



International Journal of Pharmaceutics and Drug Analysis

Content Available at www.ijpda.org ISSN: 2348:8948



REVIEW ON THE LABORATORY ANALYSIS AND PATIENT MONITORING OF GENERIC AND BRANDED DRUG FOR TYPE 2 DIABETES MELLITUS: A FOCUS ON EFFICACY, LIPID PROFILE AND SUGAR LEVEL.

J. Yeshwanth*, G. Akash Kumar, S. Sherlin Sheeba, Rahul Kumar, R. Saravanan, R. Srinivasan

Faculty of Pharmacy, Bharath Institute of Higher Education and Research, Chennai.

Received: 06 Sept 2024 Revised: 24 Sept 2024 Accepted: 02 Dec 2024

Abstract

Context: Insulin resistance and poor glucose metabolism are hallmarks of Type-2 Diabetes Mellitus (T2DM), a chronic illness that calls for long-term pharmaceutical treatment. A common prescription drug used to control blood glucose levels is metformin. It is critical to evaluate the safety and effectiveness of branded and generic formulations, particularly with regard to glycemic management, lipid profiles, and renal function, given the growing availability of generic medications. **Evaluation test for tablets:** The purpose of this study was to analyze and assess the efficacy of several marketed brands of metformin pills, both branded and generic. Two 500 mg tablets Glumetza (branded) and okamet 500mg (generic) were chosen, and their chemical and physical properties were assessed. Official standards, such as thickness, hardness, weight fluctuation, friability, disintegration time, and dissolution studies, PH measurement, Assay of API, Identification of impurities, were used to assess each brand's physicochemical equivalency. **Objective:** The objective of this study was to compare the safety and effectiveness of branded and generic forms of metformin in patients with Type-2 Diabetes Mellitus over a six-month period, with an emphasis on lipid profiles, renal function, and glycemic control. **Materials & Procedures:** Patients with type 2 diabetes were split into two groups and given either generic or branded versions of diabetes medications. At baseline, three months, and six months, fasting blood sugar (FBS) and HbA1C values were used to measure glycemic control. The safety and possible effects on renal function were assessed by measuring serum creatinine and lipid profiles, which include cholesterol levels. **Outcomes:** Over a six-month period, both branded and generic Metformin shown notable drops in HbA1C, with the former going from 8.20% to 6.70% and the latter from 8.28% to 6.85%. FBS levels dropped from 200 mg/dl to 172 mg/dl for branded products and 187 mg/dl for generic products. The branded group experienced a greater drop in cholesterol (from 195 mg/dl to 172 mg/dl) than the generic group (to 182 mg/dl). The levels of serum creatinine stayed constant. **Conclusion:** There was no discernible difference in the safety profiles of branded and generic forms of metformin, and both were equally successful in enhancing lipid profiles and glycemic management.

Keywords: Type-2 Diabetes Mellitus (T2DM), Metformin, Branded Drugs, Generic Drugs, Drug Safety, HbA1c, Lipid Profile.

This article is licensed under a Creative Commons Attribution-Non-commercial 4.0 International License. Copyright © 2024 Author(s) retains the copyright of this article.



*Corresponding Author

J. Yeshwanth

DOI: <https://doi.org/10.47957/ijpda.v12i4.615>

Produced and Published by
[South Asian Academic Publications](#)

Introduction

Generic drug

The term "generic drug" describes a medication that has the same chemical makeup as a drug that was first protected by a chemical patent. Generic drugs may be

marketed after the original drugs' patents have expired. Because the active chemical element in generic drugs is the same as that of their patented equivalents, their medical profiles function similarly. A generic medication may change from the original in terms of manufacturing technique, formulation, excipients, color, taste, and packaging, but it will always contain the same active pharmaceutical ingredient (API) [1]. When the patent protections granted to the drug's original creator expire, generic products become accessible. What Generic Bioequivalence Means A generic drug product is defined by US FDA regulations as one that is equivalent to an innovator drug product in terms of dosage form, strength, and administration route, as well as quality, performance

characteristics, and intended use [1]. Manufacturers of generic medications must provide scientific proof that their product is bioequivalent, meaning it functions similarly to the innovator medication. In order to be deemed bioequivalent, the generic version needs to enter the bloodstream with the same quantity of active chemicals in the same period of time as the original medication [2].

Branded drugs

Medication that is marketed by a pharmaceutical company under a specific brand name or trademark and is protected by a patent. You can purchase brand-name drugs with a prescription or over-the-counter[3]. Brand Drug” or “Brand” refers to any pharmaceutical product that is prescribed and covered by the Plan’s pharmacy benefit, including over-the-counter drugs that are supplied in compliance with a prescription, medicine, agent, substance, device, supply, or other therapeutic product that is not a generic drug [3].

Table 1: Comparison between Generic and Prescribed drugs

Features	Generic drug	Branded drug
Patent	Of patent	Patent protected
Trade name	Marketed under the generic name of drug	Sold under a new, proprietary brand that the firm has safeguarded
Manufactured by	Produced by a number of drug manufacturers	Invented and produced by a creative business
Animal and clinical study	Not required to perform	Important to perform
Price	Cheaper	Expensive than generic drugs
Appearances (Colour, size, shape)	Look distinct from the corresponding brand-name medication.	Distinctive appearance as medicine product development
Name variations	In any nation, the same generic medication name	Similar or dissimilar brand names in several nations

Diabetes

The chronic disease known as diabetes is typified by high blood glucose levels and abnormal protein and fat metabolism. Blood glucose levels increase because the cells cannot metabolize the glucose due to either insufficient pancreatic insulin release or ineffective cell utilization of the produced insulin [4-5].

The three primary types of diabetes are

- An inability of the pancreas to produce insulin is known as insulin-dependent diabetes mellitus (IDDM).
- Diabetes in which body cells grow resistant to the effects of insulin production is known as non-insulin dependent diabetes mellitus (NIDDM).

1. Type 1 diabetes

Type 1 diabetes mellitus (T1DM) is an autoimmune disease that damages the pancreatic β -cell that produces insulin, resulting in insulin insufficiency and hyperglycemia. The aim of treatment is to use exogenous insulin to replace the β -cell’s natural function. And try to maintain and restore euglycemia by regularly checking blood glucose levels [6]

2. Type 2 diabetes

Insulin insensitivity is a hallmark of type 2 diabetes, which is caused by insulin resistance, reduced insulin production, and ultimately pancreatic beta-cell loss. As a result, less glucose reaches the liver, muscle cells, and fat cells. The breakdown of fat increases when blood sugar levels are high. Low insulin levels and elevated insulin resistance combine to cause hyperglycemia [7].

3. Gastrointestinal diabetes

As pregnancy goes on, tissue resistance to insulin increases, necessitating the need for more insulin. The equilibrium between insulin resistance and supply is maintained because the great majority of pregnancies have readily satisfied demand. However, women get hyperglycemia when resistance takes hold. Usually rising in the second half of pregnancy, insulin resistance usually goes away quickly after delivery. Hyperglycemia occurs when the available insulin is insufficient to meet tissue needs for appropriate blood glucose regulation [8].

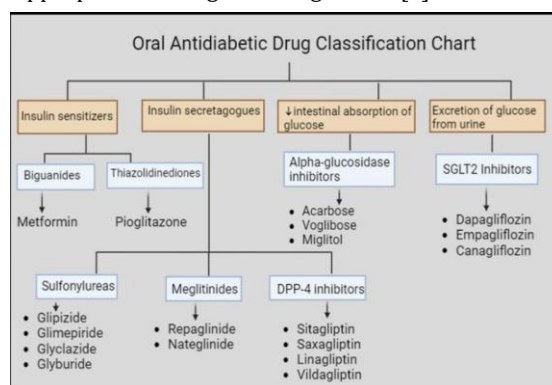


Fig: 1 Classification of anti-diabetics

Evaluation Test for Tablets

1. Evaluation of Physical and Chemical Properties Look:

Appearances: Assess the pills’ or capsules’ color, size, shape, and consistency [9].

Variation in Weight: Verify that each dose’s weight is within allowable bounds.

Friability and Hardness: Examine a solid’s ability to withstand pressure and its propensity to crumble.

Disintegration test: Calculate how long it takes for the medication to disintegrate into smaller pieces.

PH Measurement: Make sure the pH of liquid formulations is contained in the therapeutic range by testing them.

2. Assay of Active Pharmaceutical Ingredients (API)

- Pharmaceutical Active Ingredient (API) Assay to ascertain the concentration of the active component or ingredients and make sure they fulfil the claims on the label, use UV spectrophotometry or high-performance liquid chromatography (HPLC).
- Examine the API content of generic and branded medications [10].

3. Tests for Dissolution

To evaluate the bioavailability of a medicine, simulate its release under physiological settings. Make that the API is released at comparable rates and amounts in both branded and generic formulations [9] [10].

4. Identification of Impurities

The Profiling of Impurities Make use of methods such as mass spectrometry (MS), gas chromatography (GC), or HPLC to look for any contaminants or degradation products.[10].

Drug name:



Fig 2: Glumetza 500 mg branded metformin



Fig 3: Okamet 500mg generic metformin

Patient Monitoring of Generic and Branded Medicines for Diabetes

Materials and Methods

This comparison study took place over a period of six months at the Bharath Medical College, Chennai, the main goal was to compare the effects of branded and generic forms of diabetic drugs on lipid profiles, safety, and efficacy in patients with Type-2 Diabetes Mellitus (T2DM) [11].

Study Design

This study was prospective and observational. This study involved recruiting T2DM patients who were enrolled in the Bharath Medical College's outpatient department. The following two groups of 100 patients were randomly selected based on the kind of medication they were taking [11]:

Group 1(n=50): Patients receiving Generic drugs

Group 2(n=50): Patients receiving Branded drugs

Throughout the trial period, patients in each group were tracked for changes in their lipid profiles, safety measures, and glycemic control.

Inclusion Criteria

- Patients diagnosed with Type 1 or Type 2 diabetes as per ADA or WHO criteria.
- Aged 18 years and above.
- Patients using branded generic anti-diabetic medications.

Exclusion Criteria

- Pregnant or lactating women.
- Patients with severe comorbidities or those using non-generic brands.
- Non-compliant patients.

Data collection

The patient's demographics, medical history, and initial test results were all part of the baseline evaluations. Fasting blood sugar (FBS) and hemoglobin A1c (HbA1c) levels were used to measure glycemic management [12]. Measurements of lipid profiles, such as serum creatinine, HDL, LDL, triglycerides, and total cholesterol, were made in order to evaluate safety and track renal function. HbA1c, FBS, lipid profile, and serum creatinine were measured again at each follow-up appointment, which took place at the third and sixth months. All evaluations followed laboratory protocols and standardized methods [12] [13].

Statistical Analysis

Analyses of the data were conducted using suitable statistical techniques. We examined changes in serum creatinine, lipid profile, FBS, and HbA1c between baseline and follow-up visits within and between the branded and generic groups for each drug. A p-value of less than 0.05 was deemed statistically significant when assessing dissimilarities between groups [14].

Results

Over a six-month period, this study compared the safety and effectiveness of branded and generic versions of diabetic medications in patients with Type-2 Diabetes Mellitus. Serum creatinine levels, lipid profiles, and glycemic management as determined by HBA1C and

fasting blood sugar (FBS) levels were the main indicators tracked [14].

HBA1C Levels

Patients on generic and branded medications had baseline HBA1C levels of 8.00% that were comparable. By the third month, the generic formulation had a slightly less noticeable decrease to 7.40%, while the branded formulation had decreased to 7.60%. The branded formulation's final HBA1C values after six months were 6.70%, whereas the generic formulation's was 6.85%, indicating that both groups had good glycemic control [14].

FBS (FASTING BLOOD SUGAR)

The levels of FBS were successfully decreased by both diabetic medication formulations. Both groups had an initial FBS of 200 mg/dl. By the study's conclusion, the branded group's FBS dropped to 172 mg/dl, while the generic group's dropped to 187 mg/dl, indicating similar outcomes [15, 16].

Serum Creatinine and Lipid Profile

Both formulations' lipid profiles improved, increasing from baseline cholesterol levels of 195 mg/dl to 172 mg/dl for the branded formulation and 182 mg/dl for the generic. Both groups' serum creatinine levels stayed constant during the research; only the branded group's increased slightly from 0.76 mg/dl to 0.86 mg/dl, while the generic group's increased from 0.70 mg/dl to 0.88 mg/dl [16].

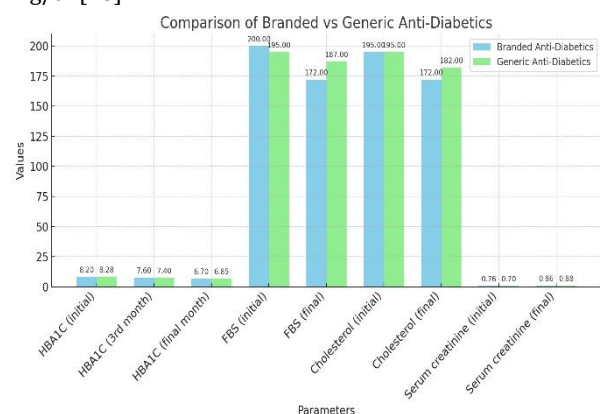


Fig 4: comparative analysis of branded and generic anti-diabetics on glycemic control, lipid profile and renal function

Table 2: Comparison of Branded and Generic anti-diabetics

Parameter	Branded Anti-Diabetics	Generic Anti-Diabetic
HBA1C (initial)	8.20%	8.28%
HBA1C (3 rd month)	7.60%	7.40%
HBA1C (final month)	6.70%	6.850%
FBS (initial)	200mg/dl	195mg/dl
FBS(Final)	172mg/dl	187mg/dl

Cholesterol (initial)	195mg/dl	195mg/dl
Cholesterol (final)	172mg/dl	182mg/dl
Serum creatinine (initial)	0.76mg/dl	0.70mg/dl
Serum creatinine (final)	0.86mg/dl	0.88mg/dl

Conclusion

In this study, the quality and physicochemical equivalency of brand-name and generic metformin hydrochloride tablets were evaluated. The investigation verified that the branded and generic metformin hydrochloride tablets met the official requirements for dissolution, assay, hardness, weight variation, and friability. Based on the results, we concluded that while the branded and generic metformin hydrochloride tablets chosen for a comparative quality assessment to ensure their potency and efficacy produce different outcomes from one another, no brand goes beyond the guidelines specified in official literature. The evaluation of branded and generic anti-diabetics reveals how important patient monitoring and stringent laboratory testing are to guaranteeing treatment efficacy and safety. Among the important conclusions are:

Effectiveness and Quality

When anti-diabetic drugs fulfil predetermined bioequivalence requirements, both branded and generic versions can produce comparable clinical results. In order to ensure efficacy comparable to that of branded medications, laboratory analysis verifies that appropriately manufactured generics contain active components in the right amounts.

Patient-Centric Monitoring

Determining each patient's unique response to treatment depends on efficient patient monitoring. Regardless of the brand name of the medication, factors like glycemic control, side effects, and patient adherence should be routinely evaluated to customize therapies to each patient's needs.

Anti-diabetic drug effectiveness will be maximized by combining thorough laboratory testing with customized patient monitoring. To maximize results, healthcare providers need to continue to take the initiative to address patient-specific variables and differences in medication formulations.

Acknowledgment

Not Declared

Conflicts of Interests

There are no conflicts of interest.

Funding

Nil

Authors Contributions

All the authors have contributed equally.

Ethical Considerations

A clearance from the institutional ethics committee was obtained. Informed consent was given by each patient before they began the trial.

References

1. Harvard Health — Ask the doctor: Are generics as good as brand-name drugs? – Harvard Health. Health.harvard.edu
2. <https://www.health.harvard.edu/staying-healthy/are-generics-as-good-as-brand-name-drugs>
3. <https://www.cornelllawreview.org/2023/07/25/pharmaceutical-patent-protection-beyond-the-twenty-year-statutory-term/>
4. Kousar S. Type 1 Diabetes: Causes, symptoms and treatments, review with personal experience. *Current Research in Diabetes & Obesity Journal*. 2019;11(4):77-83.
5. Banerji a, azad m. Review of asia-pacific's healthcare systems with emphasis on the role of generic pharmaceuticals. *Academy of health care management journal*. 2013 jun 1;9.
6. Rodgers, Anthony, Carlene Lawes, and Stephen MacMahon. "Reducing the global burden of blood pressure-related cardiovascular Disease." *Journal of hypertension*. Supplement: official journal of the International Society of Hypertension 18, no. 1 (2000): S3-6.
7. Kearney, Patricia M., Megan Whelton, Kristi Reynolds, Paul Muntner, Paul K. Whelton, and Jiang He. "Global burden of hypertension: Analysis of worldwide data." *The lancet* 365, no. 9455 (2005): 217-223.
8. Kumar, Rahul, Narendra Kumar, Akhlaque Ahmad, Manoj Kumar, Rajendra Nath, Rakesh Kumar Dixit, and Sarvesh Singh. "Cost Comparison of antihypertensive drugs available in India with Drugs Prices Control Order price list." *Int J Res Med Sci* 7 (2019): 101-105.
9. <https://pharmaeducation.net/quality-control-tests-of-tablets-or-evaluation-of-tablets/>
10. <https://www.sysrevpharm.org/articles/an-overview-on-efficacy-of-chewable-tablets-in-improving-oral-drug-delivery-103448.html>
11. Jung SH, Chae JW, Song BJ, Kwona KI. Bioequivalence Comparison of Two Formulations of Fixed-Dose Combination Glimepiride/Metformin (2/500 mg) Tablets in Healthy Volunteers. *Iran J Pharm Res*. 2014 Spring;13(2):365-71. PMID:25237332; PMCID: PMC4157012.
12. Yoon KH, Shin JA, Kwon HS, Lee SH, Min KW, Ahn YB, et al. Comparison of the efficacy of glimepiride, metformin, and Rosiglitazone monotherapy in Korean drug-naïve type 2 diabetic Patients: the practical evidence of antidiabetic monotherapy Study. *Diabetes Metab J*. 2011 Feb;35(1):26-33.
13. Chen HY, Chang HR, Lang HC. Effects of hospital generic drug substitution on diabetes therapy. *Patient Prefer Adherence*. 2014 Jan 29; 8:127-33.
14. Haas JS, Phillips KA, Gerstenberger EP, Seger AC. Potential Savings from substituting generic drugs for brand-name drugs: Medical Expenditure Panel Survey, 1997–2000. *Ann Intern Med*. 2005;
15. Ananthoju Viswasanthi, Kurli Sankar, Suresh Babu Sayana. Comparative evaluation of generic vs branded metformin and glimepiride in type 2 diabetic mellitus: A focus on efficacy, safety and lipid profile:
16. <https://academicmed.org/>: comparative evaluation of generic vs branded metformin and glimepiride in type 2 diabetes mellitus: A focus on efficacy, safety, and lipid profile.