J Bioanal Biomed 2017, 9:4, (Suppl)
DOI: 10.4172/1948-593X-C1-030

Interchangeability of medicines using metformin as a surrogate product (II)

Kolawole Jacob, Atibli Godwin and Keturah Smith
University of Jos, Nigeria

Interchangeability of medicines, either over-the-counter or prescription drugs is a general and wide spread practice in health institutions. In our recent publication on interchangeability, it was discovered that, cost, physical quality and full consent of the patient were employed in the substitution process. The current study was aimed at undertaking a bioequivalence metformin hydrochloride tablets as a surrogate medicine for general interchangeability. USP methods were used for the quality assurance on the following parameters; uniformity of weight, hardness testing, identification, friability, disintegration and dissolution tests. The physicochemical evaluation of the samples showed compliance with USP specifications. All the formulations disintegrate within 15-30 minutes. 13 brands complied with the monograph specifications (95-105%) for percent drug content, while four brands did not comply. Similarity factor (f2) value calculated for the brands were >50 indicating similarity with the innovator product, hence can be interchanged, except for the six brands (F, L, M, N, P, and Q). 15 of the 17 brands including the innovator brand passed the USP 32 general specifications standard for dissolution rate test for conventional release tablets. This study concludes that good pharmaceutical practice require that a brand should pass percent drug content and dissolution tests and that those with f2 values >50 can safely be interchanged with the innovator product. Though cost and consent of the patient should be added advantage after selection based on bioequivalence studies.

kolajac@yahoo.com