In-Vitro Evaluation of Different Marketed Brands of Metformin Tablets Using Quality Control Tests

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Introduction

- Metformin is commonly prescribed for the treatment of type II diabetes non-insulin-dependent diabetes mellitus, acts by reducing hepatic glucose production.
- World Health Organization (WHO) has continuously supported the use of generic drug products, aiming to improve the overall health care system.
- The generic substitution can be considered when a generic product of an innovator drug contains identical amounts of the same active ingredient in the same dose, same dosage form and route of administration together with meeting standards for strength, purity, quality, and identity.
- The primary aim of this study is to evaluate and compare the in-vitro quality and bioequivalence of metformin tablets available in Saudi Arabia, including a lab-formulated sample, using pharmacopeial tests.

Methodology

The comparative bioequivalence and physicochemical study of six metformin marketed tablets (M1-M6) and (M7) which made in our lab were performed through the assessment of the uniformity of weight, diameter, thickness, hardness, friability, disintegration , dissolution, and content assay, validated by HPLC with UV detector was used to measure the concentration of metformin in the dissolution medium.

Results

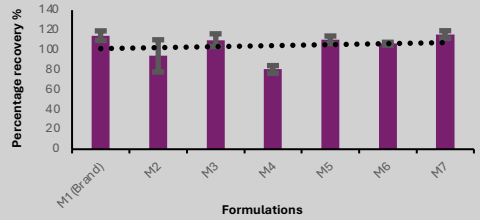

Figure 1. Percentage recovery

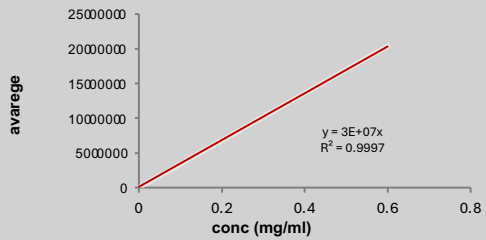

Figure 2. Validation an Callibration curve of metformin drug

Conclusion

- Similarity of generic metformin hydrochloride tablet products in Saudi Arabia to innovator were investigated.
- The physicochemical properties were studied. Some physical differences were noted in tested generic products like, tablet weight, diameter and thickness, but might have negative impact on therapeutic effect or patient compliance.
- The lab-formulated M7 tablet showed rapid disintegration and complete drug release in less than three minutes, with excellent mechanical proprieties.

❑ References

Table2.. The results of diameter and thickness showed a non-significant difference among the different formulations of metformin (p >0.05)

Tests	M1	M2	M3	M4	M5	M6	M7
Weight	527.5±4.6	728.7±10	544.7±5.7	859.2±7.7	526.4±6.7	601.7±4.6	788.8±13
Diameter	11.3±0.5	16.3±0.5	12±0	16.3±0.5	10±0	12±0	13.3±0.4
Thickness	5.3±0.5	6.6±0.5	5±0	6.33±0.5	5.6±0.5	5±0	4.6±0.5

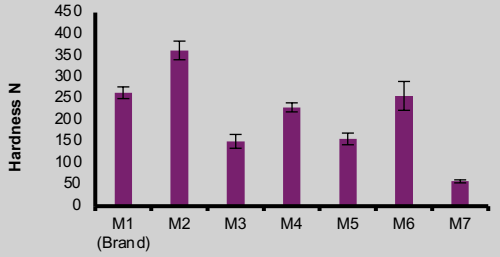

Figure 3. The results for hardness of metformin tablets (M1-M7) showed a very significant results of hardness for all formulations (p >0.05).

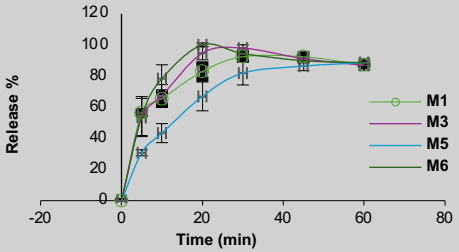

Figure 6. The dissolution profile of M1,M3,M5,and M6 metformin shows that approximately 90% of mass released was observed in less than one hour.

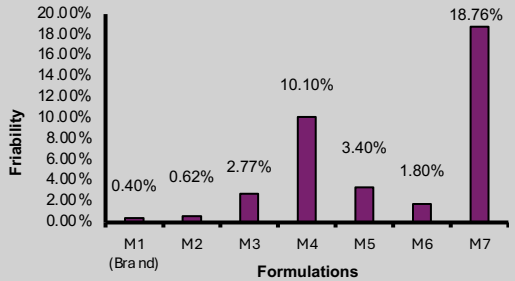

Figure 4. The results for friability for M1 and M2 were achieved the pharmacopeial limit of < 1%.

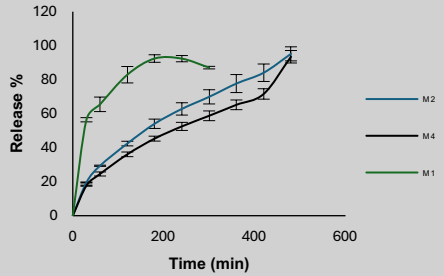

Figure 7. M2 and M4 taken more than (8 hours) to released completely due to their ER effect

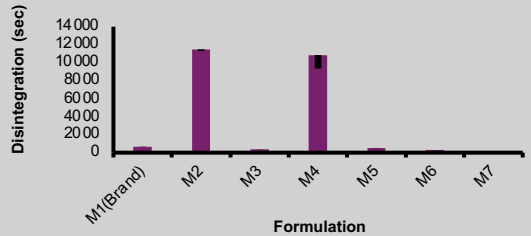

Figure 5. All formulations showed significantly different disintegration times (ANOVA, P < 0.05). M7 had the fastest disintegration (44 seconds), while M4 and M2 exceeded (3 hours)

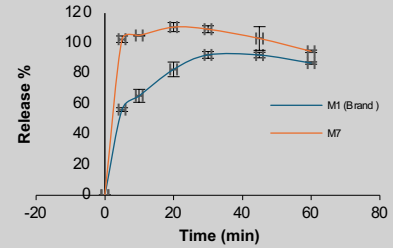

Figure 8. The dissolution profile of lab metformin (M7) shows that approximately 90% of mass released was observed at approximately 3 minutes.