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**Quality and stability studies of metformin hydrochloride tablets marketed in Sri Lanka**

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**Objective:** An attempt was made to assess the quality and stability of generic and branded products of metformin hydrochloride tablets B.P.500mg marketed in Sri Lanka.

**Method:** two generic and three branded products including the brand leader were used in this study. Three batches were selected randomly from each of the five products. Three samples of tablets from each batch were collected from different market places in this study. Each sample was tested according to British Pharmacopoeial specifications. The real time stability test was carried out for a period of six months.

**Results:** Our results showed that all the batches of five products passed the disintegration, identification and dissolution. However one batch of brand leader did not comply with the uniformity of weight test and one batch of another branded product was found to be substandard due to failure in assay test. Hence this study showed that out of fifteen batches tested only thirteen batches are of acceptable quality at present. All the batches except the one which failed to meet the pharmacopoeial specifications for assay have passed the assay and stability test. However, considering the rate of loss of potency during stability test period it can be concluded that two of the five products will not retain the stability throughout the shelf life of the product.

**Conclusion:** All three branded products of metformin hydrochloride tablets manufactured by foreign manufactures were found to be substandard. Hence through this study it is possible to contribute towards the concept of rational use of generic medicines in Sri Lanka.