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IN-VITRO PHARMACEUTICAL QUALITY CONTROL TESTING: A COMPARITIVE STUDY OF JANAUSHADHI ORAL ANTIDIABETIC DRUGS WITH REPUTED BRANDS AVAILABLE IN INDIA

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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 disintegration time, dissolution rate, and other physical and chemical parameters. 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.

INTRODUCTION: The primary goal of this study is to evaluate the pharmaceutical quality and comparability of metformin tablets available in India, sourced from both government provisions and market supplies. Metformin, a widely prescribed medication for managing type 2 diabetes was chosen due to its critical role in diabetes treatment.

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This evaluation was conducted using *in-vitro* techniques that adhere to the standards of the Indian Pharmacopoeia (IP). Generic and branded drugs are expected to have identical active ingredients in both type and quantity, ensuring their bioequivalence.

However, the pharmaceutical market is occasionally infiltrated by substandard medications due to negligence, lack of expertise, or profit-oriented motives by manufacturers. Such inferior products often vary in concentration, quality, and efficacy compared to the original formulations. To ensure the safety and reliability of pharmaceutical products, manufacturers must strictly comply with

Pharmacopoeial standards set by bodies such as IP, United States Pharmacopeia (USP), and British Pharmacopoeia (BP). Rigorous quality control testing during production and on finished products is critical to maintaining these standards. Affordability is another significant issue, as many individuals worldwide face financial barriers to accessing essential medications. This study also aims to challenge the misconception that branded medications inherently offer superior therapeutic performance compared to generic alternatives. Metformin ($C_4H_{11}N_5$, molecular weight 129.167 g/mol) works by reducing hepatic glucose production, limiting glucose absorption in the intestines, and enhancing insulin sensitivity. To assess its efficacy, various quality parameters including weight variation, hardness, friability, disintegration, dissolution, and content uniformity were analyzed. The results confirmed that both generic and branded metformin tablets met established quality standards, proving them to be safe, effective, and pharmaceutically equivalent [1].

MATERIALS AND METHOD: Pure Metformin Hydrochloride was procured from SD Fine Chemicals for use in this study. Metformin tablets, both branded and generic, with a label strength of 500 mg, were sourced from the local market. The expiration dates of all products were monitored throughout the testing process to ensure validity. All chemicals and reagents, including sodium hydroxide pellets and potassium dihydrogen orthophosphate, were of analytical grade to maintain accuracy and reliability in testing. Distilled water was used exclusively throughout the entire project to eliminate any potential contamination or interference during analysis. This standardized approach ensured that all materials used were of high quality, aligning with the requirements for pharmaceutical research and analysis [2].

IN-Process QC Test [3, 4]:

Test for Appearance: The consumer's acceptance of pharmaceutical tablets largely depends on their appearance. Key parameters such as size, shape, color, surface texture, and identifying markings were evaluated. These attributes were measured to ensure consistency in manufacturing and to maintain consumer confidence in the product's quality.

Thickness [5]: The thickness of the tablets was assessed using a Vernier caliper. This precise instrument ensures accurate measurement of each tablet's thickness, with micrometre (μm) accuracy also being applicable for finer assessments. A total of 10 tablets were randomly selected for measurement, and their thickness was recorded. To maintain uniformity, the standard deviation of the thickness was controlled to ensure deviations did not exceed 5%. This parameter is critical in ensuring consistent tablet dimensions, which directly impact packaging, consumer acceptance, and uniformity in dosage delivery.

Hardness [6, 7]: Tablet hardness refers to the force required to break a tablet. This is measured using devices like the Pfizer Hardness Tester, which compresses the tablet between two flat, parallel surfaces, and records the breaking force in units such as kg/cm^2. To ensure accurate results, the platens must be smooth, polished, and precisely aligned. Hardness testing is vital for assessing the mechanical strength of a tablet and predicting other essential properties like disintegration time and friability (how easily the tablet crumbles). These factors impact how the tablet behaves in the body. Since tablet hardness is closely linked to these physical properties, testing it helps confirm whether the tablet will meet production standards and perform correctly. Accurate hardness measurement is crucial for ensuring that the manufactured tablets maintain their integrity throughout production, handling, and ultimately, patient use.

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).

The permissible limit for friability is typically not more than 1.0%. This test helps ensure that tablets are durable enough to withstand handling and transportation without significant damage.

Weight Variation (Uniformity of Weight) [7, 9]: The objective of this test is to confirm the consistency of each batch, which ultimately reflects the consistency of drug content throughout all batches of formulation. 20 tablets were chosen at random for the test, each of which was weighed separately. The average weight, standard deviation, and percent deviation were also computed.

TABLE 1: PERCENTAGE PERMISSIBLE LIMITS

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]: Chosen tablets of each brand was calculated. The timing of disintegration was determined to be when there was no tablet granules remained on the mesh of any tablet. The amount of time it took for pills to break down Using a disintegration equipment with distilled water as the test fluid at 37 0.2 °C, the tablet disintegration time of six randomly was recorded.

Dissolution [12, 13]: Dissolution is the process in which a substance forms a solution. *In-vitro,* dissolution testing measures the extent and rate of solution formation from a dosage form (the amount of percentage of the drug substance in a dosage form such as tablets, or capsules to go into solution) within a specific time under a specified set of conditions.

The terms dissolution and drug release are used interchangeably. The USP dissolution test in the monograph is related to Bioavailability and Bioequivalence study only when closely allied with a sound regulatory determination. Without this association, the dissolution test should be regarded solely as a quality control test for batch release. It is a crucial pharmacopoeial test for the evaluation of tablets or quality control tests of tablets.

The volume of the dissolution medium is generally 500, 900, or 1000 ml. The use of a hydro-alcoholic medium is discouraged. Certainly, conduct all dissolution tests for IR dosage forms at 37±0.5°C. For the dissolution of the Metformin HCl tablets usually phosphate buffer i.e. potassium dihydro orthophosphate buffer of pH 6.8 is used 900ml of the buffer is added to the basket attached to paddle and it is left for temperature setting up to 37°C and the rpm is set for 50 then the tablet is placed into the basket and for every time interval of 15 min the sample is withdrawn from the basket and again same amount of buffer added to up to the sample is diluted and spectrophotometry is carried out using this sample to find out the drug release at different time interval.

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

Pharmacpoeial Assay [14, 15]: To determine the purity of the specific brand of metformin drug, an assay has been performed. First, an analytical balance was used to weigh 10 tablets of metformin hydrochloride from each brand, and the average weight was taken. Then, a mortar and pestle were used to powder the Tablets.

Then, a magnetic stirrer was used to stir 0.1g of metformin hydrochloride equivalent powder for 15 minutes with 70 ml of distilled water. Metformin hydrochloride corresponding to 0.1 grammes of powder was weighed and put to a volumetric flask of 100 ml, to which 70 ml of distilled water was added.

The mixture was agitated for 15 minutes before being diluted to 100 ml with distilled water and filtered it is named as stock solution. Then 100 ml of buffer was used to dilute 10 ml of this filtrate Again 1ml taken from first dilution and volume was made up to 10 ml using buffer. And the absorbance of resulting solution was taken at the maximum about 233nm.

Standard Metformin Hydrochloride Stock Solution [16]: The standard metformin hydrochloride stock solution was prepared by accurately weighing 100 mg of the reference standard and transferring it to a 100 ml volumetric flask, which was then filled to the line shown with purified water.

The UV-visible spectrophotometer was used to measure the highest level of absorption between 200 and 300 nm. It was found that the generic variant of metformin hydrochloride has a wavelength of 233 nm. The calibration curve was made by comparing the absorbances to a blank. of several dilutions of metformin The standard calibration curve is obtained.

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

The visual inspection of tablets revealed **Table 2** consistent quality across both branded and generic options, with all exhibiting a white color and smooth texture. The variations in shape, such as round, circular, and oval forms among branded tablets and a round shape in the generic version, demonstrate thoughtful design considerations.

These differences can cater to diverse patient preferences, ensuring easier handling and swallowing. The uniform smooth texture is particularly beneficial, enhancing patient comfort and reducing the risk of irritation during ingestion. Overall, these features reflect attention to both quality and patient-centric design, promoting positive user experiences and encouraging medication 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

The analysis of thickness and diameter deviations highlights consistent quality across both branded and generic tablets **Table 3.** Branded tablets, such as Metmin 500, Glycomet 500, and Okamet 500, demonstrated minimal deviations, with thickness deviations ranging from ±0.1% to ±0.2% and diameter deviations from ±0.1% to ±0.2%.

The generic tablet, Metformin HCL 500, showed an impressive uniformity with both thickness and diameter deviations at ±0.1%. These minimal deviations reflect precise manufacturing standards and ensure uniformity in tablet size, which is crucial for accurate dosing and patient trust. Such quality control measures contribute positively to medication adherence and overall user satisfaction [18].

Hardness: The Monsanto hardness tester was used to determine the tablet's hardness. The results showed that all of the metformin brands tested had an adequate crushing strength or hardness. If the crushing strength of the tablet is between 4kg/cm^2 and 10kg/cm^2, it passes the hardness test.

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 hardness test, conducted using the Monsanto tester, demonstrated that branded metformin tablets (Metmin 500, Glycomet 500, and Okamet 500) – Table 4A had average hardness values of 5.81 kg/cm², 7.49 kg/cm², and 6.55 kg/cm², respectively, all within the acceptable range of 4–10 kg/cm². This reflects robust quality control ensuring tablets maintain structural integrity during handling and transport. The generic tablet, Metformin HCl 500, **Table 4B** showed a higher variability in hardness, with values ranging from 3 kg/cm² to 15.4 kg/cm² and an average of 9.28 kg/cm². While meeting the acceptable range, the variability suggests opportunities for enhanced uniformity [19].

TABLET 5: FRIABILITY ANALYSIS OF TABLETS

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%

Friability

The friability test assesses the tablets' resistance to mechanical stress, ensuring they can withstand handling and transport. The results revealed that all branded tablets Metmin 500 (0.8%), Glycomet 500 (0.3%), and Okamet 500 (0.57%) exhibited friability values below the standard limit of 1%, indicating excellent durability. The generic tablet, Metformin HCl 500, showed a slightly higher friability of 1.86%, exceeding the acceptable limit. This suggests potential improvements in formulation or manufacturing processes are needed to enhance mechanical stability. Overall, the branded tablets demonstrate superior resistance to friability, ensuring better durability and reliability during distribution [20].

Weight Variation (Uniformity of Weight): The weight variation test, a critical quality control parameter, was conducted on both generic and branded tablets. The generic tablet showed an average weight of 0.650 g, with individual deviations ranging from -6.15% to 4.61%. The branded tablets had a lower average weight of 0.585 g, with weight variations between -2.56% and 2.56%.

Both types of tablets met pharmacopeial standards for weight uniformity, which typically allow a ±5% deviation for tablets weighing more than 0.324 g. The branded tablets exhibited more consistent weight uniformity compared to generic ones, reflecting tighter manufacturing control and ensuring dose accuracy [21].

Pharacopoeial Assay: The standard metformin hydrochloride stock solution was prepared to ensure accurate measurement of the active pharmaceutical ingredient.

The UV-visible spectrophotometer revealed that the generic variant of metformin hydrochloride absorbs at 233 nm, which is consistent with known absorption maxima for metformin. A calibration curve was constructed using several dilutions, with absorbance values compared to a blank, allowing for precise quantification of metformin in the generic formulation. This method ensures the accurate determination of metformin content, vital for ensuring quality and consistency between generic and branded formulations [22].

Disintigration Studies: The disintegration test, performed using a basket rack assembly at 37±2°C, revealed that the branded tablets (Metmin HCl 500, Glycomet 500, Okamet 500) disintegrated relatively quickly, with average times of 7.10, 6.43, and 8.28 minutes, respectively. In comparison, the generic tablet (Metformin HCl 500) took longer, with an average disintegration time of 9.42 minutes. This difference may be attributed to variations in formulation, excipients, or manufacturing processes. While all tablets passed the disintegration test, the branded tablets demonstrated faster disintegration, which may contribute to quicker onset of action and improved bioavailability [23].

Dissolution Profile:

TABLE 6: DISSOLUTION PROFILE OF TABLETS

Time	Metmin 500	Glycomet 500	Okamet 500	Metformin HCl 500
0	0	0	0	0
10	15.33 ± 0.03	18.26 ± 0.3	26.22 ± 0.3	23.45 ± 0.6
15	46.5 ± 0.056	44.3 ± 0.5	52.13 ± 0.5	68.59 ± 0.02
30	59.6 ± 0.8	68.33 ± 0.6	67.56 ± 0.51	78.62 ± 0.05
45	73.52 ± 0.12	79.85 ± 0.08	78.63 ± 0.8	89.66 ± 0.8
60	99.6 ± 0.2	97.23 ± 0.5	98.6 ± 0.1	97.66 ± 0.09

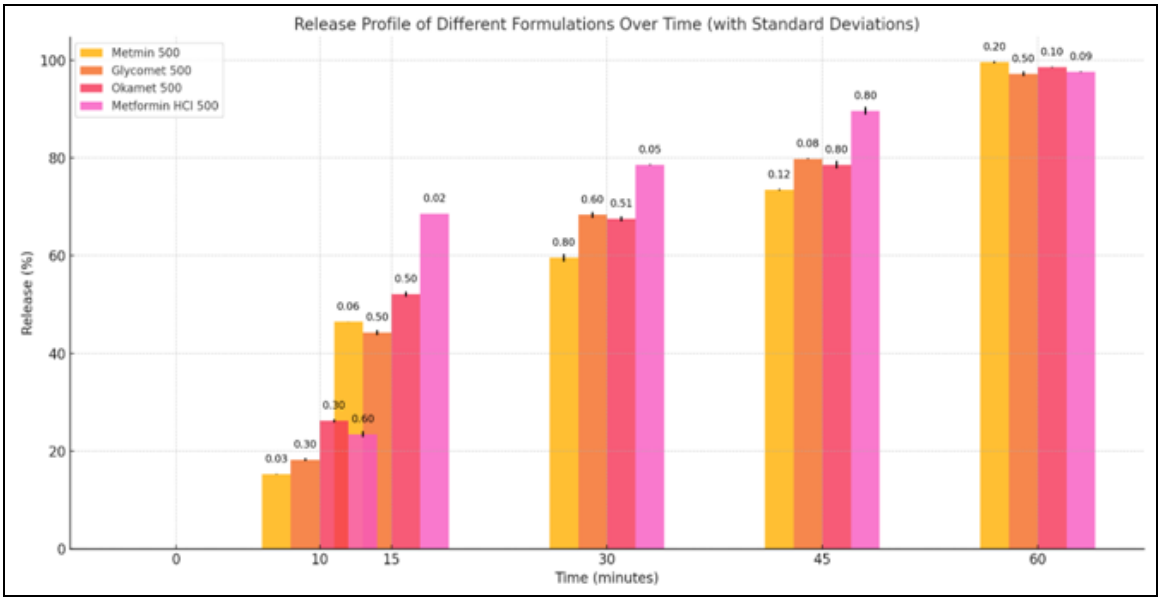

FIG. 2: DISSOLUTION PROFILE OF BRANDED AND GENERIC TABLETS OF METFORMIN HCL

The dissolution profile demonstrates the release patterns of Metformin HCl tablets (branded and generic) over 60 minutes. Metformin HCl 500 exhibited the fastest release, achieving 68.59% in 15 minutes and peaking at 97.66% in 60 minutes, indicating rapid availability. Okamet 500 showed comparable release, while Metmin 500 and Glycomet 500 lagged initially, though all formulations achieved >97% release by 60 minutes. These findings suggest similar efficacy but highlight differences in early dissolution, potentially impacting onset of action. Such profiles align with USP standards for Metformin dissolution, emphasizing bioequivalence testing for generic formulations.

CONCLUSION: This study rigorously evaluated the pharmaceutical quality of both branded and

generic Metformin tablets, emphasizing the critical role of quality control in ensuring drug efficacy and safety. Through comprehensive *in-vitro* assessments, including tests for hardness, friability, disintegration, dissolution, and weight variation, all formulations met pharmacopeial standards. Notably, the branded formulations, Metmin 500, Glycomet 500, and Okamet 500, demonstrated consistent physical and chemical properties with minimal variability.

The generic variant, Metformin HCl 500, performed comparably, although slightly higher variability in hardness and friability suggested room for improved uniformity. Dissolution profiles revealed all formulations achieved over 97% drug release by 60 minutes, aligning with USP requirements for bioavailability and bioequivalence. Metformin HCl 500 exhibited the fastest release rate, reaching 68.59% within 15 minutes, followed by Okamet 500, Glycomet 500, and Metmin 500. These findings indicate similar therapeutic potential across all products, though faster dissolution may favor quicker onset of action for Metformin HCl 500.

Overall, the study dispels the misconception that branded drugs inherently offer superior performance. It confirms that generic drugs, when produced under stringent quality standards, provide safe, effective, and affordable alternatives to branded counterparts. This is particularly important for resource-limited populations where cost considerations are critical for medication adherence and health outcomes.

The research underscores the importance of adhering to pharmacopoeial guidelines and implementing robust quality control during production. By validating the interchangeability of generic and branded Metformin tablets, the study supports broader acceptance of generics in healthcare systems, promoting equitable access to essential medications without compromising quality. This conclusion aligns with global initiatives advocating for the increased use of generics to enhance healthcare affordability and accessibility.

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