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Study of Hepatitis B and C Prevalence and Clinical Patterns in a High-Level Medical Center

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ABSTRACT:
This study evaluates the pharmaceutical quality of metformin tablets, both generic and branded, available in India. Metformin, a primary medication for managing type 2 diabetes was chosen due to its widespread use and critical role in diabetes treatment. Using *in-vitro* methods compliant with Indian Pharmacopoeia standards, several quality control parameters were assessed, including hardness, friability, disintegration time, dissolution profile, and weight variation. The research addresses a common misconception that branded drugs outperform generics in therapeutic efficacy. It aims to demonstrate that generic drugs, when meeting established pharmacopeial standards, are bioequivalent to their branded counterparts. Tablets were sourced from the market and government supply, and rigorous testing was performed to ensure the consistency of active ingredients and adherence to pharmaceutical standards. Results showed that all tested samples met the required quality benchmarks. Generic tablets exhibited comparable performance in These findings highlight the safety, efficacy, and interchangeability of generic metformin tablets with branded alternatives. This study underscores the importance of stringent quality control measures to ensure patient safety and drug effectiveness. By validating the bioequivalence of generic drugs, this research supports their use as cost-effective alternatives to branded medications, particularly for resource-limited populations. It further encourages the adoption of generics in healthcare systems, promoting affordability without compromising quality. These findings advocate for the broader acceptance of generics in combating diseases like diabetes, where medication adherence and affordability are critical.

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INTRODUCTION: This study's main objective is to assess the pharmaceutical quality and comparability of metformin tablets that are sold in India, derived from both market and government sources. Because of its vital function in the treatment of type 2 diabetes, metformin, a drug that is often recommended for this condition, was selected. The in-vitro methods used for this assessment were compliant with the Indian Pharmacopoeia (IP) guidelines. To ensure their bioequivalence, generic and branded medications should have the same active components in the same kind and amount. However, owing to carelessness, inexperience, or profit-driven manufacturing goals, inferior pharmaceuticals might sometimes reach the market. When compared to the original formulations, these subpar items often differ in concentration, quality, and effectiveness. In order to guarantee pharmaceutical goods' dependability and safety, producers must closely adhere to pharmacopoeial standards established by organizations like the British Pharmacopoeia (BP), United States Pharmacopoeia (USP), and IP. To maintain these requirements, thorough quality control testing on both completed goods and throughout manufacturing is essential. Another major problem is affordability, because many people throughout the globe struggle to pay for necessary prescription drugs. Additionally, this research seeks to dispel the myth that branded drugs always provide better therapeutic results than generic substitutes. Metformin ($C_4H_{11}N_5$, molecular weight 129.167 g/mol) functions by improving insulin sensitivity, decreasing intestinal glucose absorption, and decreasing hepatic glucose synthesis. Numerous quality characteristics, including as weight fluctuation, hardness, friability,

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disintegration, dissolution, and content homogeneity, were examined in order to evaluate its effectiveness. The findings demonstrated that metformin pills, both branded and generic, were safe, effective, and pharmaceutically comparable, meeting quality requirements 1.

MATERIALS AND METHOD: For this investigation, SD Fine Chemicals provided pure metformin hydrochloride. Branded and generic metformin pills with a 500 mg label strength were purchased at the neighborhood store. To guarantee legitimacy, the expiry dates of every product were tracked throughout the testing procedure. To ensure accuracy and dependability in testing, all chemicals and reagents, including potassium dihydrogen orthophosphate and sodium hydroxide pellets, were of analytical quality. To avoid any possible contamination or influence during analysis, only distilled water was utilized for the duration of the experiment. In accordance with the standards for pharmaceutical research and analysis 2, this systematic technique guaranteed that all materials used were of the highest quality.

IN-Process QC Test [3, 4]:

Test for Appearance: The way pharmaceutical tablets look has a big impact on whether or not consumers accept them. Important characteristics were assessed, including size, form, color, surface roughness, and distinguishing marks. In order to preserve customer trust in the product's quality and to guarantee consistency in production, these properties were assessed. **Thickness 5:** A Vernier caliper was used to measure the tablets' thickness. Each tablet's thickness may be accurately measured with this exact tool, and finer measurements can also be made with micrometre (μm) precision. Ten pills in all were chosen at random to be measured, and their thickness was noted. The thickness's standard deviation was managed to guarantee that variations did not surpass 5% in order to preserve homogeneity. This characteristic is essential for maintaining regular tablet dimensions, which have a direct effect on packaging, customer acceptability, and dose administration consistency.

Hardness 6, 7: The force needed to shatter a tablet is referred to as tablet hardness. The Pfizer Hardness Tester, which compresses the tablet between two flat, parallel surfaces and measures the breaking force in kilograms per centimeter, is one tool used to test this. The platens need to be perfectly aligned, polished, and smooth in order to provide accurate results. In order to determine a tablet's mechanical strength and forecast other critical characteristics like disintegration time and friability (the ease with which the tablet crumbles), hardness testing is important. These elements affect how the tablet functions throughout the body. Testing helps determine if the tablet will fulfill manufacturing requirements and function as intended since tablet hardness is strongly related to these physical characteristics. For the produced tablets to retain their integrity throughout manufacturing, handling, and eventually patient usage, an accurate hardness assessment is essential.

Friability [9]: This test, closely related to tablet hardness, is conducted to assess the potential loss of tablet material due to wear and tear during transportation. The Roche Friabilator is typically used for this purpose. In this procedure, five tablets are selected at random, and their initial weight (W1) is recorded. These tablets are then placed in the friabilator, which rotates at 25 rpm for four minutes (equivalent to 100 revolutions). After this, the tablets are weighed again (W2).

The percentage of friability, or weight loss, is calculated using the following formul

$$\text{Friability (\%)} = [G1 - G2] / G1 \times 100$$

Where, G1 = Initial weight of the tablets (before testing), G2 = Final weight of the tablets (after testing).

Generally speaking, friability cannot be allowed to exceed 1.0%. Tablets that pass this test are more likely to be robust enough to survive handling and transit without suffering serious harm.

Weight Variation (Weight Uniformity) 7, 9: This test's goal is to verify batch consistency, which in turn represents the constancy of drug content across all formulation batches. For the test, 20 randomly selected pills were weighed individually. Additionally, the percent deviation, standard deviation, and average weight were calculated.

TABLE 1: PERCENTAGE PERMISSIBLE LIMITS

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Average weight of tablets (mg)	% Difference allowed
<80mg	10%
80 mg -250mg	7.5%
>250mg	5%

Finished Product QC Test:

Disintegraton Test [4, 10, 11]: Each brand's selected pills were computed. When no tablet grains were left on any tablet's mesh, the disintegration was said to have occurred. The duration required for the breakdown of tablets The disintegration time of six tablets was recorded at random using a disintegration apparatus with distilled water as the test fluid at 37 0.2 ℃.

Dissolution [12, 13]: The process by which a material turns into a solution is called dissolution. In vitro,

The quantity of drug ingredient in a dosage form, such as tablets or capsules, that dissolves in a given period of time under a certain set of circumstances is measured by dissolution testing, which also determines the extent and rate of solution production from a dosage form. Drug release and dissolution are interchangeable phrases. Only when closely linked with a reliable regulatory result does the USP dissolving test in the monograph relate to bioavailability and bioequivalence studies. The dissolving test should only be considered a batch release quality control test in the absence of this relationship. For tablet assessment or quality control testing, it is an essential pharmacopoeial test. Typically, the dissolving medium has a capacity of 500, 900, or 1000 milliliters. It is not recommended to utilize a hydro-alcoholic media. Without a doubt, do all dissolution experiments at 37±0.5℃ for IR dosage forms. Phosphate buffer, specifically potassium dihydro orthophosphate buffer with a pH of 6.8, is often used to dissolve Metformin HCl pills. The basket attached to the paddle receives 900ml of the buffer, which is then allowed to reach 37℃ and a rpm of 50. The tablet is then placed inside the basket, and at 15-minute intervals, the sample is taken out. The same amount of buffer is then added again until the sample is diluted, and spectrophotometry is performed using this sample to determine the drug release at various intervals.

FIG. 1: TYPICAL DISSOLUTION TEST OF TABLETS OF METFORMIN HCl

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Pharmacpoeial Assay [14, 15]: An assay has been carried out to ascertain the purity of the particular brand of metformin medication. First, ten metformin hydrochloride pills of each brand were weighed using an analytical balance, and the average weight was determined. The tablets were then ground into a powder using a mortar and pestle. After that, 0.1g of powdered metformin hydrochloride equivalent was stirred for 15 minutes with 70 ml of distilled water using a magnetic stirrer. 70 milliliters of distilled water were added to a 100 milliliter volumetric flask containing 0.1 grams of powdered metformin hydrochloride, which had been weighed. The combination, known as the stock solution, was agitated for fifteen minutes before being diluted with one hundred milliliters of distilled water and filtered. 10 ml of this filtrate was then diluted with 100 ml of buffer. Once again, 1 ml was removed from the initial dilution, and buffer was used to bring the volume up to 10 ml. Additionally, the highest absorbance of the resultant solution was measured at around 233 nm.

Standard Metformin Hydrochloride Stock Solution [16]: After precisely weighing 100 mg of the reference standard, it was transferred to a 100 ml volumetric flask and filled with filtered water to the indicated line to create the standard metformin hydrochloride stock solution. The maximum amount of absorption between 200 and 300 nm was measured using a UV-visible spectrophotometer. It was discovered that the wavelength of the generic version of metformin hydrochloride is 233 nm. The absorbances of several metformin dilutions were compared to a blank to create the calibration curve. It yields the standard calibration curve.

RESULTS AND DISCUSSION: Shape, colour, and texture of the tablets were visually inspected & results are given below:

TABLE 2: DATA OF TABLETS

Brand Name	Colour	Shape	Texture
Metmin 500	White	Round	Smooth
Glycomet 500	White	Circular	Smooth
Okamet 500	White	Oval	Smooth
Generic			
Metformin HCL 500	White	Round	Smooth

Visual examination of the tablets showed that both branded and generic versions were of comparable quality (Table 2), with a smooth texture and white hue. The different shapes of the branded tablets—round, circular, and oval—and the generic version's round shape show careful design considerations. These variations may accommodate a range of patient preferences while guaranteeing simpler ingestion and handling. Particularly advantageous is the consistent, smooth texture, which improves patient comfort and lowers the possibility of discomfort during swallowing. All things considered, these characteristics demonstrate a focus on patient-centered design and quality, fostering favorable user experiences and boosting drug adherence 17.

Diameter and Thickness:

TABLE 3: THICKNESS AND DIAMETER OF TABLETS

Brand	Thickness (%) Deviation	Diameter (%) Deviation
Metmin 500	±0.1	±0.2
Glycomet500	±0.2	±0.2
Okamet 500	±0.1	±0.1
Metformin HCL 500	±0.1	±0.1

Consistent quality across both branded and generic pills is highlighted by the examination of thickness and

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diameter discrepancies. Table 3. With thickness differences ranging from ±0.1% to ±0.2% and diameter deviations from ±0.1% to ±0.2%, branded tablets including Okamet 500, Glycomet 500, and Metmin 500 showed very little variations. With thickness and dimension variances of ±0.1%, the generic tablet Metformin HCL 500 demonstrated remarkable homogeneity. These little variations guarantee consistency in pill size and reflect exact production standards, both of which are essential for precise dosage and patient confidence. Medication adherence and general user satisfaction are favorably impacted by such quality control procedures (18). **Hardness:** The tablet's hardness was assessed using the Monsanto hardness tester. The findings demonstrated that the crushing strength or hardness of every metformin brand examined was sufficient. The tablet passes the hardness test if its crushing strength falls between 4 and 10 kg/cm2.

TABLE 4 (A): DISPLAYS THE OUTCOMES OF HARDNESS OF THE TABLETS

Tablet no	Hardness of branded tablets kg/cm^2		
	Metmin 500	**Glycomet 500**	**Okamet 500**
1	5.80	7.50	6.45
2	5.75	7.45	6.85
3	5.90	7.55	6.45
4	5.85	7.80	6.55
5	5.65	7.30	6.20
6	5.90	7.35	6.75
7	5.80	7.60	6.55
8	5.80	7.40	6.70
9	5.75	7.20	6.85
10	5.90	7.80	6.55
Average	5.81kg/cm^2	7.49kg/cm^2	6.55kgcm^2

TABLE 4(B): DATA OF GENERIC TABLETS

Hardness of Generic tablets kg/cm3										
Tablet no	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Metformin HCl 500	3	10	13	11.2	8.8	5.8	10.2	3.6	11.8	15.4
Average = 9.28kg/cm^2										

The branded metformin tablets (Metmin 500, Glycomet 500, and Okamet 500) in Table 4A had average hardness values of 5.81 kg/cm², 7.49 kg/cm², and 6.55 kg/cm², respectively, all falling within the permissible range of 4–10 kg/cm², according to the hardness test, which was carried out using the Monsanto tester. This illustrates strict quality control that guarantees tablets

TABLET 5: FRIABILITY ANALYSIS OF TABLETS

preserve structural soundness when being handled and transported. With hardness values ranging from 3 kg/cm² to 15.4 kg/cm² and an average of 9.28 kg/cm², the generic tablet Metformin HCl 500, Table 4B, showed a greater degree of variability. The variability indicates chances for improved uniformity, even if it is within the permitted range 19.

Brand Name	**Initial weight (w_1)**	**Final weight (w_2)**	**%Friability**
Metmin 500	5.88	5.83	0.8%
Glycomet 500	5.87	5.85	0.3%
Okamet 500	5.22	5.19	0.57%
Metformin HCl 500	6.45	6.33	1.86%

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Friability

To make sure the tablets can survive handling and transportation, the friability test evaluates their resistance to mechanical stress. The findings showed that all of the branded tablets, including Okamet 500 (0.57%), Glycomet 500 (0.3%), and Metmin 500 (0.8%), had friability values below the typical 1% level, showing exceptional durability. The permitted limit was exceeded by the slightly greater friability of 1.86% shown by the generic tablet, Metformin HCl 500. This implies that in order to increase mechanical stability, either formulation or manufacturing process modifications are required. All things considered, the branded tablets exhibit improved resistance to friability, guaranteeing increased dependability and durability during distribution 20.

Weight Variation (Uniformity of Weight):): A crucial quality control metric, the weight variation test, was performed on both generic and branded pills. Individual variations ranged from -6.15% to 4.61%, with the generic pill weighing an average of 0.650 g. The average weight of the branded pills was lower, at 0.585 g, with weight differences ranging from -2.56% to 2.56%. Pharmacopeial weight uniformity guidelines, which normally permit a ±5% variance for tablets weighing greater than 0.324 g, were fulfilled by both kinds of tablets. When compared to generic pills, the branded tablets showed more constant weight uniformity, indicating stricter quality control and guaranteeing dosage accuracy 21. Pharacopoeial Assay: To guarantee precise measurement of the active pharmaceutical component, a standard stock solution of metformin hydrochloride was made. According to the UV-visible spectrophotometer, the generic version of metformin hydrochloride absorbs at 233 nm, which is in line with metformin's reported absorption maxima. In order to precisely quantify metformin in the generic formulation, a calibration curve was created using several dilutions and absorbance measurements compared to a blank. In order to guarantee quality and uniformity across generic and branded formulations, this approach guarantees the precise measurement of metformin content 22.

Disintigration Studies: The disintegration test, performed using a basket rack assembly at 37±2°C, showed that, on average, the branded tablets (Metmin HCl 500, Glycomet 500, and Okamet 500) decomposed in 7.10, 6.43, and 8.28 minutes, respectively. By contrast, the average disintegration time of the generic pill (Metformin HCl 500) was 9.42 minutes. Variations in formulation, excipients, or manufacturing procedures might be the cause of this discrepancy. Even while every pill passed the disintegration test, the branded tablets disintegrated more quickly, which might have a positive impact on bioavailability and a speedier start of effect 23.

Dissolution Profile:

TABLE 6: DISSOLUTION PROFILE OF TABLETS

Time	Metmin 500	Glycomet 500
0	0	0
10	15.33 ± 0.03	18.26 ± 0.3
15	46.5 ± 0.056	44.3 ± 0.5
30	59.6 ± 0.8	68.33 ± 0.6
45	73.52 ± 0.12	79.85 ± 0.08
60	99.6 ± 0.2	97.23 ± 0.5

FIG. 2: DISSOLUTION PROFILE OF BRANDED AND GENERIC TABLETS OF METFORMIN HCL

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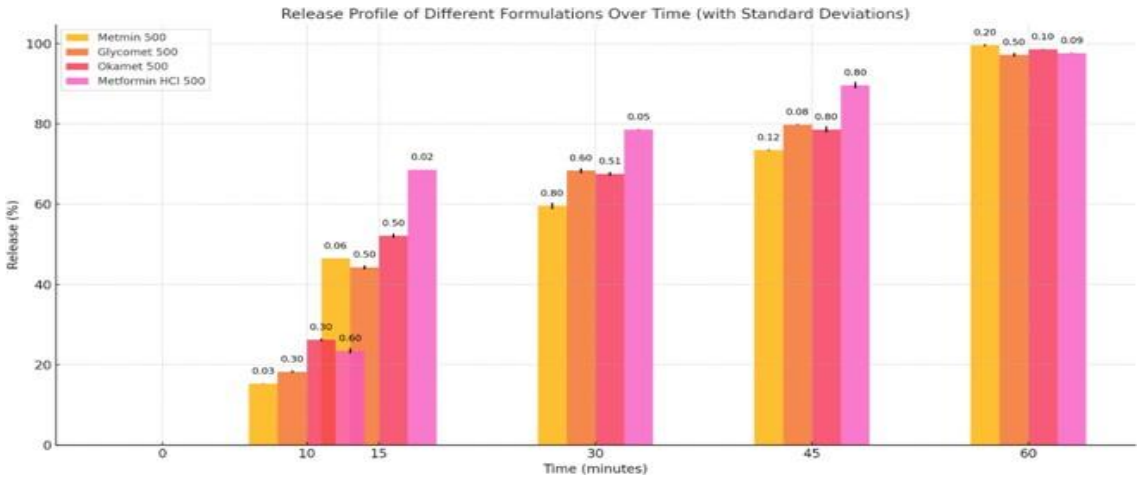

The dissolving profile shows the release patterns of both generic and brand-name metformin HCl tablets over a 60-minute period. Rapid availability was shown by the quickest release of metformin HCl 500, which reached 68.59% in 15 minutes and peaked at 97.66% after 60 minutes. Although all formulations attained >97% release after 60 minutes, Okamet 500 had similar release, whereas Metmin 500 and Glycomet 500 initially trailed. These results point to variations in early dissolution, which may affect the commencement of action, but they also imply comparable effectiveness. These profiles emphasize bioequivalence testing for generic formulations and are in line with USP criteria for metformin dissolving.

CONCLUSION: The pharmaceutical quality of both branded and generic Metformin tablets was thoroughly assessed in this research, highlighting the vital role that quality control plays in guaranteeing the safety and effectiveness of the medication. All formulations were found to meet pharmacopeial requirements after thorough in-vitro evaluations, which included testing for hardness, friability, disintegration, dissolution, and weight variation. Notably, there was little variation in the physical and chemical characteristics of the marketed formulations, Metmin 500, Glycomet 500, and Okamet 500. Metformin HCl 500, the generic version, behaved similarly, however there was potential for better consistency given the somewhat greater variety in hardness and friability. According to dissolution profiles, all formulations met USP standards for bioavailability and bioequivalence by achieving over 97% drug release by 60 minutes. The fastest-releasing medication was metformin HCl 500, which reached 68.59% in 15 minutes. Okamet 500, Glycomet 500, and Metmin 500 were next in line. These results suggest that all products have comparable therapeutic potential, albeit Metformin HCl 500 may have a speedier beginning of effect due to its faster dissolving. All things considered, the research refutes the myth that branded medications always perform better. It demonstrates that generic medications provide safe, efficient, and reasonably priced substitutes for their branded equivalents when manufactured in accordance with strict quality standards. For communities with low resources, where economic concerns are crucial for drug adherence and health outcomes, this is especially crucial. The study emphasizes how crucial it is to follow pharmacopoeial criteria and use strong quality control throughout the manufacturing process. The research promotes equal access to necessary pharmaceuticals without sacrificing quality by confirming the interchangeability of generic and branded Metformin tablets, hence supporting greater adoption of generics in healthcare systems. This finding is in line with international campaigns calling for more generics to be used in order to improve the accessibility and cost of healthcare.

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