

**COMPARATIVE STUDY OF DISSOLUTION PROFILE STUDIES OF
DIFFERENT MARKETING TABLETS OF METFORMIN HCL*****Nishigandha Mane**

India.

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ABSTRACT

Metformin hydrochloride is an oral anti-diabetic drug used mainly to treat type II diabetes mellitus and available as several brands in the market which make it difficult to select the safe, effective and economic one. The aim of this research work was to compare dissolution profile studies and check and evaluate the quality standards of different brands of Metformin hydrochloride tablets available in local market of Solapur, India. Three brands of Metformin tablets (500mg) were selected and evaluated comparatively for their physical and chemical parameters specially dissolution profiles of each brand as per official method. The physiochemical equivalence of all the tablet brands were assessed through evaluation of

both official. By comparing dissolution profiles of various marketed Metformin HCl tablets, this research aims to evaluate their compliance with pharmacopeial standards and detect potential deviations that may impact clinical outcomes. The findings reinforce the need for stringent dissolution testing as a key quality control tool to ensure patient safety and maintain product performance throughout its shelf life. Overall, comparative dissolution studies ensures product integrity, supports therapeutic reliability, and helps safeguard public health.

INTRODUCTION

Dissolution profile studies of marketed tablets are vital to ensure consistent drug performance and therapeutic effectiveness. They evaluate how quickly and how much of the active pharmaceutical ingredient (API) is released under controlled conditions. These studies help confirm that tablets meet quality standards throughout their shelf life, maintaining bioavailability and clinical efficacy. Improper dissolution can lower the drug's bioavailability,

potentially affecting its therapeutic effect and safety. Dissolution studies are important to maintain uniformity between batches and are required by regulatory authorities like the FDA and EMA for product approval and regulatory compliance.

Dissolution profile studies are essential for identifying hidden formulation issues that may not arise during early development or clinical testing. Factors like excipient changes, manufacturing variations, or storage conditions can affect how a tablet dissolves. Regular testing helps manufacturers detect these changes early and take corrective action to protect patient safety. These studies are also vital in generic drug development, where matching the reference product's dissolution profile proves bioequivalence. Additionally, they support the design of advanced drug delivery systems like extended- or controlled-release tablets. Overall, dissolution studies ensure the quality, safety, and effectiveness of tablet products throughout their lifecycle.

Ensuring Consistent Drug Release, Regulatory Requirements, Bioavailability and Clinical Efficacy, Detecting Formulation Issues, Supporting Generic Drug Development, Improving Formulation Design, these are some key reasons why dissolution studies are essential.

Comparative dissolution profile studies significantly impact generic drug approval, post-marketing evaluation, and formulation enhancement. They are essential for demonstrating bioequivalence, a regulatory requirement confirmed by matching the generic drug's dissolution profile with that of the reference product (FDA, 2021). This ensures similar API release rates and therapeutic outcomes. Regulatory agencies like the FDA and EMA rely on such studies to assess bioequivalence and ensure product safety and efficacy (FDA, 2018). These evaluations support consistent drug performance and regulatory compliance across the pharmaceutical industry.^[8]

Additionally, comparative dissolution studies are important for monitoring the stability and consistency of marketed products, especially when there are changes in manufacturing processes or formulation. For example, when there is a change in the excipient or the manufacturing equipment used to produce the tablet, comparative dissolution studies can help ensure that the dissolution characteristics remain unaffected and meet the product's specifications. The European Medicines Agency (EMA) emphasizes that any significant changes in formulation or production processes that may affect dissolution must be closely monitored (EMA, 2020). This is crucial for maintaining the therapeutic efficacy of the drug

throughout its shelf life and ensuring patients receive a product that performs consistently. Moreover, comparative dissolution studies serve as an early detection mechanism to identify potential formulation issues that could impact the drug's release profile, thus ensuring the continued safety and effectiveness of marketed tablets.^[9]

The WHO reported that 15.8% of substandard or falsified products are used to treat non-communicable diseases (NCDs), which make up 80% of the global health burden, including diseases like diabetes, cancer, and heart disease, leading to higher mortality. Diabetes, a common and incurable condition, requires lifelong management. It occurs when the body can't produce enough insulin or respond to it effectively. By 2030, 643 million people are expected to have diabetes, with most cases in low- and middle-income countries. Metformin is a widely prescribed drug for treating type II diabetes, as it helps reduce glucose production and increases insulin sensitivity.

Metformin hydrochloride is a white crystalline powder, highly soluble in water, and has a molecular weight of 165.62 g/mole. It's usually formulated in its hydrochloride salt form due to its low permeability, which affects absorption. This means strict dissolution testing is needed for this Class-III drug.

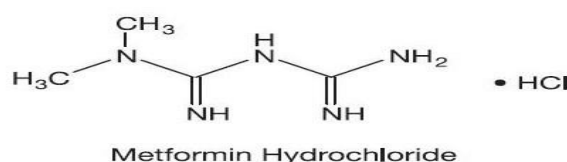


Fig. No. 1 Structure Of Metformin Hydrochloride.

Metformin hydrochloride (HCl) is a cornerstone therapeutic agent primarily used in the management of type 2 diabetes mellitus (T2DM), a chronic condition that affects millions of individuals worldwide. Originally derived from *Galega officinalis* (goat's rue), a plant historically used for treating diabetes-like symptoms, metformin was first synthesized in the 1920s by chemist Jean Sterne.^[10] However, its clinical use did not commence until the 1950s in Europe and only reached the United States market in 1995, following rigorous evaluation

of its safety and efficacy (Bailey & Turner, 1996). Metformin belongs to the biguanide class of drugs, which also includes the now largely discontinued phenformin. It primarily works by reducing hepatic glucose production (hepatic gluconeogenesis), which is one of the major contributors to hyperglycemia in type 2 diabetes.^[11] Metformin achieves this by inhibiting mitochondrial respiratory chain complex I, leading to an increase in AMP-activated protein kinase (AMPK) activity, which subsequently reduces glucose production. This action is complemented by an enhancement of insulin sensitivity in peripheral tissues, notably muscle and fat cells, increasing glucose uptake. Metformin also appears to have a beneficial effect on lipid metabolism, lowering triglyceride levels, and may modestly reduce body weight, making it particularly advantageous for overweight or obese patients with diabetes. This dual effect of lowering blood glucose levels and reducing insulin resistance makes metformin the preferred first-line drug in managing T2DM, as it does not typically cause hypoglycemia (hypoglycemic events are rare compared to insulin or sulfonylureas). The safety profile of metformin is generally favorable, although gastrointestinal side effects, such as diarrhoea and nausea, are common. Serious but rare adverse effects include lactic acidosis, a potentially life-threatening condition, especially in patients with impaired renal function or other contraindications.^[12]

In addition to its well-established role in diabetes management, metformin has garnered considerable attention for its potential therapeutic benefits in other areas, including obesity, polycystic ovary syndrome (PCOS), and even cancer. Evidence suggests that metformin may exert anti-inflammatory effects and improve cardiovascular outcomes, which is of particular importance since individuals with type 2 diabetes often face a higher risk of cardiovascular diseases.^[13] The drug's potential beyond diabetes has spurred interest in its use for weight management. Metformin may help with weight loss or prevent weight gain in patients with obesity, and its beneficial effects on appetite and metabolic processes are thought to involve alterations in gut microbiota, reduced fatty acid synthesis, and enhanced fat oxidation. In PCOS, metformin is often used off-label to regulate menstrual cycles, reduce androgen levels, and improve fertility outcomes. Furthermore, preclinical and clinical studies have suggested that metformin may possess anticancer properties.^[14] It is hypothesized that metformin's ability to activate AMPK, inhibit mTORC1 signaling, and reduce insulin levels may decrease the growth of cancer cells, particularly in hormonally driven cancers such as breast and endometrial cancer. However, the precise mechanisms by which metformin may influence cancer progression are still under investigation, and while some clinical trials have

shown promising results, more research is needed before metformin can be definitively recommended for cancer prevention. Additionally, metformin is being explored for its potential to mitigate the effects of aging, with several studies suggesting it may delay the onset of age-related diseases and improve lifespan by enhancing mitochondrial function and promoting autophagy.^[15] Despite its broad range of potential benefits, metformin is not without risks. While rare, lactic acidosis remains a significant concern, especially in patients with renal insufficiency or those undergoing procedures that involve contrast agents, which can impair kidney function. The drug's reputation as a safe and effective treatment for type 2 diabetes continues to grow, but its full spectrum of benefits, especially in non-diabetic conditions, remains a subject of ongoing research.^[16]

Dissolution testing is a crucial quality control measure in pharmaceutical manufacturing, ensuring that solid oral dosage forms such as tablets and capsules release the active pharmaceutical ingredient (API) at the intended rate and extent. The Indian Pharmacopoeia (IP), United States Pharmacopeia (USP), and British Pharmacopoeia (BP) provide well-defined regulatory guidelines and acceptance criteria to standardize dissolution testing across different formulations. According to USP the dissolution test is conducted using specific apparatus types, such as Apparatus 1 (Basket) and Apparatus 2 (Paddle), under controlled conditions of agitation, temperature, and dissolution media. Acceptance criteria in USP are based on a three-stage testing procedure: Stage 1 (S1) requires that six units be tested, and all must meet the dissolution limit (typically $Q+5\%$). If one or more units fail, testing proceeds to Stage 2 (S2), where six additional units are tested, requiring at least 75% compliance. If the criteria are still not met, a final Stage 3 (S3) involves testing another 12 units, with more stringent acceptance criteria. Similarly, BP and IP follow comparable tiered approaches, ensuring that a product consistently meets its dissolution specifications before it can be released for patient use.

Regulatory authorities also emphasize biorelevant dissolution testing to establish a correlation with *in vivo* drug release and absorption. Dissolution acceptance criteria are typically expressed as $Q = 75\%$ to 80% drug release within a specified time (e.g., 30 to 45 minutes) for conventional immediate-release tablets, though extended-release and delayed-release formulations have unique requirements based on their modified-release profiles. Regulatory agencies like the FDA, EMA, and CDSCO mandate that dissolution testing methods be validated for accuracy, precision, specificity, and robustness, ensuring reliable and

reproducible results. Furthermore, dissolution specifications must comply with the specific drug monographs listed in USP, BP, or IP, and additional comparative studies may be required for regulatory submission of generic formulations. In cases where significant variability is observed, regulatory agencies may require in vitro–in vivo correlation (IVIVC) studies to justify dissolution behaviour. Ensuring adherence to pharmacopeial dissolution criteria is critical for regulatory approval, bioequivalence studies, and maintaining product quality throughout its shelf life.^[17]

❖ MATERIAL AND EQUIPMENTS

• Selection of different marketed tablet formulations

To carry out a comparative dissolution profile study of different marketed tablet formulations of Metformin HCL, it involves selection of suitable branded formulations.

• Selection Criteria for Marketed Metformin Tablets

Strength: Commonly available strengths include 500 mg, 850 mg, and 1000 mg. For consistency, I chosen one strength i.e. 500 mg

• **Dosage Form:** In this we have to Focus on immediate release (IR) or extended release (XR), depending on study objectives. Here I took uncoated immediate release tablets.

• **Manufacturer/Brand Diversity:** I chosen 3 different brands available in my region to ensure meaningful comparison.

• **Availability:** Ensure formulations are readily available from pharmacies for procurement and testing.

• **Regulatory Approval:** I Preferred brands that are approved by national regulatory authorities (e.g., FDA, EMA, CDSCO).^[18]

➤ Table of Selected Brands

➤ Table No. 1: Selected Brands of Metformin HCL tablets.

Brand	Batch No.	Mfg. Date	Exp. Date	Manufacturer
Metatime	K1AFX004	12/24	11/27	MANKIND PHARMA
Glycomet	26010362	11/24	10/27	USV Limited
Glyciphage	K23127	08/23	07/26	FRANCO-INDIAN Remedies Pvt. Ltd.

➤ Chemicals and Reagents

➤ Table No. 2: Chemicals and its manufacturer.

Chemical	Manufacturer
Potassium Hydrogenphosphate	S.D. Labchemical Centre Mumbai
Hydrochloric acid	S.D.Lab Chemical Centre

➤ Equipments/ Instruments

Analytical Balance, pH meter Tablet Dissolution Test Apparatus(DS8000 LABINDIA), Double Beam UV–Spectrophotometer (AU 2702SystronicsIndia Ltd.), Roche Friabilator, Monsanto hardness tester, Tablet Disintegration Test Apparatus(Scientific Laboratory Instruments for School and College), Vernier caliper.

❖ EXPERIMENTAL WORK

EVALUATION TEST FOR SELECTED BRANDS OF TABLETS:

1. Visual Examination

The appearance, including shape, size, and color, of various Metformin tablet brands was assessed through visual observation. Additionally, a Vernier caliper was used to measure the dimensions and thickness of the tablets from each brand.

2. Uniformity of Weight

Twenty tablets from each brand were individually weighed using a digital analytical balance. The average tablet weight was calculated, and the percentage deviation of each tablet from this mean value was determined. To comply with the weight variation test as per Indian Pharmacopoeia (I.P.) standards, each tablet must fall within the permissible percentage deviation range.^[19]

3. Hardness Test

The hardness of tablets from different brands was measured using a Monsanto hardness tester, and the results were recorded in Kg/cm². Ten tablets from each brand were tested. Each tablet was placed between the device's spindles and pressure was applied until the tablet broke. The amount of pressure needed to break each tablet was then noted.

4. Friability Test

Ten tablets from each brand were weighed and then placed in a Roche friabilator, where they were rotated 100 times over 4 minutes to simulate handling and transport. Afterward, the tablets were gently cleaned to remove any dust and weighed again. The percentage of weight loss was calculated using the formula:

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

These shows how much weight the tablets lost, which indicates how easily they might break or crumble.

5. Disintegration Test

Six tablets were randomly selected from each brand to check how quickly they break down. The test was carried out using a disintegration apparatus with distilled water at 37°C. The disintegration time was recorded as the point when no particles from any tablet remained on the mesh screen.^[20]

❖ Dissolution Study

• Preparation of Dissolution medium (Buffer solution)

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.^[21]

• Dissolution procedure

The dissolution test was carried out following the guidelines of the USP pharmacopeia. Using a paddle stirrer and an 8-compartment Veego dissolution test device, the dissolving rate of each brand of tablet was measured at 37±0.5°C and 100 rpm. The dissolving fluid was 900 millilitres of phosphate buffer pH 6.8. For every test, a single tablet containing 500 mg was used. Ten millilitres of the dissolving fluid sample were taken out five, ten, fifteen, thirty, forty-five, and sixty minutes apart. To maintain sink condition, a new 10 ml dissolve medium was added after every sampling.

Every sample that was taken out was filtered, and the filtrate was then diluted. The Systronic 2201 U.V. Visible double beam spectrophotometer was used to measure the absorbance at λ_{max} 232 nm. The concentration was measured using the same medium and a standard solution of the medication metformin hydrochloride. The percentage (%) of drug release at a certain time interval was calculated from the concentration. Three duplicates of each dissolving experiment were conducted. The formula is used to determine the percentage of medication released.

Percentage of Drug release (%) = [Amount of drug released (mg/ml)/ drug content in label (mg)] × 100

❖ ESTIMATION OF METFORMIN HYDROCHLORIDE BY UV VISIBLE SPECTROPHOTOMETER

➤ **Selection of Wavelength**

▪ **Preparation of Standard solution**

10 mg of Metformin HCL powder was weighed accurately and dissolved it in 100 ml of phosphate buffer solution, pH 6.8, 0.05 M (solution A). From solution A, 1 ml solution was pipetted out into a 10 ml volumetric flask and diluted to mark with Phosphate Buffer Solution pH 6.8, 0.05 M (solution B)^[22]

▪ **PROCEDURE**

The prepared standard solution was scanned using a UV-visible spectrophotometer in the wavelength range of 200–800 nm with phosphate buffer with pH 6.8 as the blank. The spectrum obtained was carefully examined to identify the wavelength of maximum absorbance (λ_{max}). The region between 200 nm and 400 nm was observed for peak clarity and baseline stability. The λ_{max} was found at approximately 233 nm, showing a sharp and well-defined peak with minimal interference. Based on the absorbance intensity, spectral stability, and absence of noise or solvent interference, 232 nm was selected as the analytical wavelength for the estimation of Metformin HCl in tablet dosage form.

▪ **Calibration Curve procedure**

Metformin hydrochloride was estimated using a UV spectrophotometric method by measuring absorbance at the maximum wavelength (λ_{max}) of 232 nm in a phosphate buffer with pH 6.8. Before conducting the dissolution test, ten serial dilutions of a reference standard solution of Metformin hydrochloride were prepared, and a standard calibration curve was created. The curve was linear within the concentration range of 1–10 $\mu\text{g/ml}$. The average absorbance values were plotted against the corresponding concentrations to generate the calibration curve, and a regression equation was derived.

❖ **Calibration curve**

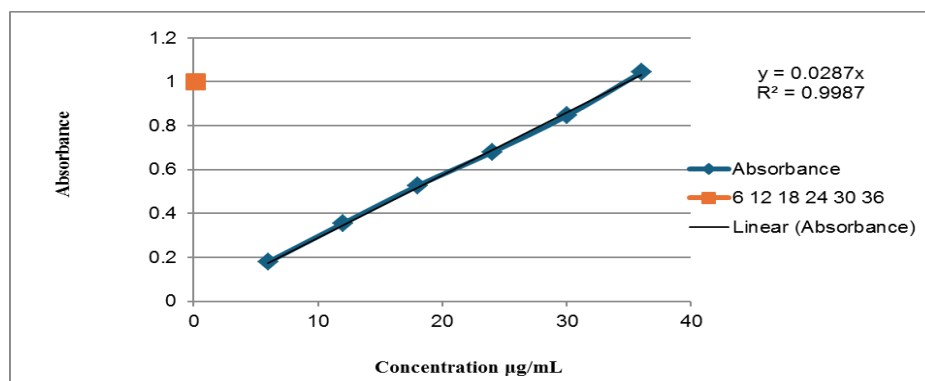


Figure 2: Calibration Curve.

❖ Assay

Twenty metformin hydrochloride tablets were weighed and ground into a fine powder using a mortar and pestle. A portion of this powder, equivalent to 0.1 g of metformin hydrochloride, was mixed with 70 mL of distilled water and shaken for 15 minutes. The mixture was then diluted to 100 mL with distilled water and filtered. From the filtrate, 10 mL was taken and further diluted to 100 mL with distilled water. Subsequently, 10 mL of this solution was again diluted to 100 mL to obtain a final concentration of 10 µg/mL. The absorbance of this solution was measured at 232 nm, and the drug content was determined using an A (1%, 1 cm) value of 798. Distilled water was used as the blank for the measurement.^[23]

RESULT

The evaluation tests are performed for each brand of metformin HCl tablets and the obtained readings are as follow

Table No. 11: shows the in vitro % drug release for tablets containing metformin hydrochloride.

Brand	Size	Thikness	Uniformity of Wieight	Hardness	% Friability	%Purity	Disintegration time
Metatime	1.62	0.32	0.629±0.005	7.48±0.21	0.464	97.73	7 min 58 sec
Glycomet	1.32	0.35	0.606±0.007	7.99±0.18	0.169	96.58	5 min 18 sec
Glyciphage	1.61	0.312	0.554±0.006	5.602±0.13	0.112	102.38	5 min 26 sec

Drug Released (%)

Table No. 11: Percentage Drug Release.

Brand	5 min	10 min	15 min	30min	45min	60min	±SD
Metatime	26.72	43.40	62.20	82.60	93.16	95.92	28.16
Glycomet	28.14	47.06	66.02	84.07	94.12	98.05	27.78
Glyciphage	30.15	43.92	68.04	81.16	88.05	94.92	25.74

The dissolution profile of every tested brand of Metformin hydrochloride tablet is shown in Figure 3.

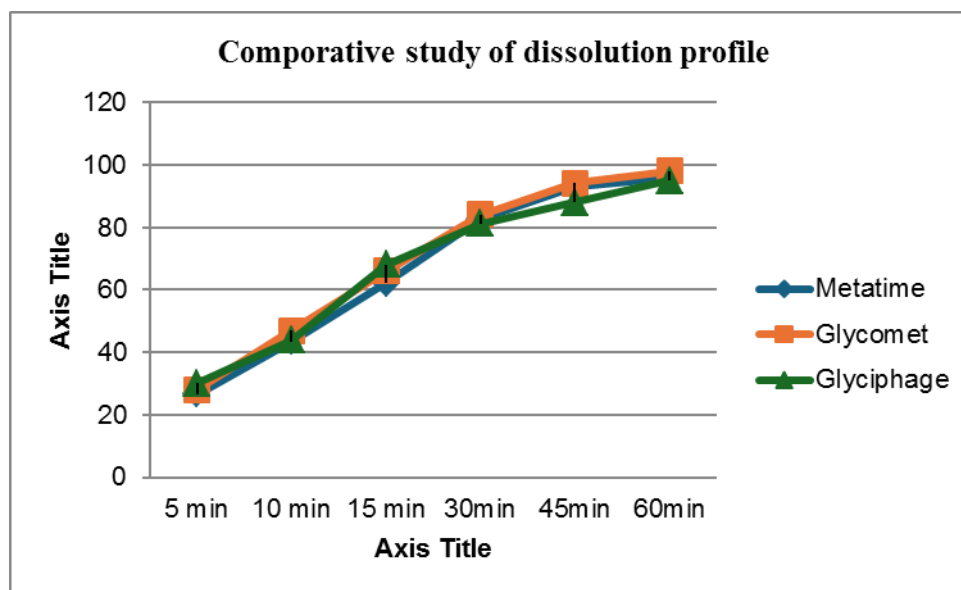


Fig. No. 3: Graphical representation of Comparison of dissolution profiles.

DISCUSSION

The current study's goal is to compare and assess three distinct brands of metformin hydrochloride, in order to evaluate their equivalent in biopharmaceuticals.

The branded Metformin tablet products were assessed for a number of physiochemical characteristics (Table 2). All three brands included tablets that ranged in size from 1.32 to 1.62 cm. The three brands of metformin hydrochloride tablets had consistent weights that complied with I.P. specifications and varied by less than 5% from the average value. The tablets' strength was evaluated using a hardness tester. With all three brands, the tablets' hardness ranged from 3.5 to 4.1 kg/cm².

Every brand tested had remarkable friability scores ranging from 0.110% to 0.821% w/w. No batch should have a friability rating higher than 1% w/w, per I.P.

Glycomet brand tablet had the quickest rate of breakdown, while Metatime was the slowest brand. As shown in table results of the evaluation of the percentage drug content of three different brands of metformin hydrochloride tablets fell between 95% and 105% of the specified amount of metformin HCl within the monograph specification.

For every brand of metformin hydrochloride under investigation, the observed disintegration times were less than the official compendium's 15-minute limit. One crucial component of medication bioavailability is the dissolution of oral solid dose forms. The designed and sold tablets' in-vitro drug release properties were examined. Only the average values were presented because the dissolution data from every experiment was quite repeatable. The dissolving of all threebrand tablets showed that over 80% of the medication was released in 30 minutes.

CONCLUSION

The analysis indicates that all three tested brands of Metformin HCl tablets available in the Solapur, India market comply with established pharmaceutical quality standards. Each brand met the required specifications for weight uniformity, friability, disintegration, assay, and dissolution, as outlined in pharmacopeial guidelines.

The comparative dissolution profile study demonstrated consistent and acceptable drug release among the three brands, with only minor variations observed. These differences remained within pharmaceutically acceptable limits, indicating therapeutic equivalence.

Therefore, switching between these brands of Metformin HCl is generally safe and feasible, particularly in cases where cost or availability is a concern. However, such substitutions should be made under proper medical supervision, and patients should be informed about the potential for mild and temporary gastrointestinal side effects during the transition.

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