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# QUALITY OF GENERIC AND BRANDED DRUGS IN SRI LANKA

### A PROJECT REPORT PRESENTED BY

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to the Board of Study Chemical Science of the

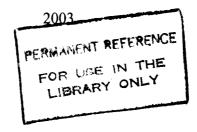
#### POSTGRADUATE INSTITUTE OF SCIENCE

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#### **ABSTRACT**

There is a marked price difference between generic and branded drug products available in Sri Lanka and also in other countries. The pharmaceutical products available in the market should be of better quality, whether it comes under generic or branded name. World Health Organisation (WHO) has drawn some guidelines to ensure the safety and effectiveness of drugs, which reflects the quality of the drugs used. Therefore, we have to ensure the quality status of the drugs consumed by patients within the specified limits of the given guidelines.

Although in pharmaceutical products, the active ingredients is same, the major variation is in bioavailability of generic and its corresponding brands, this arise due to the difference in formulation and other reasons.

Thorough literature survey and field studies were carried out to select item to be investigated on its quality. The Questionnaires were distributed among consumers, pharmacists, doctors, distributors, manufacturers and importers during the field studies. Apart from above criteria the analytical the facilities available at the Drug Quality Assurance and Research Laboratory of State

Pharmaceuticals Corporation of Sri Lanka are also taken into consideration.

The comparative basic tests were carried out on five different generic and its equivalent brands. The test parameters such as weight variation, disintegration, related substance, identification, dissolution and assay are taken into account.

These tests involve suitable analytical methods, which should provide prompt and effective results. The performance liquid chromatography enables to achieve this goal. Other methods like Ultra Violet (UV) absorption also useful but they involve multiple way and cause delay and inconvenience.

The result on quality status of generic and branded drugs shows that all the products fall within the acceptable limits given by standard pharmacopoeias.

In conclusion this study shows that the available drug products are of comparative quality, but that the cost per daily define dose could vary depending on the prescription. Finally if consumers are given knowledge on the generic and branded drugs, quality drugs at affordable prices is to be achieved.