Abstract No: 725 ***Health and Hygiene***

A COMPARATIVE EVALUATION OF THE *IN VITRO* EFFICACY OF GENERIC AND BRAND DRUGS COMMERCIALLY AVAILABLE IN SRI LANKA

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Availability of numerous brands of drugs with marked price variation compared to their generic drugs in the current drug market of Sri Lanka, places health practitioners, pharmacists and patients in a dilemma of generic substitution. This study was aimed at comparing the *in-vitro* efficacy of some low priced generic drugs with their higher priced brands commonly available in Sri Lanka.

Based on a survey of commonly used tablets and capsules in the Sri Lankan market, two frequently used drugs, Metformin HCl tablet 500 mg, [one locally manufactured generic (M1) and 3 brands (M2-M4)] and Paracetamol tablet 500 mg [one locally manufactured generic (P1) and two brands P2-P3)] were selected for the study. All the products were examined visually for their organoleptic properties and tested for uniformity of weight, disintegration time, assay value, dissolution rate, hardness or crushing strength and friability. Pertinent official guidelines were followed throughout the tests.

The results of aesthetics assessment showed no evidence of defects in all tested tablets. Metformin HCl tablets disintegrated within 30 minutes and all Paracetamol tablets disintegrated within 15 minutes conforming to disintegration standards. Crushing strength of Metformin HCl tablets varied from 51.0 N (M4) to 122.1N (M2). Paracetamol tablets showed hardness values from 477.7N (P2) to 152.1N (P1). P2 had the highest percentage of friability (0.937 %) that is close to the maximum acceptable limit of 1%. Assay values of all Metformin HCl tablets were within the range of 97.52% (M3) to 102.44% (M2) of the stated amount of Metformin HCl. For Paracetamol tablets, it was within the range of 95.79% (P1) to 97.43% (P2). The British Pharmacopeia standard assay limit for both tablets was 95.0 –105.0%. The dissolution test revealed that the release of Paracetamol and Metformin HCl in simulated gastric fluid from all the generics and brands tested were greater than 90%. According to specifications, dissolution should be greater than 80%.

Thus, the required absorption of all the tested drugs could be assured. Despite some apparent minor differences in tablet hardness, the other *in-vitro* characteristics of the tested brands of Paracetamol and Metformin HCl, and their locally manufactured generics appear to be similar and not significantly different from each other. Therefore, in accordance with *in-vitro* official quality control tests, all the generics and brands of the drugs tested could be regarded as equally effective. However, *in vivo* tests are needed to assess the clinical efficacy of the tablets.