Differences between the branded and generic solid dosage form medicines: In-vitro dissolution testing

Mubarak Al Ameri¹, Nanda Nayuni¹, Anil Kumar², David Perrett¹, Arthur Tucker¹, Atholl Johnston¹

¹William Harvey Research Institute, London, UK, ²UAE General Hospital, Abu Dhabi, United Arab Emirates

Introduction: Dissolution is defined as the amount of substance that goes into solution per unit time under standardised conditions of liquid/solid interface, solvent composition and temperature. Dissolution is considered one of the most important tools to predict the in-vivo bioavailability and in some cases to determine bioequivalence. Assessment of bioequivalence between the branded drug and its generic counterpart is required to assure interchangeability. Aim: To compare the differences in dissolution behaviour of solid dosage forms between different brands (reference products) and their generic counterparts (tested products). Methods: A PT-DT70 dissolution tester (Pharma Test) was used to conduct dissolution tests with time on 12 branded medicines and their generic counterparts to detect any differences in behaviour. The test was carried out on four replicates for each batch. Tablets and capsules contained the same amount of drug substances but different types and/or amount of excipients were obtained locally and internationally. They were tested according to the British Pharmacopeia, European Pharmacopeia and the US Pharmacopeia with the rate of dissolution determined by ultra-violet Spectrophotometery. The repeatability and reproducibility of the method were checked and the temperature of the dissolution medium was maintained at 37 ± 0.5 ºC. Results: The dissolution profile revealed that all the studied medicines comply with the Pharmacopeia specifications and completely dissolved within 60 minutes. However, some generics showed significant differences in dissolution rate at the 5, 15 and 30 minutes. For example, when 40% of the branded amoxicillin 500 mg capsules (antibiotic) dissolved within 5 minutes, only 10% of its generic counterpart dissolved. Dissolution test of other generics showed that they can even dissolve faster than their branded counterparts. For example, when 70% of the generic form of simvastatin 20 mg tablets (anticholesteremic agent) dissolved within 5 minutes, only 28% of its branded form dissolved. In addition, some generic medicines from different batches of the same manufacturer showed significant differences at different time intervals. Other differences were also detected between the branded and its generic counterparts within 15 and 30 minutes. Conclusion: All medicines studied in this experiment fulfilled the medicine agencies’ requirement of bioavailability. Yet, dissolution profiles obtained from the studied formulations showed that the release characteristics vary considerably among different manufacturers and even identical formulations showed different dissolution profiles. This illustrates the importance of monitoring patients when switching their medicine to promote safe and effective generic substitution.