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Comparative Evaluation of Marketed Sustained Release Metformin Tablets: A Quality Control Study

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ABSTRACT

This research examined and compared four brands of Metformin HCl sustained-release tablets of Metformin HCl, Sustained Release tablets, each containing 500 mg of the active emulsion. Employing rigorous evaluation parameters outlined in Compendia such as IP, the study scanned colourful aspects including uniformity of weight, frangibility, hardness, disintegration time, dissolution profile, and drug content. Remarkably, all brands stuck to the strict norms set forth, showcasing invariant tablet weight, satisfactory resistance to mechanical stress, and harmonious disintegration within the specified timeframe. also, dissolution rate tests revealed that over 80 of the active components was released within 30 minutes, meeting the sanctioned specifications for pharmacological efficacity. Importantly, analysis of drug content verified that all brands maintained active component situations within the specified range of 95- 105%. While variations were observed among brands, the overarching conclusion underlined their collaborative compliance with quality control marks, affirming their interchangeability in clinical practice, should one brand be unapproachable. These findings carry significant counteraccusations for healthcare interpreters and cases, offering assurance regarding the trust ability and effectiveness of available metformin phrasings in managing type II diabetes mellitus. likewise, the study serves as a precious resource for informed decision- making in opting the most suitable metformin brand grounded on factors similar as cost and vacuity without compromising on remedial efficacity.

1. INTRODUCTION:

This study aims to evaluate and compare marketed sustained-release Metformin tablets used in diabetes management. The ideal of this present exploration work is to compare and estimate retailed anti-diabetic metformin sustain- release tablets by using colourful evaluation styles. This helps identify variations in drug release patterns and overall performance, abetting healthcare professionals in defining opinions grounded on case requirements and treatment thing. Oral drug delivery isn't only the most rapid-fire and favoured system of administering specifics but also represents the largest and most established member of the pharmaceutical request. Among these specifics, metformin holds significance as it's the tradition drug approved by the USFDA for managing diabetes. Metformin hydrochloride, classified as an oral anti-diabetic drug belonging to the biguanide class of oral hypoglycaemic agents, serves as the primary treatment option for individualities with type II diabetes, particularly those who are fat or fat and maintain normal order function.

Two biguanide antidiabetics, phenformin and metformin were introduced in the 1950s. Because of advanced threat of lactic acidosis, phenformin has been banned in India since 2003. Metformin it's differs markedly from Sulfonylureas causes little or no hypoglycaemia in no diabetic subjects, and indeed in diabetics, hypoglycaemia is rare. therefore, it's ‘euglycemic’, rather than ‘hypoglycaemic’. It doesn't stimulate pancreatic β cells. Metformin is reported to ameliorate lipid profile as well in type 2 diabetics.

Metformin hydrochloride is an orally administered biguanide, which is extensively used in the operation of type- II diabetes, a common complaint that combines blights of both insulin stashing and insulin action. Unlike other ant diabetic drugs metformin HCl doesn't induce hypoglycaemia at any reasonable cure, and hence it's called as an anti-hyperglycaemic rather than a hypoglycaemic drug Metformin hydrochloride has fairly short tube half- life, low absolute bioavailability The advantages of metformin are a veritably low threat of hypoglycaemia, weight impartiality and reduced threat of cardiovascular morbidity and mortality The need for the administration two to three times a day when larger boluses are needed can drop patient compliance. Sustained release products are demanded for metformin to protract its duration of action and to ameliorate patient obedience. This study aims to compare the quality and performance of different marketed sustained-release Metformin HCl tablets to ensure their efficacy and safety in clinical practice.

2. MATERIALS AND METHODS:

2.1 Chemicals and reagent

Metformin hydrochloride, having a marker strength of 500 mg of four different brands were bought from registered drugstore shop of pastoral area of Solapur and were enciphered as M1, M2, M3 and M4. All the study was performed within product expiration dates. All the used reagents like potassium- di- hydrogen phosphate, Sodium Chloride, HCl, Disodium hydrogen phosphate, were of logical grade. lately set distilled water was used throughout the work. Eventually the following four different brands were taken for evaluation.

Table 1: Information about four brands of Metformin HCl tablets.

Brand Code	Brand Name	Manufacturers
M1	Gluconorm	Lupin.Ltd
M2	Glyciphage	Franco-Indian Pharmaceuticals Pvt. Ltd
M3	Glycomet	USV Ltd.
M4	Metadose	Biocon .Ltd

2.2 Apparatus and Equipment:

Double beam UV-Visible Spectrophotometer, Analytical balance, Hardness Tester, Tablet Friability Tester, Disintegration Apparatus, Dissolution test apparatus and Ultrasonicator and pH meter were used.

3. Methods:

3.1 Unique identification marking:

This test may be required or may not be required in the tablet based upon the presence of marking. During evaluation, marking is observed for the clarity and fineness. These markings include company name or symbol, product code, product name etc.

3.2 Weight variation test:

The purpose of this test is to verify the uniformity of each batch of tablets, which is vital for ensuring consistent drug content across all expression batches. To conduct the test according to sanctioned procedures, 20 tablets were erratically named from the batch. Each tablet was individually weighed to determine weight variation. also, the average weight, standard deviation, and percent deviation were calculated from the individual tablet weights to give a comprehensive assessment of batch uniformity.

$$\% \text{ Deviation} = W_{average} - W_{individual} / W_{average}$$

3.3 Friability test:

This test is generally conducted to assess the implicit wear and tear and gash that tablets may witness during transportation, which is nearly linked to tablet hardness. It's generally performed using a Roche Friabilator. Five tablets were aimlessly chosen, and their original weights(W1) were recorded. These tablets were also placed in the friabilator, which operated for 4 minutes at a speed of 25 rpm, completing 100 revolutions. subsequently, the tablets were reweighed(W2), and the chance loss(friability) was calculated using the formula handed.

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

The official permissible limit for friability is 1%.

3.4 Hardness Test:

The hardness of tablets from different brands was assessed using a Monsanto hardness tester, which measures hardness in terms of kg/ cm ². For each brand, five sample tablets were collectively placed between the spindle of the hardness testing machine until they fractured, and the pressure needed to break each tablet was recorded. The average pressure demanded to break the tablets was calculated and expressed in units of Kg/cm^2.

3.5 Tablet Disintegration Test:

The disintegration time of six aimlessly named tablets from each brand was measured using disintegration time with distilled water as the test fluid, maintained at 37 ±0.2 °C. The disintegration time was recorded as the moment when no grains from any tablet remained on the mesh. The duration taken for the tablets to disintegrate fully was noted.

3.6 Tablet Dissolution Test:

The UV-visible spectrophotometer was calibrated before use, and the dissolution medium was prepared as per IP guidelines. The dissolution test for four brands of metformin hydrochloride tablets was conducted using a single beaker dissolution outfit. A dissolution medium conforming of a0.68 w/v result of potassium dihydrogen phosphate, acclimated to pH6.8 with 1 M sodium hydroxide, was prepared. Each tablet (500 mg) was placed in a rotating basket submerged in 900 mL of the phosphate buffer medium at 37 ±0.5 °C. The basket rotated at 100 rpm for 45 minutes. At intervals of 5, 10, 15, 20, 30, and 45 minutes, 10

mL samples were withdrawn using a bulb pipette, with 10 mL of fresh dissolution medium added after each slice to maintain Gomorrah conditions. Each withdrawn sample was filtered, adulterated, and the absorbance of the performing result was measured at a wavelength of 233 nm using a UV-visible double ray spectrophotometer. The chance of drug release from each brand of metformin hydrochloride tablet was calculated using the standard estimation wind system.

3.7 Pharmacopeial Assay:

The assay aimed to determine the chance chastity of four brands of metformin tablets. originally, 20 tablets from each brand were counted using a logical balance, and the average weight was calculated. The tablets were also pulverized using a mortar and pestle. A portion of the powder equivalent to 0.1 g of metformin hydrochloride was stirred with 70 ml of distilled water for 15 minutes using a magnetic stirrer. This result was transferred to a 100 ml volumetric beaker, and 70 ml of distilled water was added. After stirring for another 15 minutes, the result was adulterated to 100 ml with distilled water and filtered. From this filtrate, 10 ml was taken and adulterated to 100 ml with distilled water. This process was repeated formerly more, performing in a further adulterated result. The absorbance of the performing result was measured at a wavelength of roughly 232 nm, and the drug content was calculated using a value of 798 for A (1%, 1 cm) at that wavelength.

4. RESULT AND DISCUSSION:

4.1. Unique identification marking:

Brand M2 has unique identification markings that passed the test as per IP standards.

4.2. Weight Variation:

The tablets were counted collectively, and their average weight was determined. The test concluded that all four brands of metformin hydrochloride tablets passed the weight variation uniformity test, meeting the specifications outlined in the Indian Pharmacopeia (IP). None of the brands displayed a deviation of further than ± 5 from the mean weight. The results are presented in Table 2.

4.3. Friability:

Five tablets from each selected brand were weighed and subjected to the Roche Friability apparatus. The percentage friability of the tablets was assessed against the Indian

Pharmacopeia (IP) specification, which states that tablets must not lose more than 1% of their initial weight during the friability study. The results, demonstrating compliance with the IP specification, are presented in Table 2

4.4. Hardness:

The crushing strength or hardness of the tablets was estimated using the Monsanto hardness tester. The observed results for all the named brands of metformin tablets demonstrated satisfactory situations of hardness, indicating their capability to repel crushing forces. These findings are epitomized in Table 2, furnishing a detailed overview of the hardness measures for each brand.

4.5. Disintegration:

Effective disintegration of tablets is crucial for improved bioavailability, leading to better absorption and therapeutic outcomes. The results of the disintegration test indicate that the disintegration time for all four different brands of metformin tablets is lower than 10 minutes, which is shorter than the standard disintegration time specified by the pharmacopoeia. This demonstrates that all these brands of metformin tablets meet the quality control criteria outlined in the pharmacopoeia. The disintegration times for each tablet brand are detailed in Table 2.

4.6. Pharmacopeial Assay:

The assay test aims to determine the precise quantity of the active component present in the tablet and corroborate if it matches the labelled quantum. The chance of drug release for all brands of tablets fell within the specified range outlined by the Indian Pharmacopoeia (IP). The percent drug content for each brand is presented in Table 2.

4.7. Dissolution:

Another crucial aspect under scrutiny was dissolution, which directly influences the absorption and bioavailability of the drug. The dissolution of all the chosen brands of metformin hydrochloride tablets met the specified criterion of not less than 80% within 30 minutes, as per the IP Pharmacopeia standards. See Table 2 for detailed results.

Table 2: Comparative data of different quality control parameters of four brands of Metformin HCl tablets

Brand Name	Weight Variation Mean weight ± Standard deviation(mg)	Friability (%)	Hardness Kg/cm^2	Disintegration Time (min)	%Drug Content	%Drug release
M1	701±35.05	0.6	18.6	6.16	96.78	86.45
M2	676.5±33.82	0.6	11.4	5.24	97.82	89.12
M3	678±33.9	0.6	18.5	5.42	96.56	93.19
M4	700.5±35.02	0.6	14.2	4.10	98.28	82.72

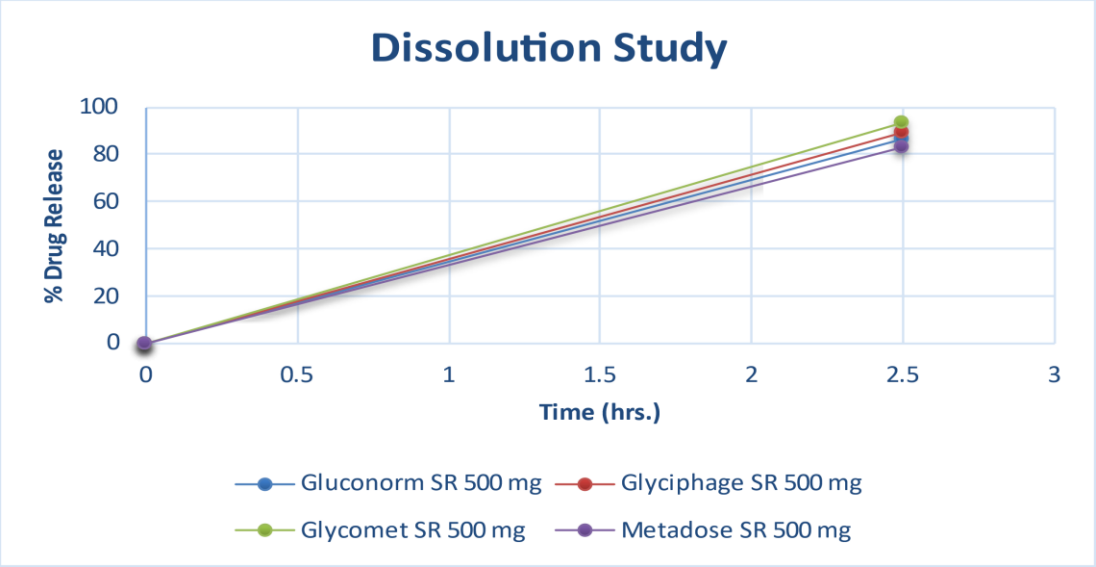

Figure 1: Comparative Dissolution Profile of Four Different Brands of Metformin HCL Sustain Release Tablets

5. CONCLUSION:

The ideal of this research was to strictly assess the quality and physicochemical equivalence of four distinct brands of metformin hydrochloride tablets available in the request. The study methodically examined colourful parameters including weight variation, hardness, Friability, disintegration, assay, and dissolution to ensure compliance with sanctioned specifications. Remarkably, all estimated brands of metformin hydrochloride tablets met the quested functionary norms for the forenamed parameters. Specifically, the tablets displayed uniformity in weight, acceptable hardness, minimum friability, timely disintegration, accurate

drug content, and applicable dissolution rates. specially, each brand demonstrated the release of roughly 80 of the metformin hydrochloride within the specified 2 hours and 30 minute timeframe, aligning with Pharmacopeial conditions. still, despite meeting these nonsupervisory criteria, variations were observed in the release biographies among the different brands. This suggests that while all brands perform satisfactorily in terms of meeting sanctioned specifications, subtle differences live in their release kinetics.

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