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TITLE

Is there Variability in Release Profiles and Physical Characteristics of Drugs From Different Commercially Available Formulations? Possible Therapeutic Implications

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In recent years, the number of generic products of important prescription medicines has increased significantly. As generic medicine products are approved based on bioequivalence testing against the market leader, the generic products are rarely tested against each other. The aim of this study was to test whether there is variability in release and physical characteristics of drugs from different commercially available formulations, in particular assessing amiodarone (low solubility, high permeability) and metformin (high solubility, low permeability). Available formulations of amiodarone and metformin were tested for drug dissolution, content uniformity, hardness, weight variation, friability, and disintegration in accordance with the USP specifications. The tested formulations exhibited variable dissolution behaviours. In particular, amiodarone generics 1 and 2 exhibited the fastest dissolution, generic 3 showed the slowest dissolution, and Cordarone dissolution was the medium. Similar findings were observed for metformin formulations. After 3 months exposure to high temperature (40 ± 2°C) and relative humidity (75 ± 5%), amiodarone formulations exhibited a relatively higher degree of disparity, with drug release profiles of the generic formulations being markedly different from that of Cordarone. Most products met the USP specifications for drug content uniformity and other test physical characteristics. Variability in in vitro drug release profiles of multiple available formulations might be a potential indicator of a compromised bioavailability, with possible interferences on the therapeutic response, especially for low solubility high permeability drugs such as amiodarone, an antiarrhythmic with a narrow therapeutic index. The findings also suggested possible implications on bioequivalence for patients who live in rural areas.

Biography

An academic pharmacist, Dr Suong Ngo is a senior lecturer at the University of Adelaide, Australia. She completed her PhD (2004) in molecular pharmacology, BPharmHons (2001) and BPharm (2000) at the University of South Australia (UniSA). After a postdoctoral training (2004-2007) at UniSA Centre for Pharmaceutical Research, she became a senior lecturer in pharmaceutics in 2007 (Charles Darwin University, Australia) and was appointed by Adelaide University in 2009. She has broad research interests in molecular pharmacology and pharmaceutical science, including drug metabolism disposition in Australian marsupials and assessing in vitro bioequivalence of multiple generic medicine products. She has published 20 scientific papers since 2003 and is an editor of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologist Annual Scientific Meeting.