IN-VITRO BIOAVAILABILITY OF TWO COMMONLY USED, POST-MARKETED MEDICINES IN SRI LANKA

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Pharmaceutical care is a key component of the health care service. The bioavailability of a drug refers to the rate and extent of active drug that reaches systemic circulation. The bioavailability and bioequivalence study for orally administered drug products indicates that usage of in-vitro bioavailability as an important parameter for quality assurance, quality control as well as comparison studies of different formularies. Dissolution testing is a very practical and economic approach to identifying bioavailability problems and assess the need for *in vivo* bioavailability. It also serves as an important tool in identifying unacceptable or substandard drug products. Research presented here was carried out to assess the in vitro bioavailability of locally available Paracetamol 500 mg and Losartan Potassium 50 mg and to evaluate the bioavailability difference in branded and generic products.

The experimental quantitative data assessing method was used to compare the in vitro bioavailability behaviour of Paracetamol 500 mg and Losartan Potassium 50 mg that are available in the local market. Four branded drugs of Paracetamol and Losartan Potassium were selected for the study. Branded drugs of Paracetamol 500 mg were coded as A, B, C and the generic drug was coded as D. Branded drugs in Losartan Potassium 50 mg was coded as E, F, G and the generic drug was coded as H. The in vitro dissolution test of each brand and generics was carried out according to British Pharmacopoeia (BP) using a dissolution tester. Tests results were analysed according to Pharmacopeia standards and Food and Drug Administration (FDA) guidelines. The innovator products of Paracetamol and Orange book (United .2018) bioequivalence product of Losartan tablets were used as reference products.

Four Paracetamol tablet 500 mg formularies tallied with British Pharmacopoeia standards for dissolution test since all values were above the limit of 80%. However, in the comparison of innovator with four formularies only sample ‘A’ showed ±15% deviation at 5, 10 and 15 minutes. Therefore, ‘A’ formulary cannot be considered as a bio equivalent as per FDA guidelines. Comparison graph of Losartan Potassium tablet formularies indicated that final dissolution % of all formulas are within th**e** range and therefore complied with BP standards. But the ±15% criteria of FDA are not met by formula ‘E and ‘H’ since negative deviations were observed at 5, 10, 15 minutes than the reference. The formulary ‘F’ showed negative deviation compared to comparator by more than 15% at 5

and 10 minute time intervals. Therefore all 'E', 'F', 'H' formularies were identified as non-bio equivalent formularies with respect to innovator.

Only Paracetamol 500 mg brands B, C and D and Losartan Potassium 50 mg G only complied with FDA bioequivalence criteria. Paracetamol 500 mg brand A and Losartan Potassium 50 mg brands E, H and F deviated by ±15% from innovator dissolution profile graphs. According to the guidelines all tested samples complied with the pharmacopoeia criteria. Therefore, more stringent pharmaceutical bioequivalent consideration should be included in regulation and prequalification levels in drug procurement agencies to ensure safe and effective medicinal usage by the patients.

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