

Invitro evaluation of generic vs branded product of metformin tablet

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Abstract

The main aim and objective of present research work is to evaluate and compare the standards concerning quality of generic and branded anti hyperglycemic drug (Metformin Hcl). Metformin tablets are evaluated as per standard protocol and results shows that branded and generic meets the pharmacopoeial specifications. All tablets passed the test of weight variation, hardness, thickness, friability, disintegration, dissolution and assay as per Indian pharmacopoeia. Both the generic and branded tablets of metformin shows similar results. So, health care professionals are suggested to prescribe generic drug so, that everyone can reach the cost of the drug and maintain good health.

Keywords: Metformin; Generic vs brand; Evaluation tests; Product

1. Introduction

Metformin hydrochloride is an orally administered biguanide, widely used in the management of type-2 diabetes, a common disease that combines defects of both insulin secretion and insulin action. Jean Sterne, the French physician who first reported the use of Metformin to treat diabetes in 1957. Glucophage was the first branded formulation of Metformin to be marketed in the U.S in 1995. Some of the marketed products of metformin are Glycomet, Okamet, Metrose, Melmet. The mechanism by which metformin increases insulin sensitivity and glucose uptake into cells, and inhibits hepatic gluconeogenesis. It is a hydrophilic drug which slowly and incompletely absorbed from the gastrointestinal tract; the absolute bioavailability is reported to be of 50 - 60% has relatively short biological half life of 1.5 - 4.5 h. However, frequent dosing schedule and risk of gastrointestinal symptoms make its dose optimization complicated. Thus, it is reasonable to assume the requirement of sustained release metformin.

Table 1 Labeling Contents of Metformin tablet

Tablet Name	Cost of drug (per 10 tablets)	Manufacturer	Batch No	MFG Date	EXP Date
Metformin Hydrochloride (generic)	Rs.6.60	Maharashrtra based company	LJJ2309	03/2023	02/2025
Glycomet	Rs.18.70	Mumbai based company	28024308	05/2023	04/2026

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2. Material and methods

Metformin hydrochloride was obtained as a marketed product sample from USV Ltd Mumbai as well as from the government hospital pharmaceutical store. All other chemicals used were of analytical reagent grade. Freshly prepared distilled water was used in the study.

2.1. Methodology

Various analytical methods and test are important for the development and manufacture of pharmaceutical formulation. Metformin tablets were evaluated as per Indian pharmacopoeial standard

2.2. Evaluation test for tablets

2.2.1. Weight variation test

The test was performed using a Digital Electronic Balance and followed the procedure of Indian Pharmacopoeia. Twenty tablets of Metformin chosen from each batch randomly and weighed individually and then collectively. The weight variation was checked for individual tablets and deviation can be calculated by the given formula.

$$\% \text{ Weight variation} = (\text{weight of single tablet} - \text{Average weight of 20 tablets}) \times 100\%$$

2.2.2. Tablet Hardness (h)

The tablet hardness was measured by using a Monsanto hardness tester. The hardness of a tablet determines its ability to withstand a mechanical shock while being handled.

2.2.3. Friability (%F)

Ten tablets of each brand were taken and weight, these tablet subjected to abrasion using a Roche Friabilator at 100 revolutions for 4 mins. The tablets Were dedusted carefully and weighed accurately again then percentage of weight loss recorded. The friability of the tablets was calculated using the formula.

$$\% \text{ Friability} = [(\text{Initial weight} - \text{Final weight}) / \text{Initial Weight}] \times 100$$

Thickness (t) and diameter of the tablet

Vernier calliper was used to determine the diameter and thickness (mm) of the tablets. 10

tablets from each batch were used and average values were calculated.

2.2.4. In-Vitro Disintegration test

Disintegration time was determined using the disintegration apparatus USP distilled water at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ was used a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds .

2.2.5. In-Vitro Dissolution test

The USP paddle type II Dissolution equipment was used to examine the in vitro dissolution of a matrix tablet at a speed of 50 rpm. For the first two hours 900 mL of acid buffer (pH 1.2), was used, followed by phosphate buffer (pH 6.8) solution for the next 12 hr. The temperature of the dissolution medium was kept constant at 37.5°C throughout the study. At regular intervals, a sufficient volume of samples was collected and promptly filtered using a membrane filter. After each sampling, a volume of dissolving medium equal to the volume of the samples removed was added to the vessel. The UV-visible spectrophotometer was used to determine the concentration of the drug in the samples at 233 nm.

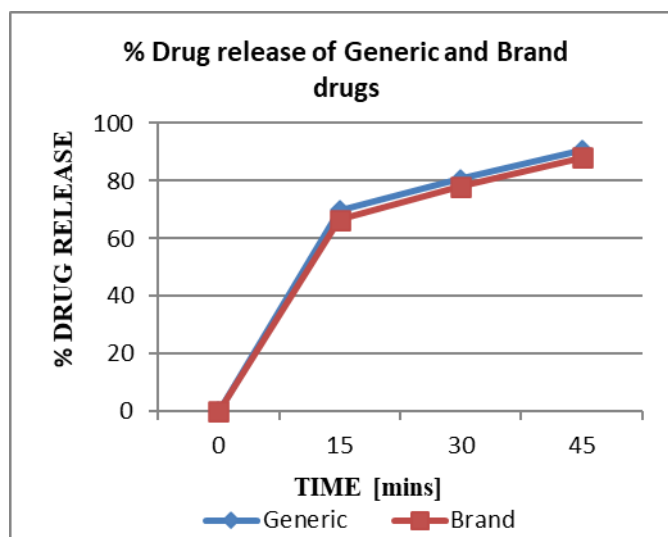


Figure 1 Dissolution profile of generic and branded drugs of Metformin.

2.3. Assay

2.3.1. Preparation of stock solution

A standard solution of Metformin hydrochloride was prepared by dissolving 100 mg of Metformin hydrochloride in 100 ml of distilled water and further diluted with water to get concentration of 100 $\mu\text{g/ml}$

2.3.2. Selection of wavelength

1 ml of aliquot of stock solution was diluted to 10 ml with water and absorbance was measured in the scanning mode from 200 to 400 nm against water as reference. Wavelength corresponding maxima absorbance in water was found at 232 nm.

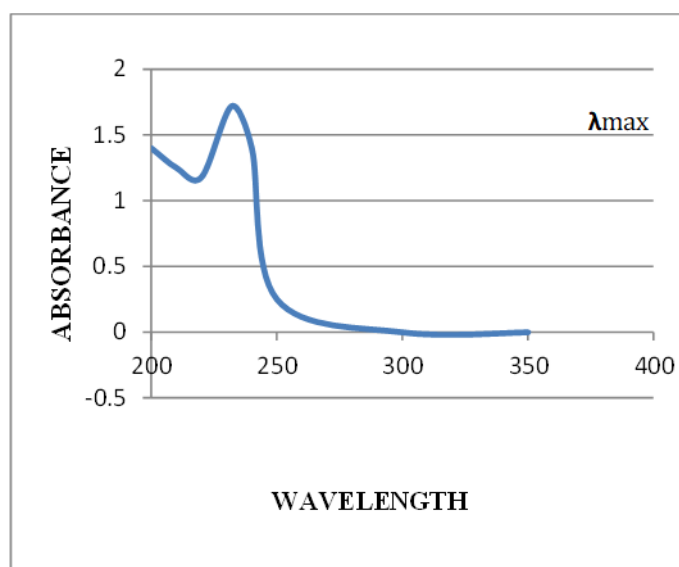


Figure 2 UV spectrum of Metformin

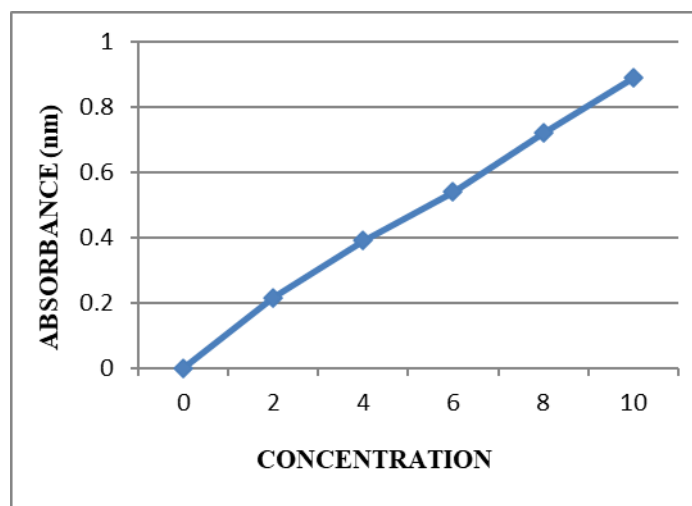


Figure 3 Calibration curve of Metformin.

2.4. Procedure

Weigh and powder 20 tablets. Weigh quantity of the powder containing about 0.1 g of metformin hydrochloride shake with 70 ml of water for 15 minutes. Dilute to 100ml with water and filter. Dilute 10 ml of the filtrate to 100 ml with water. Further dilute 10 ml to 100 ml with water and measure the absorbance of the resulting solution at the maximum at about 232 nm. Calculate the content of C₄H₁₁N₅, HCl taking 798 as the specific absorbance at 232 nm.

Table 2 Calibration curve data of Metformin

S.No	Concentration (µg/ml)	Absorbance (nm)
1	0	0
2	2	0.215
3	4	0.390
4	6	0.540
5	8	0.720
6	10	0.890

Table 3 Evaluation test for Metformin

SI NO	Tablet name	Weight variation	Hardness Test	Friability test	Thickness test	Disintegration Test	Disolution rate	Assay
	Standard as per I.P	±5% For >250mg	3-10 Kg/cm ²	<1%	±5%	30 mins	Not less than 70%	95-105%
1	Generic drug	±0.669%	7.17	0.42%	±0.183	12 mins- 6 secs	90.79%	98.3%
2	Brand drug	±0.983	6.81	0.4%	±0.83	8 mins- 33 sec	87.98%	101.2%

3. Result and discussion

The present study was aimed to compare the branded and generic tablets based on the cost and evaluation test of tablets. It was observed that weight variation, hardness, thickness, friability, disintegration, dissolution and assay results show similar for both branded and generic drugs. The results shown by both the generic and branded drugs met the requirements of IP specified limits. The disintegration time of both branded and generic drug are in the specified limit while generic tablet show slightly higher disintegration time.

4. Conclusion

Finally, this study shows that the test specifications of both the generic and branded Metformin tablets were found to be comply with Indian pharmacopoeial standards. Hence health care authorities are advised to widely use generic form of drug which is cost efficient and easily affordable and promotes good health.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

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