symposium. Ahmad is an official delegate in the International Pharmacy Students Federation's world congress and is the upcoming president of LPSA.

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