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COMPARATIVE STUDIES OF VILDAGLIPTIN GENERIC PRODUCT VS BRAND

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ABSTRACT

The present study was conducted to evaluate and compare the pharmaceutical quality of generic and branded Vildagliptin 50 mg tablets available in the market by performing various in-vitro quality control tests in accordance with Indian Pharmacopoeial standards. The investigation included the assessment of key physical parameters such as tablet thickness, hardness, friability, weight variation, disintegration time, and dissolution profile. In addition, the drug content was determined using UV–visible spectrophotometric analysis.

Vildagliptin is a selective dipeptidyl peptidase-4 (DPP-4) inhibitor widely used in the treatment of Type 2 diabetes mellitus. The purpose of this evaluation was to determine the pharmaceutical equivalence between the generic and branded tablet formulations. The experimental findings revealed that both formulations complied with the pharmacopeial quality requirements for the tested parameters. Minor variations were observed in the dissolution and disintegration characteristics, with the branded product showing slightly faster performance compared to the generic formulation.

Overall, the results suggest that generic Vildagliptin tablets can be considered effective and economical alternatives to branded products without significant compromise in

quality or therapeutic performance. However, further *in-vivo* bioequivalence studies are recommended to establish a direct correlation between in-vitro findings and clinical efficacy.

Keywords: Vildagliptin , Evaluation, Type2 diabetes mellitus, generic vs brand.

INTRODUCTION

According to FDA "a drug product that is comparable to branded product is dosage form strength route of administration, quality and performance, characteristics, and intended use. It is a copy of branded drug whose patent has expired which has no longer exclusive rights to produce and distribute medicines [1].

It is the original product that has been developed by pharmaceutical company. It has sole right to manufacture and distribution for a period of time (patent). A brand name drug is a small medicine that's discovered developed and marketed, by pharmaceutical company [2]. One's a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drugs. At this point the drug has two names - a generic name and a brand name to make it stand out in the market place [3].

Difference between generic and brand drugs

(a) It may/may not contain different inactive ingredients.
(b) Generic drugs are cheaper than brand.
(c) They look different due to difference in shape, size, colors, marking, in generic and branded medicines.
(d) Brand drug has sole right (patent) to manufacture and distribution for a period of time, while generic drug has not any patent on its manufacturing and distribution [4].

Type 2 diabetes mellitus (T2DM) has become a rapidly growing public health problem worldwide, posing significant clinical and socioeconomic burdens (1). Evidence indicates that effective control of hyperglycemia plays a vital role in preventing or delaying the onset of serious complications related to this chronic condition (1). The current pharmacotherapy for managing T2DM and its precursor states, such as insulin resistance, involves various classes of compounds including biguanides, thiazolidinediones, sulfonylureas, peptide analogues, dipeptidyl peptidase-IV (DPP-4) inhibitors, and alpha-glucosidase inhibitors (2).Sustained-release oral delivery systems have been developed to

maintain therapeutically effective plasma drug concentrations for an extended duration, improving patient compliance, minimizing dosing frequency, and reducing adverse effects (3). Conventional dosage forms, especially in long-term therapy for chronic diseases like diabetes, often require multiple daily administrations, which can lead to poor adherence and variable therapeutic outcomes (4). Matrix-based drug delivery systems, due to their chemical stability and efficient drug-embedding properties, have gained considerable popularity for sustaining drug release over prolonged periods (5).Among newly emerging therapeutic classes, incretin-based drugs have shown remarkable potential in T2DM management. These drugs enhance the activity of glucagon-like peptide-1 (GLP-1), an incretin hormone that regulates glucose homeostasis (6). Vildagliptin, belonging to the DPP-4 inhibitor class of antidiabetic agents, acts by inhibiting the enzymatic degradation of incretin hormones, primarily GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) (6). The activation of these hormones leads to decreased glucagon secretion and enhanced insulin sensitivity, contributing to improved glycemic control (6).Vildagliptin (LAF237) is an orally active, selective DPP-4 inhibitor designed to regulate blood sugar levels in T2DM patients (7). By blocking DPP-4, Vildagliptin preserves the physiological activity of GLP-1 and GIP, both of which play critical roles in stimulating insulin secretion and maintaining glucose balance (7). Furthermore, clinical findings indicate that Vildagliptin has a low risk of hypoglycemia compared to older oral antidiabetic medications, supporting its favorable safety and tolerability profile (7).Chemically, Vildagliptin is a cyanopyrrolidine-based compound whose cyano moiety undergoes hydrolysis, and its inactive metabolites are primarily excreted through urine (8). It has the molecular formula C17H25N3O2, molecular weight of 303.399 g/mol, and is marketed under various brand names (9). Vildagliptin exhibits its pharmacological activity by covalently binding to the catalytic site of DPP-4, causing prolonged enzyme inhibition and increased GLP-1 levels, which in turn stimulate insulin secretion (10).This high-affinity DPP-4 inhibitor enhances islet beta-cell function and improves overall glycemic control without significant interference with other dipeptidyl peptidases such as DPP-8 or DPP-9 (11,12). Studies reveal that a single dose of Vildagliptin provides DPP-4 inhibition for up to 24 hours, elevating both fasting and postprandial GLP-1 and GIP levels (12). The improvement in beta-cell responsiveness is correlated with the initial impairment level of the patient, and in normoglycemic individuals, Vildagliptin does not stimulate unnecessary insulin secretion (13). By increasing GLP-1 activity, the drug reduces glucagon release,

thereby insulin-to-glucagon ratios and decreasing hepatic glucose production after meals (13,14).

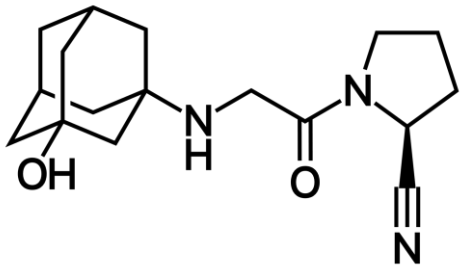

Fig1. CHEMICAL STRUCTURE OF VILDAGLIPTIN

MATERIAL AND METHOD

Shimadzu 1800 double beam UV/Vis spectrophotometer, digital balance (Citizen Co. Mumbai, India), and micropipette (The Modern scientific industries, Meerut, India) were used in this study. Vildagliptin API was obtained from Private store. All other chemical used were of analytical reagent grade. Freshly prepared distilled water was used in the study [15].

METHODOLOGY

Vildagliptin Tablet 50mg of both generic and branded drug was subjected for quality control test as per Indian Pharmacopoeia 2022 [16].

TABLE1:LABELLINGCONTENTSOFVILDAGLIPTIN TABLET

Tablet Name	Cost of Drug	Manufacturer	Batch No.	Mfg.Date	Expiry Date
Generic	20.00	Synmedic Laboratories	MT251643	06/2025	05/2027
Brand (Glipta great)	90.42	Mankind Pharma Ltd	1A5X003	12/2024	11/2026

EVALUATION OF TABLETS

1. THICKNESS

Select 10 tablets at random from the batch. A vernier caliper was used to measure the thickness of the tablet. Place each tablet between the jaws of the instrument. Apply no

excessive pressure that may deform the tablet. Record the thickness of each tablet in millimeters (mm).Determine the average thickness of the 10 tablets. Note the individual variations from the mean value. Variation should not exceed ±5% from the average value [17].

2. HARDNESS

Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression was measured using Pfizer hardness tester. Ten tablets were tested for each formulation as per standard value 2-5. It is expressed in kg/cm^2[18]

3. FRIABILITY

For tablets with an average weight of 0.65 g or less take a sample of whole tablets corresponding to about 6.5 g and for tablets with an average weight of more than 0.65g take a sample of 10 whole tablets . Dedust the tablets carefully and weigh accurately the required number of tablets. Place the tablets in the drum and rotate it 100 times. Remove the tablets, remove any loose dust from them and weigh them accurately

$$\textbf{Friability} = \frac{\textbf{Initialweight} - \textbf{Finalweight}}{\textbf{Initialweight}} * \textbf{100}$$

Limit: Less than 1.0%

4. WEIGHT VARIATION

The test for uniformity of weight is performed by weighing individually 20 tablets randomly selected from a tablet batch and determining their individual weights. The individual weights are compared with the average weight.The sample complies with IP standard if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.Coated tablets are exempted from these requirements but must confirm to the test for content uniformity [19].

$$\%\ \textbf{Deviation} = \frac{\textbf{Averageweight} - \textbf{individualweight}}{\textbf{Averageweight}} \times \textbf{100}$$

TABLE 2: IP STANDARDS FOR WEIGHT VARIATION TEST

S.No	Average weight of tablet (mg)	Max percentage difference allowed (%)
1	80 or less	10
2	80 – 250	7.5
3	More than 250	5

5.DISINTEGRATION

For tablets, the first important step towards drug dissolution is breakdown of the tablets into granules or primary powder particles, a process known as disintegration. All USP tablets must pass a test for disintegration, which is conducted in vitro using a disintegration test apparatus

The apparatus consists of a basket-rack assembly containing six open-ended transparent tubes of USP-specified dimensions, held vertically upon a 10-mesh stainless steel wire screen

During testing, a tablet is placed in each of the six tubes of the basket, and through the use of a mechanical device, the basket is raised and lowered in a bath of fluid (e.g. water, or as prescribed in the individual drug monograph) at 29 to 32 cycles per min, the wire screen always below the level of the fluid. For most normal release tablets, the time permitted is 15 min [20].

Tablets are said to have disintegrated if no fragments (other than fragments of coating) remains on the screen, or if particles remain, they are soft without an unwetted core. Chewable tablets are not required to comply with the test.

6.DISSOLUTION

Apparatus No: 1 (Paddle Type)

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. As per the (USP), the

dissolution test using Apparatus II (Paddle type) is performed by placing the dosage form in a vessel containing a specified volume of dissolution medium, generally 900 mL, maintained at 37 ± 0.5 °C, with the paddle rotating at a specified speed, commonly 50 rpm, unless otherwise stated in the monograph. The tablet or capsule is placed at the bottom of the vessel without floating, and samples are withdrawn at specified intervals from a point midway between the surface of the medium and the top of the rotating paddle, not less than 1 cm from the vessel wall. The withdrawn samples are filtered immediately and analyzed,typically by UV spectrophotometry or HPLC, to determine the percentage of drug released, which must meet the acceptance criteria prescribed in the respective IP monograph [21].

This dissolution study was carried out using IP apparatus type-I. The dissolution medium was 900 ml of Distilled water which was maintained at 37±0.5ºC. Rotations were 50rpm. Samples of 5 ml were withdrawn after 5 and 15 min and then every 5 min and analyzed spectrophotometrically at 217nm using Shimadzu-1700 UV-visible-spectrophotometer. The samples withdrawn were replaced by fresh Distilled water . Determine the concentration of samples help from the standard curve of pure APIwastaken .Using the Y=mX+C equation,

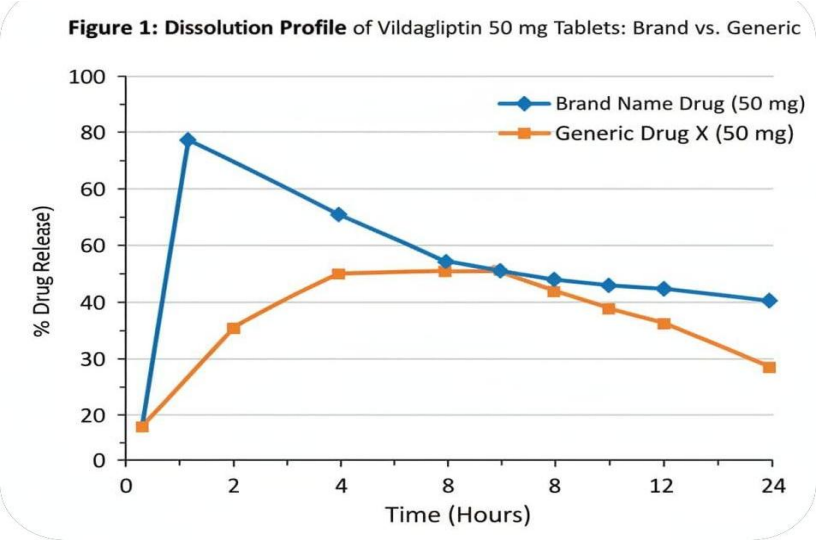

FIG2: DISSOLUTION PROFILE OF VILDAGLIPTIN TABLET BRAND VS GENERIC

7 .ASSAY

Preparation of Stock solution

Weighing and crushing 10 tablets, transferring amount of drug powder equivalent to 10 mg (100mcg/ml) in distilled water and placing it in sonicator.

Preparation of Working standard solution

The portion of solution 10ml/100ml was filtered and the filtrate was suitably diluted to give concentration of 1mcg/ml respectively. Absorbance was taken at 217 nm by using UV-visible spectrophotometer [22]. Finally, the potency of different tablets was determine by using the following equation.

Y=0.0054X+0.0505[24]

Procedure for Calibration curve

Accurately weighed 100 mg of vildagliptin was transferred in 100 ml volumetric flask. The drug was dissolved and diluted upto the mark with water to give a solution with concentration of 1000 µg/ml. An aliquot of 10 ml from the above solution was withdrawn and diluted upto 100 ml with water to obtain a stock solution having concentration of 100µg/ml.[23]

Preparation of solutions to obtain calibration curve

Appropriate aliquots from stock solution of vildagliptin (0.2, 0.4, 0.6, 0.8, 1 and 1.2 ml) were accurately withdrawn in 10 ml volumetric flask and diluted upto the mark with water to obtain the final concentration of solution in range of 2-12 µg/ml and scanned at λmax. Absorbance of these solutions of vildagliptin were recorded at their λmax using water as blank.[24]

TABLE 3: RESULTS OF CALIBRATION CURVE DATA OF VILDAGLIPTIN

S. No	Concentration (µg/ml)	Absorbance
1	2	0.055
2	4	0.071

3	6	0.488
4	8	0.699
5	10	0.804
6	12	0.999

TABLE 4: QUALITY CONTROL TEST FOR VILDAGLIPTIN

S.No	Tablets Name	Weight Variation (%)	Hardness Test (kg/cm^2)	Friability Test (%)	Thickness Test (mm)	Disintegration Test (min)	Dissolution Test (%)	Assay (%)
	Standard as per I.P	±7.5 % for 80-250mg	4-8	<1	±5	NMT30	Not less than 80	95 - 105
1.	Generic	0.8	3.0	0.4	3.5	2.42	85.8	95.29
2.	Brand	0.9	3.5	0.5	3.4	1.55	86.1	98.01

3. RESULTSANDDISCUSSION

The results of the research work conducted on generic and branded vildagliptin tablet, met the Indian pharmacopoeial specification of quality control test within specified limits. It is carried out in an *invitro* study. Generic tablets comply with IP limits for most evaluatedparameters and show acceptable physical and chemical quality. Weight variation values (0.8%) fall within the ±10% limit for 130 or less mg tablets. Hardness (3.0 kg/cm^2) is within the standard 3-5 kg/cm^2, indicating adequate strength. Friability values (0.4%) are below 1%, meaning they will not easily break during handling. Thickness is uniform 3.5 mm), and tablet disintegrate within IP limits, at 2min 42s, which is the NMT15 minute requirement. Dissolution meets the acceptance criteria, with 85.8%. The assay results (95.29%) indicate the drug content lies within the acceptable 95–105% range. The generic tablets are generally available in standard round or oval shapes, medium size, and typically white or green, depending on excipients and coating used.

Brand tablets meet all IP requirements and demonstrate slightly superior performance in dissolution and assay compared to generics. Weight variation (0.9%), hardness

(3.5kg/cm²), and friability (0.5%) remain within acceptable limits. Thickness (3.4mm) is slightly lower than the generics but consistent, and disintegration times (1min 55 s) are faster than generics, showing better formulation efficiency. Dissolution values (86.1) exceed the minimum limit, and assay values (96.33%) fall within the 95–105% specification. Brand tablet are typically manufactured with more uniform colour (often white or green film-coated with a brand colour), a well-defined shape (commonly oval or capsule-shaped), and a slightly smaller or thinner size, making them more patient-friendly in appearance and handling. However, *invivo*tests should be performed to correlate the *invitro* studies, it will give correct correlation.

CONCLUSION

The present study indicates that both the branded and generic versions of the tablets have identical quality and they fulfilled all the criteria prescribed by the I.P. standards. Therefore, for many patients, generic vildagliptin can be a suitable and more affordable option without compromising effectiveness or safety. However, individual responses to medications may vary, and some patients may prefer or require the branded version due to personal preferences or specific medical considerations. Consulting with a healthcare professional can help determine the most appropriate choice based on individual needs and circumstances. The government must take up generic promotional schemes, general awareness programs on quality of generics to build confidence among prescribers, pharmacists, and consumers. Availability of generics or branded medications in the market with lower price tag and assured quality is essential to make the medicines affordable.

Finally, this study suggests that both generic and branded tablets shown similar results in *invitro.* Hence generic form drug can be widely prescribed to the patient to reduce the medication cost which makes the treatment economically provided that Bioequivalence should be same. However, the *invitro* study should correlate with *invivo* study in human being.

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