

Review Article

COMPREHENSIVE EVALUATION OF DIFFERENT BRANDS OF METFORMIN HYDROCHLORIDE TABLETS: A COMPARATIVE ANALYSIS

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KEYWORDS

Metformin, Dissolution, Assay, Weight Variation

ARTICLE HISTORY

Received Date: 11/07/2026

Revised Date: 15/07/2026

Accepted Date: 13/08/2026

Published Date: 10/09/2026

DOI: 10.69557/ujrra.v5i3.313

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ABSTRACT

Objective: Metformin, a drug with high solubility but low permeability, is commonly prescribed for managing Type 2 diabetes, especially among obese individuals. This study intends to conduct a comparative assessment of three different 500 mg Metformin hydrochloride brands available in the Mandsaur market. The evaluation includes dissolution, assay, and weight variation tests.

Methods: Dissolution, assay, and weight variation tests were performed in accordance with the United States Pharmacopeia (USP) guidelines. The dissolution tests utilized a 6.8 phosphate buffer.

Results: All three Metformin brands complied with USP specifications. The dissolution rates after 30 and 45 minutes varied from 72-78% and 88-96%, respectively. The percentage purity of all three brands of metformin hydrochloride was within the USP monograph standards (95-105%). Additionally, all tablets showed weight variation within the acceptable range ($\pm 5\%$) according to USP norms.

Conclusion: This study confirmed that all three brands of 500 mg Metformin hydrochloride tablets consistently met the quality standards set by the United States Pharmacopeia.

INTRODUCTION

Metformin is utilized to manage high blood sugar levels in individuals suffering from type 2 diabetes mellitus. In this condition, the pancreas is unable to adequately facilitate the uptake of sugar into the cells via insulin. Metformin can reduce elevated blood glucose levels and enhance the body's ability to convert food into energy, whether taken alone, with sulfonylureas (a type of oral antidiabetic), or alongside insulin.

This medication is not effective for those with insulin-dependent diabetes, or type 1 diabetes, as these individuals lack pancreatic insulin production and typically need insulin injections for optimal blood sugar control. Notably, a substantial number of these patients are not receiving appropriate treatment, which is alarming. The rates of diabetes and untreated cases have been climbing over recent decades, emphasizing a significant global health issue. This trend illustrates the critical need for enhanced access to diabetes treatment and care, particularly in under-resourced areas.

According to the Biopharmaceutics Classification System (BCS), metformin is categorized as a class III drug, indicating its absorption is more limited by permeability than solubility. Quick dissolution of the drug is essential to maximize the interaction time between the dissolved drug and the absorbing mucosa. Thus, it is critical to define stringent dissolution time guidelines for medications like metformin. In vitro testing allows for the differentiation between acceptable and substandard pharmaceutical products, where acceptable products demonstrate bioequivalence in vivo, while non-compliant ones fail to meet these benchmarks.

An assay is conducted to ascertain the purity percentage of the active pharmaceutical ingredient (API) in the formulation, ideally falling within 95-105%. Metformin shows peak absorbance at 233 nm. The weight variation test assesses dosage uniformity, a key factor in ensuring the overall quality of the product.

Despite the growing number of drug brands entering the global pharmaceutical market aimed at improving public health, the issue of substandard drugs persists. Pharmaceutical products must adhere to strict standards for safety, potency, efficacy, and consistency in addition to regulatory guidelines. Conducting quality assessment studies, such as in vitro dissolution and assay tests, on marketed drug products offers invaluable insights into the quality of pharmaceuticals available to the public. This study seeks to evaluate critical quality parameters—specifically dissolution and assay—of various brands of metformin hydrochloride.

MATERIALS AND METHOD

Study Area and Period

The research was carried out from February 2025 to March 2025 at B.R. Nahata College of Pharmacy, Mandsaur University, situated in Mandsaur district, Madhya Pradesh, India.

Study Design

An investigation into the in vitro dissolution test, assay, and weight variation test of available metformin hydrochloride tablet brands in Mandsaur City.

Instruments

- UV Spectrophotometer (Shimadzu, Japan, UV-1900i)
- Digital Analytical Balance (Denver Instrument)
- Dissolution Test Apparatus (TDT-08L)
- Digital pH Meter (DPH-115 PM)

Chemicals and Reagents Used

- Potassium Dihydrogen Orthophosphate (CAS no. 7778-77-0)
- Sodium Hydroxide (GACL)
- HPLC Graded Water (Loba Chemie Pvt. Ltd, Batch no. K053402407)
- Metformin Standard
- Methanol (HPLC Graded)
- Distilled Water

Preparation of 6.8 pH Phosphate Buffer

68 g of Potassium Dihydrogen Phosphate was dissolved in 10 liters of distilled water, and the pH was adjusted using 9 g of filtered Sodium Hydroxide solution.

Sampling Technique and Sample Collection

Three distinct brands of Metformin HCl 500 mg tablets were acquired from the Central Medical store in Mandsaur city. Relevant information is detailed in Table 1.

Table 1: Relevant Information on Metformin Tablets

Brand Code	Trade Name	Manufacturing Date	Expiry Date	Country of Origin	Manufacturer
M1	Glycomet	03/2024	02/2027	India	USV Private Limited
M2	Glyciphage	10/2024	09/2027	India	FRANCO-INDIAN
M3	Okamet	03/2024	02/2027	India	Cipla

Dissolution Test

Standard Preparation

A stock solution was prepared by dissolving 100 mg of metformin hydrochloride in 10 mL of methanol and sonicating it for 5 minutes. The volume was then adjusted to 200 mL with HPLC Graded water. From this stock solution, 2 mL was pipetted, filtered through a 45µ nylon filter, and transferred to a 100 mL volumetric flask. The volume was completed with 6.8 pH phosphate buffer to create a 10 µg/mL solution. This method was repeated three times to

prepare three standard solutions of 10 µg/mL.

Dissolution Procedure

The dissolution apparatus was set up according to USP specifications:

- Dissolution medium-6.8 phosphate buffer Temperature- $37 \pm 0.5^{\circ}\text{C}$
- RPM- 100
- Apparatus- USP-1 (Basket)
- Volume- 1000ml
- Sampling time point- 30min. and 45 min.

The dissolution test is performed only when the apparatus met all the USP specifications. Six tablets from different brands of metformin hydrochloride tablets were fallen in the dissolution vessel containing dissolution medium for the dissolution test. 10 ml samples were withdrawn from each dissolution vessel at the intervals of 30 min and 45 minutes. After the withdrawal of sample, 10 ml dissolution media was added to each dissolution vessel to maintain constant volume. All the six samples from each brand were filtered through 45 µ nylon filter paper. 2 ml from each sample was pipetted out and transferred to 100 ml volumetric flask and the final volume was made up by the buffer to form the solution of 10 µg/mL. At last, the absorbance of each sample was measured at the wavelength 233nm This procedure was repeated for all three brands of metformin hydrochloride.

Assay

Preparation of Standard Solution of Metformin

100 mg of the metformin standard was accurately weighed and placed into a 100 mL volumetric flask. A small volume of HPLC Graded water was added, and the mixture was sonicated for 5 minutes. Following sonication, the volume was adjusted to 100 mL with HPLC Graded water. 5 mL of this stock solution was filtered using 45µ nylon filter paper, transferred to a 100 mL volumetric flask, and the volume was brought to 100 mL with HPLC Graded water to yield a 10 µg/mL solution.

Preparation of Samples of Three Brands of Metformin

Average weight of 20 tablets from each brand of metformin hydrochloride was calculated and the 20 tablets were crushed. The weight of powdered drug equivalent to 100 mg of actual metformin hydrochloride was weighed of each brand. The powdered tablet is dissolved in small amount of HPLC graded water in 100 ml volumetric flask. The mixture was sonicated till the drug dissolved and the volume was adjusted using HPLC graded water. 5ml of this solution was pipetted out and filtered using 45 µ nylon filter paper and transferred to a 100 ml volumetric flask, in which volume was adjusted using HPLC graded water. Finally, 10 µg/mL solution of each brand was prepared. This process was repeated for all three brands of metformin hydrochloride tablets.

Weight Variation Test:

Average weight of twenty tablets of each brand of metformin hydrochloride was calculated. As the tablets are 500 mg, according to USP the acceptable range of variation is $\pm 5\%$ of the average weight of the tablet.

RESULT

Dissolution Test

Standard preparation

Three standards were prepared for the dissolution calibration of metformin tablets, and their absorbance was determined by UV- visible spectrophotometer and was consistently found at 233 nm.

Dissolution of Tablets from Different Brands

According to USP specifications, the dissolution test requires at least 75% of the active ingredients to dissolve within a 45-minute period for the test to be considered successful. The drug release profiles (%) for the different Metformin tablet brands are displayed in Table 2.

Table 2: Drug Release Profile (%) of Different Metformin Tablet Brands

Sr. No.	Brand	Drug Release Profile (%) 30min	Drug Release Profile (%) 45min
1	M1	72%	88%
2	M2	76%	96%
3	M3	78%	95%

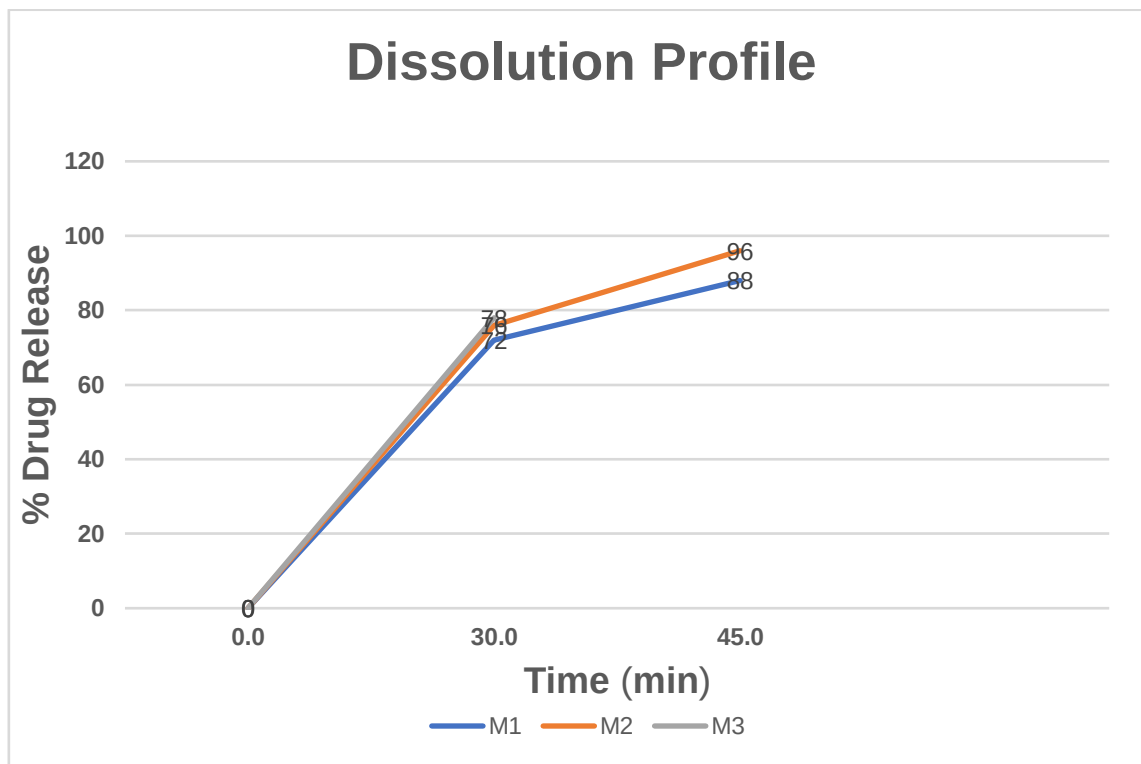


Figure 1: Dissolution Profiles of Three Commercial Metformin 500 mg Tablets.

Assay

All three brands of 500 mg Metformin hydrochloride tablets met USP specifications, with percentage purity ranging from 95% to 105%. The absorbance and percentage purity of the different brands of metformin tablets were determined by UV-visible spectrophotometer and are summarized in Table 3.

Table 3: Percentage Purity, Labelled Weight, Average Weight, and Absorbance Spectra of Three Metformin Tablet Brands

Brand	Labelled Weight (mg)	Average Weight (mg)	Absorbance	Assay (%)
M1	500	593.28	0.744	97.97%
M2	500	549.50	0.789	99.87%
M3	500	522.78	0.798	101.01%

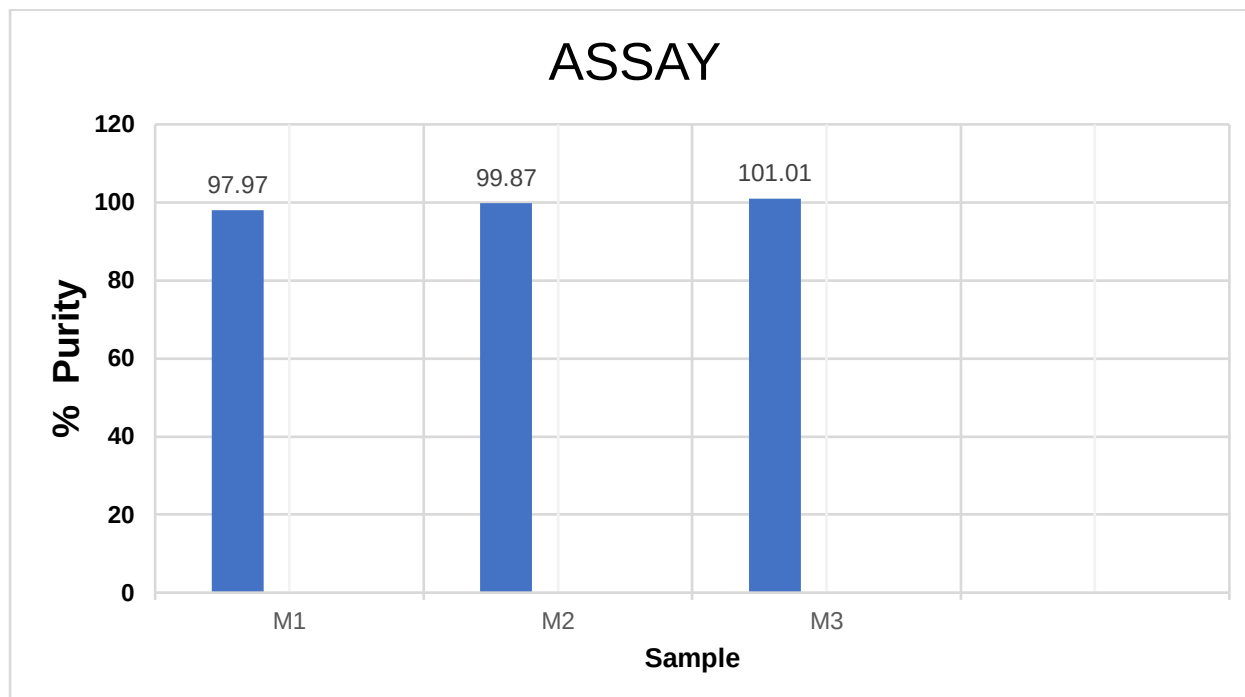


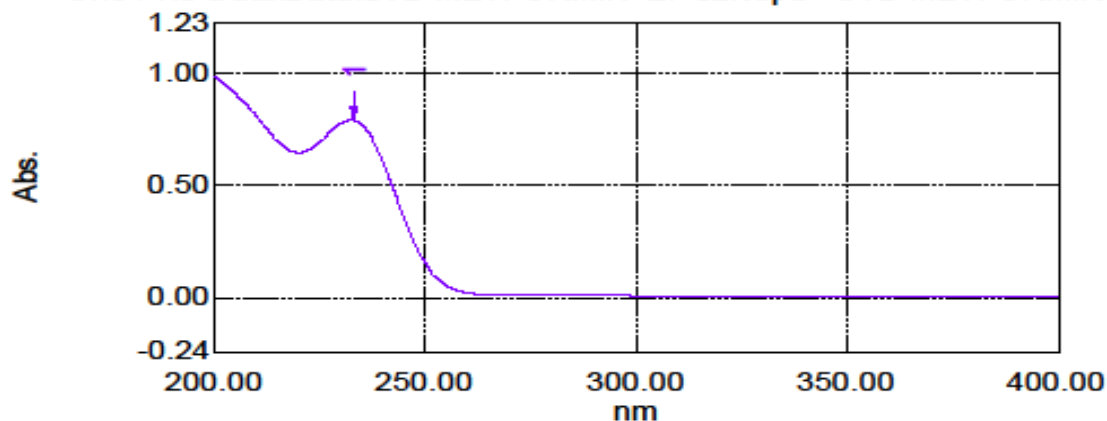
Figure 2: Percentage Purity of Three Metformin Tablet Brands.

Spectrum Point Pick

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C:\UVVis-Data\Data\STD METFORMIN 27-02.vspd - STD METFORMIN 27-02



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Sample ID: STD METFORMIN 27-02
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Analyst: PRIYANKA SISODIYA
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Software Information

Software Name: LabSolutions UV-Vis
Version: 1.11

Instrument Information

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Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12535880854)

Report File Name:

[Point Pick Table]

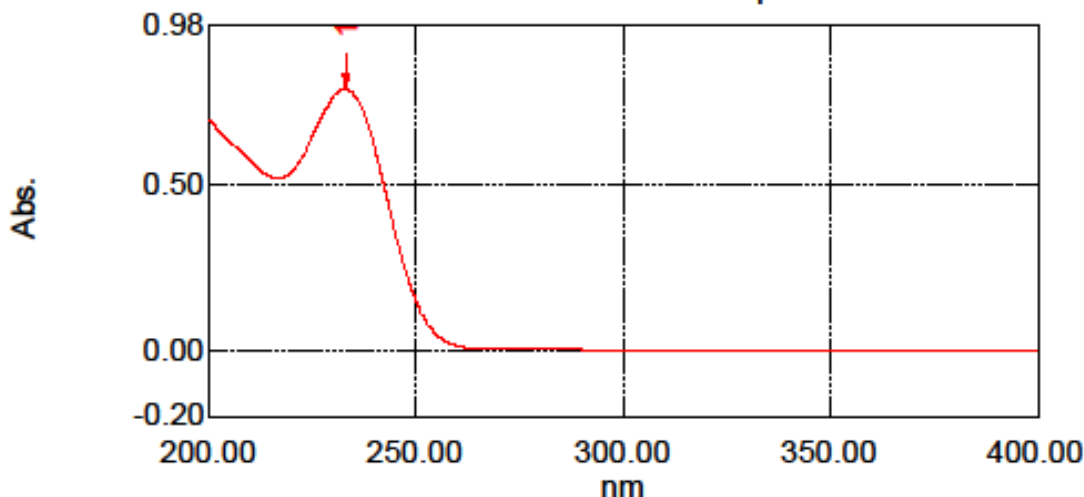
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Spectrum Point Pick

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[Summary]

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Report File Name:

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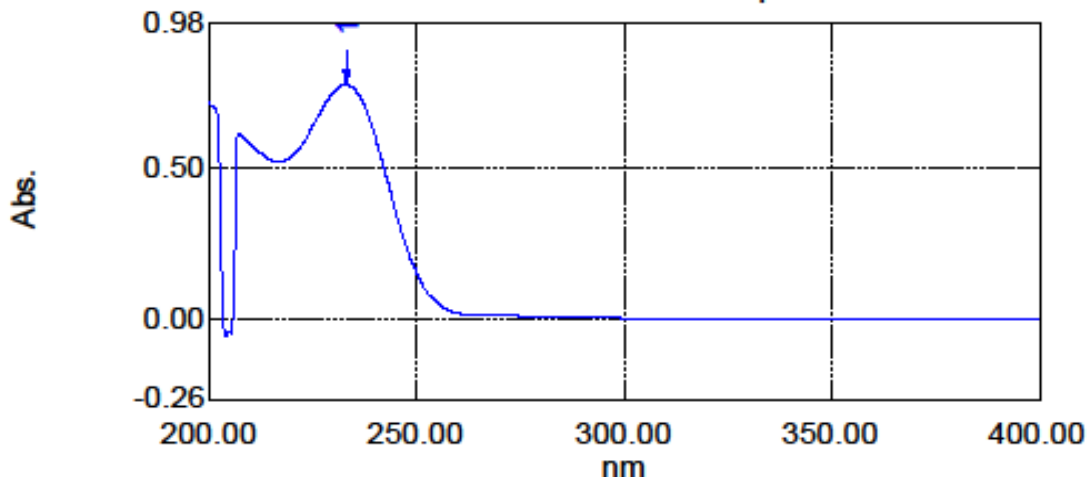
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Software Information

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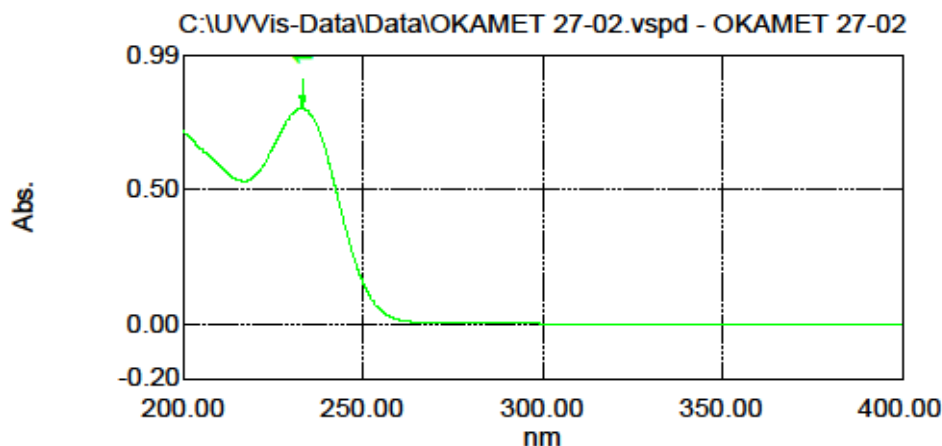
[Point Pick Table]

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1	233.0	0.774	

Spectrum Point Pick

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Software Information

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Version: 1.11

Instrument Information

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Instrument Type: UV-1900 Series
Model (S/N): UV-1900i (A12535880954)

Report File Name:

[Point Pick Table]

No.	Wavelength nm.	Absorbance	Description
1	233.0	0.798	

Weight Variation Test

All three tablet brands confirmed the weight variation test criteria as per USP standards. The test is deemed successful as the weight of all the tablets are within the range of $\pm 5\%$ of the

average weight of the twenty tablets.

Table 4: Weight Variation Test of Metformin Tablets

Brand	Total Weight (20 Tablets) (mg)	Average Weight (mg) $\pm$ SD	No. of Tablets Deviating by $\pm 5\%$
M1	11865.6	593.28 $\pm$ 29.66	Nil
M2	10990.1	549.50 $\pm$ 27.47	Nil
M3	10455.6	522.78 $\pm$ 26.13	Nil

CONCLUSION

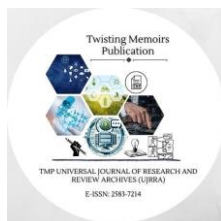
This study determined that all brands adhered to the specifications of the USP pharmacopoeia regarding drug release, percentage purity, and weight variation. Based on factors such as fit factors and variations in dissolution efficiency, all brands may be used interchangeably with the innovator drug, although it is advisable to consult regarding potential minor gastrointestinal complications that could arise from using these alternative medications.

Acknowledgement

The author expresses gratitude to B.R. Nahata College of Pharmacy (Mandsaur University) and the Faculty of Pharmacy for their invaluable assistance and support.

REFERENCES

1. Abozaid, D. M., & Saleh, W. M. (2024). Evaluation of some metformin hydrochloride brands available in the Libyan market. *Mediterranean Journal of Pharmacy and Pharmaceutical Sciences*, 2(4), 6-12.in Ghana. *Br J Pharm Res*, 9(1), 1-14.
2. Afifi, S. A., & Ahmadeen, S. (2012). A comparative study for evaluation of different brands of metformin hydrochloride 500 mg tablets marketed in Saudi Arabia. *Life Sci J*, 9(4), 4260-4266.
3. Afifi, S. A., & Ahmadeen, S. Comparative evaluation of different brands of Metformin hydrochloride 500mg tablets marketed in Saudi Arabia.
4. Flatie Alemu, A., Tegegne, A. A., & Getaw, N. S. (2024). Evaluation of Seven Different Brands of Metformin Hydrochloride Tablets Available in the Market in Gondar City, Ethiopia. *Drug, Healthcare and Patient Safety*, 19-28.
5. Hamdan, I., & Jaber, A. B. (2010). Pharmaceutical evaluation of metformin HCl products available in the Jordanian market. *Jordan Journal of Pharmaceutical Sciences*, 3(1).
6. Jahan, N. (2017). *In-vitro Comparative Dissolution Study of Three Different Brands (Comet, Informate, Bigmet) of Metformin Hydrochloride Tablets Available in Bangladesh* (Doctoral dissertation, East West University).



7. Kassahun, H., Asres, K., & Ashenef, A. (2019). In vitro quality evaluation of metformin hydrochloride tablets marketed in Addis Ababa. *Bangladesh Journal of Scientific and Industrial Research*, 54(2), 169-176.
8. Lakmali, E. M. M. S., Thanujah, M., Thuvaragan, S., & Kuruppu, K. D. A. (2021). Comparative evaluation of metformin hydrochloride brands available in Sri Lanka.
9. Rabbi, M. F. (2016). *In-vitro Comparative Dissolution Study of Different Brands (Glucomet, Met and Daomin) of Metformin Hydrochloride Tablets Available in Bangladesh* (Doctoral dissertation, East West University).
10. Sougi, A., Ofori-Kwakye, K., Kuntworbe, N., Kipo, S. L., & El Boakye-Gyasi, M. (2016). Evaluation of the physicochemical and in vitro dissolution properties of metformin hydrochloride tablet brands marketed in five cities.