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Assessment of quality control parameters and in vitro bioequivalence/interchangeability of multisourced marketed metformin hydrochloride tablets

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ABSTRACT

Background: Metformin hydrochloride (MH) is a widely used medication for diabetes mellitus. For that, the availability of numerous multisourced MH in the drug market puts health care providers in a difficult situation for choosing the suitable brand and the possibility of interchangeable use.
Objective: The aim of this study is to test 10 brands and generics of local and regional MH multisourced tablets to assess their in vitro bioequivalence and interchangeability.
Methods: The in vitro bioequivalence assessment tests were carried out for ten brands of MH tablets (500 mg except one brand of 850 mg dose) based on the US Pharmacopoeia (USP 34) guideline recommendations. The content analysis test was done on 20 tablets for each brand using the UV method following USP 34 procedure and phosphate buffer (pH 6.8). Dissolution test was performed for six tablets from each brand using apparatus one (basket), with a rate of 100 rounds per minute (rpm) and 1000 ml phosphate buffer. UV scanning and calibration curve were performed to calibrate and validate the UV spectrophotometer. Dissolution profiles were compared with the reference Glucophage from Qatar by calculating the similarity factor (f2).
Results: Product numbers 2, 4, 5, 8, 9, and 10 had percent dissolved within 95 – 105% as an acceptable range for a content test according to USP 34. All the brands had more than 70% dissolved within 45 minutes. Similarity factor results revealed that product numbers 1, 3, 4, 5, 7, and 10 were bioequivalent with the reference because they had f2 more than or equal to 50%.

Conclusion: From the 10 tested products, only Glucophage® (Qatar), Diaphage®, Diamet® (Palestine), Glucophage® (Oman), Glucomet, and Glucophage® (Thailand) can be interchangeable with the chosen innovator brand (Glucophage®).

Keywords: Metformin Hydrochloride, Quality Control, Interchangeability, Dissolution, Bioequivalence