INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA):IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Comparative Study of Marketed Branded and Generic Metformin Hydrochloride Tablets

Ahire Priyanka Sanjay*, Aher Preeti Bapu, Tufail Dana Shakeel Ahamad, Manohar Baburao Nikam

Swami Vivekanand Sanstha's Institute of Pharmacy (B.Pharm), Mungase, Tal. Malegaon, Dist.Nashik-423201

ARTICLE INFO

Received: 19 June 2024
Accepted: 23 June 2024
Published: 13 July 2024

Keywords:
Generic drugs, Branded drugs, Bioequivalency, Comparative pricing, Worldwide prevalence

DOI:
10.5281/zenodo.12737933

ABSTRACT

The usage of branded or generic medications has generated a lot of global debate in recent years. Additionally, the government of several nations is adamantly encouraging the substitution of generic medications for branded ones. A generic medication has the same active ingredient or components as its branded equivalent and has been demonstrated to have comparable therapeutic efficacy. Because generic medications do not require the extensive and expensive pre-clinical or clinical trials that are required for branded medications, their costs are significantly lower than those of branded medications. This review sheds insight on the relative efficacy of generic and branded medications additionally, an effort is made to draw attention to the expense differences between the two groups. Generic medications are not covered by a patent; branded medications are for a set period of time. All that generic medications need to do is satisfy the same bioequivalency standards as their branded equivalents. Additionally, it takes a lot longer for approved brands of pharmaceuticals to be approved than it does for approved generics. Because of the length of time it takes for branded pharmaceuticals to be approved and the expenses associated with their research, branded drugs end up being highly expensive on the market compared to generic drugs.

INTRODUCTION

Cost of medicines is a major concern today. Generic drugs provide major saving opportunity in healthcare expenditure since they usually have lower price. However, physicians and patients are apprehensive regarding their quality, although they are bio-equivalents of the innovator products. The present study therefore compares the price structure and activity of the branded products and their branded-generic counterparts(1-3)

Generic drugs:-

Instead of the innovator drug, which has a brand name under which the chemical composition of the drug is sold, generic drugs refer to the chemical

***Corresponding Author:** Ahire Priyanka Sanjay
Address: *Swami Vivekanand Sanstha's Institute of Pharmacy (B.Pharm), Mungase, Tal. Malegaon, Dist.Nashik-423201*
Email : ahirepriyanka69@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

composition of a drug. It usually performs the same function as a proprietary drug interms of dose, potency, administration method, quality, and action. When referring to house hold goods, the term "generic" means that the item is less expensive, potentially less effective, and a replica of a name brand product. But, when it comes to generic medications, they are just as effective and of equal quality to their branded counterparts. The drug's active pharmaceutical ingredient, which is what gives the medication its therapeutic effects, is known by its generic name(4-6)

Branded drugs:-

Drugs with a trade name and patent protection are referred to as branded drugs (means that a drug can be manufactured and sold by the innovator company). A pharmaceutical company invests significant funds and resources to create, develop, and discover novel medication substances; as a result, they are granted the only right to produce and distribute the medicine for a predetermined period of time. Many people trust and are familiar with proprietary pharmaceuticals because only the innovator firm can manufacture them during the period of the patent protection(7-10)

MATERIALS AND METHODS:

Equipments used-

UV-spectrophotometer (LT-291, India), analytical balance, lab junction tablet hardness tester , disintegration tester (Model B.J-3, Shanghai Famo Machinery manufacture), dissolution test apparatus (RC-6, India), etc.

Reagents Used-

Hydrochloric acid (Blulux Laboratories Pvt. Ltd., India), Potassium Hydrogen Phosphate (Blulux Laboratories Pvt. Ltd., India), and distilled water. The dissolution medium (0.68% w/v of Potassium Hydrogen Phosphate adjusted to pH 6.8 by the addition of 0.2 M hydrochloric acid) was prepared by dissolving 6.8 gm of potassium hydrogen phosphate in sufficient distilled water to make 1000 mL solution(11-14)

Evaluation tests-

1. General appearance

The general appearance of a tablet, its visual identity and overall "elegance" is essential for consumer acceptance, for control of lot-to-lot uniformity(15)

Appearance of a tablet involved the measurements of tablets:-

Table no. 1: General Appearance(11)

Sr. No.	Parameters	Standard	Generic
1.	Size	14x14x3(mm)	17x7x3(mm)
2.	Shape	Round	Cylindrical
3.	Colour	White	White
4.	Oduor	None	None
5.	Taste	Metallic	Metallic

2. Uniformity of Weight

Sample tablets 20 of each brand were weighed together and the average weight was determined. Each tablet was weighed individually on an analytical balance and the percentage deviation of the tablets was calculated using the following expressions(16)

(%) deviation = [(individual weight - average weight)/average weight] × 100

Table no. 2: Uniformity of weight(11)

Brand	Total weight(g)	Mean weight(g) ±SD	No. Of tablets deviating by 10%

Standard	10.63	0.530±0.005	Nil
Generic	10.49	0.523±0.004	Nil

3. Hardness test:

Fig. No. 1: Lab Junction Hardness Tester

A hardness testing apparatus (Monsanto Hardness Test Apparatus) was used to measure the hardness of ten tablets, one at a time, from each brand. To find the compressive force that broke the tablet, the tablets were positioned between two anvils and forces were applied to the anvils(17)

Table no. 3: Hardness test(11)

Brand	Mean force applied(kg± SD)
Standard	15.325±0.82
Generic	±0.013

4. Friability:

Fifteen tablets were chosen, meticulously dusted, and weighed for both branded and generic medications before testing. After that, the tablets were put into the friability tester's drum and turned for four minutes at a speed of 25 rpm. Tablets were reweighed and the friability percentage was computed using the following formula after 100 revolutions and dedusting.27 Per USP rules, the maximum amount of weight loss that can be achieved is 1%(18)

% Friability = [(Initial weight – Final weight)/Initial weight] ×100

Fig. No. 2: Friability test Apparatus

5. Disintegration test:

Using a disintegration device, tablet disintegration was measured at 37±0.5°C. In 900 millilitres of distilled water, the disintegration time of six randomly chosen tablets from each brand was measured. The amount of time required to break down the tablet and go through the mesh was noted, and the average amount of time was computed.

Fig. No. 3: Disintegration test Apparatus

Table no. 5: Disintegration test(11)

Brand	Disintegration time/ min.
Standard	7.33
Generic	7.20

6. Assay of Metformin Hydrochloride Tablets:

Using a mortar and pestle, twenty metformin hydrochloride tablets were weighed and ground into powder. Following a 15-minute shake of a powder containing 0.1 g of metformin hydrochloride in 70 ml of distilled water, the volume was increased to 100 ml of distilled water and filtered. Ten millilitres of the filtrate were then diluted to 100 ml of distilled water, and ten millilitres of the resulting solution were diluted still further to 100 ml of distilled water to yield a nominal concentration of 10 µg/ml. Using 798 as the value of A (1%, 1 cm), the absorbance of the resultant solution was measured at its maximum at 232 nm, and the amount of metformin hydrochloride was computed.

Table no. 6: Assay of Metformin HCL(11)

Brand	Mean Absorbance	Assay(%)
Standard	0.8426	102.76
Generic	0.7756	97.13

7. Dissolution test:

Fig. No. 4: Dissolution test Apparatus

The USP Pharmacopoeia was followed for conducting the dissolving test. The basket was rotated at a constant speed of 100 rpm while the medium containing 900mL of phosphate buffer (pH 6.8) was kept at 37 ±0.5°C. Each brand's six tablets were chosen at random before being put to the test. After 10, 15, 20, 30, 45, and 60 minutes, the samples were removed. One hundred revolutions per minute (rpm) were applied to the paddle. At each sampling interval, 10 millilitres of samples were extracted from every dissolution test vessel. Immediately after, the same volume of a new 10 ml dissolving medium was added to keep

the vessel volume constant for the duration of the analysis. The samples underwent filtering, and their absorbance was measured at a maximum of 233nm. Next, using 806 as the value of A (1%, 1 cm), the total amount of metformin hydrochloride in the medium was computed(19-20)

Brand	Drug released (%)	
	30 min.	45 min.
Standard	84.4	88.3
Generic	87.1	92.6

CONCLUSION

On both brand-name and generic metformin hydrochloride tablets, a number of quality-control tests were carried out, including assays, weight variation, friability, hardness, and disintegration time. It was discovered that the test parameters for every product that was chosen complied with official quality control standards. These goods' pharmaceutical quality hardness test results differed significantly from the specifications. There is a strong argument for manufacturers to strengthen the tablets' mechanical construction in order to significantly lower the possibility of breaking during handling and shipping by customers. It is recommended that drug regulatory bodies step up their post-market surveillance efforts, and that manufacturers also step up their post-market surveillance.

REFERENCES

1. Aggarwal K. Generic drugs vs patented drugs vs branded drugs vs generic names of the drug.
2. Arafat Mosab, Ahmed Zahaa, Arafat Osama. Comparison between generic drugs and brand name drugs from bioequivalence and thermoequivalenceprospective.InternationalJournal of Pharmacy and Pharmaceutical Sciences.2017; 9(6): 1-4.
3. Annals of Pharmacotherapy. 2009; 43:1583-97
4. Bhangale V (2007) OTC Marketing of Drugs. International Marketing Conference on Marketing &Society IIMK 1: 397-402.
5. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: A secondary analysis. Lancet 2009; 373:240-9.
6. Singal GL, Nanda A, Kotwani A. A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. Indian J Pharmacology 2011;43:131-6.
7. Johnson T. Available from: http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055 (Updated: August 3/11).
8. https://en.m.wikipedia.org/wikiGeneric_drug
9. https://toolbox.eupati.eu/glossary/brandedmedicines/#:~:text=Branded%20medicines%20are%20medicines%20which,known%20as%20the%20generic%20name.
10. https://journals.lww.com/jfmpc/fulltext/2023/12120/a_comparative_study_on_perception_and_use_of.35.aspx#:~:text=Generic%20medications%20are%20interchangeable%20with,if%20prescribers%20use%20generic%20medications
11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6415809/
12. Singal GL, Nanda A. A comparative study of branded versus branded generics in India. International Journal of Pharmacy & Technology 2010;2:960-8.
13. Shafie AA, Hassali MA. Price comparison between innovator and generic medicines sold by community pharmacies in the state of Penang, Malaysia. J Gen Med 2008;6:35-42.
14. Figueiras MJ, Marcelino D, Cortes MA. People′s views on the level of agreement of

generic medicines for different illnesses. Pharm World Sci 2008;30:590-4.

15. Vetchy D, Vetcha M, Rabiskova M, Gryczova E, Bartosikova L. Comparison in vitro felodipine release rate from the original versus generic product with controlled release of the drug. Medicina (Kaunas) 2007;43:326-31.
16. Briesacher BA, Andrade SE, Fouayzi H, Chan KA. Medication Adherence and the Use of Generic Drug Therapies. The American journal of managed care 2009;15:450.
17. Reisman M. Generic Drugs: Caveat Emptor! (And Other Advice from Cybersp
18. Wilner AN. Therapeutic equivalency of generic antiepileptic drugs: Results of a survey. Epilepsy and Behavior.2004;5(1): 995-998.
19. Thakkar KB, GauriBilla (2013) The concept of: generic drugs and patented drugs vs. Brand name drugs and nonproprietary generic name drugs. Front Pharmacol 4: 113
20. Dunne S, Shannon B, Dunne C, Cullen W (2013) A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. BMC PharmacolToxicol 14: 1

HOW TO CITE: Ahire Priyanka Sanjay , Aher Preeti Bapu, Tufail Dana Shakeel Ahamad, Manohar Baburao Nikam, Comparative Study of Marketed Branded and Generic Metformin Hydrochloride Tablets, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 7, 915-920. https://doi.org/10.5281/zenodo.12737933