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Research Article

Comparative Study Of Vildagliptin Branded And Generic Marketed Antidiabetics Tablets

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ABSTRACT

Vildagliptin is an important antidiabetic drugs used for treatment of diabetes mellitus. The main goal of the current study is to assess the pharmaceutical equivalence of four marketed generics of vildagliptin 50 mg tablets compared to the branded product (Vylda & Agivilda 50 mg). This surveillance study aims to evaluate the product quality of different generics and brands of Vildagliptin tablets, sourced from various pharmaceutical manufacturer's in India by assessing their pharmaceutical and chemical equivalence to determine the appropriateness of their interchangeability. We calibrated pure Vildagliptin & tested the tablets for the content uniformity, hardness, friability, disintegration, dissolution, and potency. The dissolution data were fitted with kinetic models to investigate the release pattern of the studied brands. The in vitro dissolution test was used as a quality control tool to obtain the dissolution profile of vildagliptin compared to the reference drugs. The results revealed that all tested samples exhibited dissolution behavior like standard drug. Comparison studies of innovator drug product & generic drug products were conducted to determine percentage drug release. In-vitro chemical equivalence is not always correspond to bioequivalence. Therefore, continuous evaluation of marketed products is essential to ensure the desired quality. In this study, all the six types of the tablets passed the IP/BP or USP standards for in vitro evaluation tests with a very slight deviation. All brands complied with the standards for weight variation, Hardness, thickness, disintegration and dissolution to determine percentage drug release.

INTRODUCTION

Vildagliptin is an important antidiabetic medication used in combination or monotherapy regimens to treat diabetes mellitus1. Vildagliptin is an antidiabetic drug belonging to Dipeptidyl Peptidase-4 (DPP-4) inhibitors and approved to be used in monotherapy and combination therapy to

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control type 2 diabetes mellitus1,2. Vildagliptin is a BCS-I compound with high solubility and permeability and does not to have a narrow therapeutic index which account for its applicability to be assessed using in vitro dissolution approach. Brand-name medicines (Innovator drugs) are those generated by a company and patented to increase the economic gain of being the exclusive manufacturer of such a drug1. Other pharmaceutical manufacturing businesses may apply to regulatory bodies for permission to commercialize generic versions of the original medications when the patent on the innovator drug product expires. When the patent on the Innovator drug product expires, other pharmaceutical manufacturing businesses can apply to regulatory authorities for clearance to market generic versions of the original medicines.1,3 The dissolution test is an effective quality control method for monitoring batch-to-batch consistency during drug development. Furthermore, dissolution testing can be utilized to optimize formulations and evaluate medication stability over time.1,4 In this study, the equivalency of four commercially available generic versions of vildagliptin 50 mg tablets to the branded product (Vylda & Agivilda 50 mg) is evaluated using the in vitro dissolving test as a quality control method to determine the dissolution profile. As a result, the biopharmaceutics classification system (BCS) was developed as a substitute for in vivo bioequivalence studies and is applicable to highly soluble drugs with known absorption rate and extent in humans, drugs with a broad therapeutic index, and orally administered drugs with immediate release.1,5 Regular quality assessments of marketed pharmaceutical products are crucial for achieving intended pharmacological effects and reducing drug usage hazards6. Low-quality drugs raise healthcare costs and harm people. The spread of low-quality medicine with minimal therapeutic effects increases the risk of drug resistance and undermines treatment effectiveness and weakening people's trust in the health-care system and its providers. Post-marketing quality evaluations are crucial for monitoring drug safety, effectiveness, and patient compliance7. Substandard or counterfeit pharmaceutical items are prevalent in low-income and developing nations. This study evaluated the quality of locally made vildagliptin 50 mg tablets8.

Background of study:

In the comparison study of the Vildagliptin tablets of branded drugs & generic drugs to understand that basic characterization of the Vildagliptin pure drug is necessary as follows1:

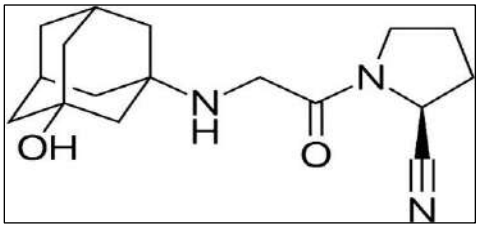


Fig. no. 1 Structure of Vildagliptin

Specific background of Vildagliptin drug 1,2,5:

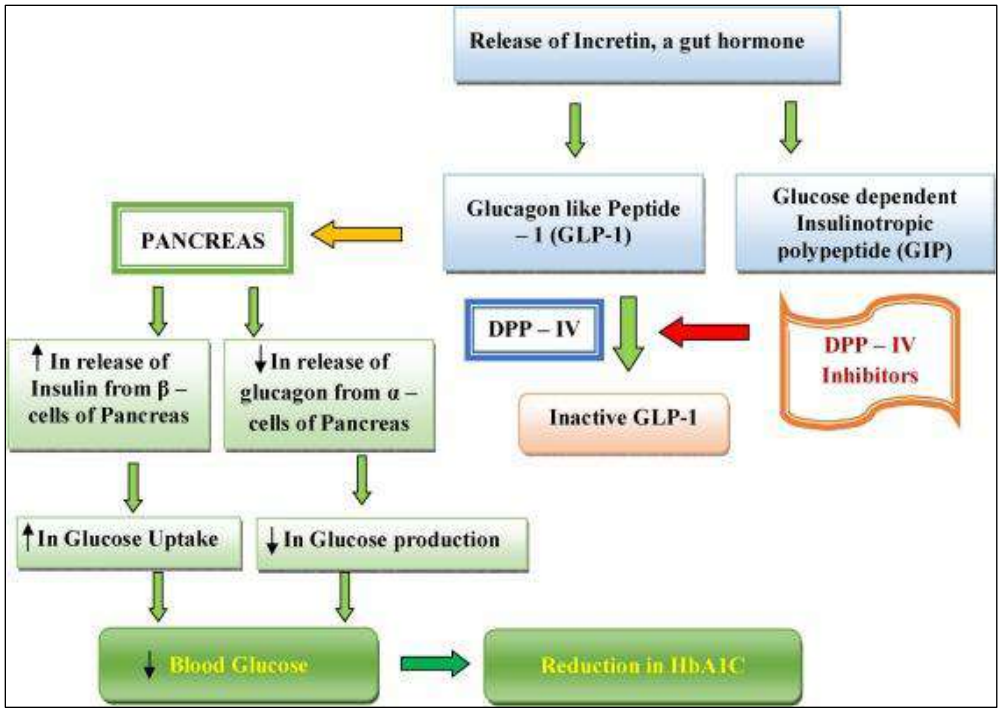
Table no.1

Drug characteristics	Description
Drug name	Vildagliptin
Chemical name	(S)-1-[2-[(3-hydroxyadmant -1-ylaminoacetyl] pyrolidine- 2-carbonitrile.

Mol. Formula	C17H25N3O2
Category	Antidiabetics (DPP-4 Inhibitors).
BCS Class	BCS class - I (High solubility & high permeability).
Solubility	Freely soluble in water, soluble in organic solvents such as ethanol, DMSO, DMF.
Stability	≥ 2 years at 20°C.

Mechanism of action of antidiabetics drugs :

Type 2 diabetes mellitus is chronic disease that requires a patient treatment strategies. Effective therapy for type 2 diabetes requires comprehensive blood glucose management. To establish glycemic control, practitioners must consider patient factors such as age, disease duration, complications, weight, cholesterol levels, and blood pressure. Effective diabetes care requires monitoring glycemic factors such HbA1c, FPG (Fasting plasma glucose), and postprandial glucose levels. Fluctuations in postprandial glucose and FPG levels during a 24-hour period can significantly worsen long-term diabetic problems. A patient-centric therapy regimen for type 2 diabetes should prioritize efficacy, safety, and tolerability, while also taking into account patient features and comorbidities2,10. Vildagliptin has an 85% oral bioavailability and is quickly and thoroughly absorbed when taken orally. Vildagliptin has a 9.3% minimum binding to plasma proteins. This medication is mostly eliminated via hydrolysis in a variety of tissues and organs. The DPP-4 enzyme helpful to the formation of the major hydrolysis metabolite, LAY151; therefore, vildagliptin is also a substrate of DPP-42,10.



Objectives

The objectives of this research are :

1. To study the comparison of Vildagliptin 50 mg drug products.
2. To evaluate and determine the major ingredients in the selected Vildagliptin tablets.
3. To study the dissolution profile of Vildagliptin tablets to deterrmine the drug release profile.

4. To compare empirical data obtained from experimentation to the standard ones.
5. To ascertain which brand is best or save for human consumption.
6. To determine the impact of availability of medical aid, cost, and safety of medicines have on the use of generic or branded medicine.
7. The finding of this study may serve as a guide to consumers to provide a better healthcare intervention programme3.

Research Questions:

Given the objectives, the researcher would like to provide answers to the following questions below:

1. What are the differences in efficacy, safety, quality and patient outcomes between branded and generic formulations of Vildagliptin?
2. What are the quality parameters of each brand of Vildagliptin tablet?
3. How are the different brands of Vildagliptin different in its Quality parameters?
4. Which one of these brands of Vildagliptin tablet are effective and economical for human consumption?
5. Does generic ones and branded dispensed tablets complies with specifications given in pharmacopoeias?

Delimitations

This study focuses on the comparative analysis study of different brands of Vildagliptin tablets. As the needs for type II diabetes relieve tablets have grown in the health sector it is important to check the quality of these tablets so as to limit the circulation of defective ones. This is based on some instances that there are some drug being sold in India whose quality does not meet standard ones. Therefore, this research has identified and examine the active ingredients taking into consideration the various physiochemical properties of different brands of Vildagliptin tablets. This research was conducted at SVPM's COP main campus in Baramati. Moreover, the research has examined six brands of Vildagliptin tablets sold in pharmacies around India .

Limitations

There were several constraints the researcher encountered doing the comparative study of vildagliptin tablets1. Firstly to obtain the active pharmaceutical ingredient i.e. pure vildagliptin drug. To perform the different dilutions for prediction of calibration graph of pure vildagliptin drug. Some of those were the unavailability of some apparatus (most especially a photo spectrometer with a wavelength of 100nm to 300nm) or chemicals in many laboratories in the country is a serious challenge. The absence of appropriate solvents that are more useful for analysis and the lack of time arrangement of chemical distribution and instrumental uses from the laboratory of the university are some of the challenges.

Significance of study

Comparative study of different marketed drugs of Vildagliptin such as branded drugs & generic drugs is important to improve the quality, safety, efficacy of the marketed Vildagliptin antidiabetics tablets. Comaparative study is neccesory to reduces the side effects & adverse effects of Vildagliptin marketed tablets. It is very significant role to improve the cost effectiveness & improve the patient compliance6,7. The outcome of this study promises tremendous benefits to a diverse academic and medical interested groups in India. First, this research will not only enable the researcher to determine which brand of Vildagliptin tablet is better or qualified enough for human consumption, but it will also serve as a reminder to manufacturers or the pharmaceutical industries and users of the ineffectiveness or substandard drug that are also being produced or sold on the Indian market. Secondly, students and researcher stand a chance to benefit from the organizations of the materials and the flow of

thoughts exhibited. This will guard them in carrying out similar research .

Definition of key terms :

1. Antidiabetic : Any drug used to prevent or alleviate diabetics. Antidiabetic control blood glucose and are used to treat diabetes mellitus2.
2. Brand-name medicines : Brand-name medicines are originator products or medicines that have been discovered by a company and are patented to maximise any economic gain that may result from being the sole company producing a new drug treatment for a particular illness or disease condition3.
3. Generic drug : A generic drug is identical to a brand name drug in dosage form and strength, safety, route of administration, quality, performance characteristics and intended use. The generic medicines are bioequivalent to branded medicines3.
4. Disintegration: the breaking down of tablet into small particles or into its constituent elements11.
5. Physicochemical property: it is relating to physical and chemical properties of a substance.
6. Disintegration time : the breaking of the interparticulate linkages that were created during the tablet's compression, which results in the mechanical breakdown of the broken tablet into tiny granules upon ingestion11.
7. Dissolution time : The drug is present in solution form extent and rate of solution formation from a dosage form.
8. Calibration curve : The curve used for determination of concentration14.
9. Spectroscopic analysis: is an analytical method in chemistry meant to determine the chemical composition of a substance such as a drug16.
10. Drug release: the process in which drug solutes migrate from the initial position in the polymeric system to the polymer's outer surface and then to the release medium17.
11. Efficacy : Ability of drug to produce desired therapeutic effect.
12. Stability : Ability of pharmaceutical product to retain its chemical, physical and biopharmaceutical properties within specified limits through shelf-life.

LITERATURE SURVEY:-

Literature survey on comparative study of Vildagliptin Branded & generic drug products.

General Review

Ghadah H.et al. (2024):

Marketed medications, whether brand or generic, are of poor quality and do not satisfy accepted standards. Vildagliptin is a popular antidiabetic medicine used alone or in combination with other medications to treat diabetes mellitus. This study aims to comparison of two available brands of vildagliptin 50 mg tablets to the four generic product 50 mg. Current study presents an in vitro protocol for quality evaluation of recently released generic drugs1.

Sohel Daria, et al. (2022):

Continuous monitoring of pharmaceutical products is important because it matters to human health. Regular quality assessment of marketed pharmaceutical products is necessary for achieving intended pharmacological effects and reducing drug usage risk factors. In low- and middle-income nations, adulterated, faked, and substandard pharmaceuticals pose serious health risks. Post-marketing evaluation study of quality characteristics is essential for monitoring drug safety, efficacy, and patient compliance6.

Drugs and chemicals

Sohel Daria et al. (2022):

We randomly collected two brands and four generics of vildagliptin 50 mg tablet from various local pharmacies. We meticulously examined the purchased products for physical appearance, name of the manufacturer, batch number, date of

manufacturing, date expiry, manufacturing license number, and price. All the chemicals and reagents used in this study were analytical grade6.

Vildagliptin uses:

Santwana Padhi et al. (2020):

Diabetes mellitus (DM) is a metabolic disorder that occurs in the body because of decreased insulin activity and/ or insulin secretion. In the present review article, we have made an attempt to explore the pathophysiology of type II DM. DM is caused either by deficiency of insulin secretion, damage of pancreatic β cell or insulin resistance related to non-use of insulin. Conventional approach for the treatment of type II DM10.

Irin Dewan et al. (2015) :

Vildagliptin is an orally active, powerful, and specific inhibitor of dipeptidylpeptidase (DPP) that blocks incretion hormone inactivation. It has been proved to be an effective and safe choice for better glycemic control in a wide variety of TDM patients. It has demonstrated HbA²C reduction capability when administered as monotherapy or in combination with other OADs, without weight gain and minor hypoglycemia12.

Pharmacokinetics of Vildagliptin:

Yan-Ling et al. (2012) :

Vildagliptin was absorbed rapidly (median time to reach maximum concentration 1 hour) and had a mean terminal elimination half-life ranging from 1.32 to 2.43 hours. The peak concentration and total exposure increased in an approximately dose-proportional manner. Vildagliptin inhibited DPP-4 (>90%) at all doses and demonstrated a dose-dependent effect on the duration of inhibition. The areas under the plasma concentration-time curves of glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP) were increased13,24.

UV Spectrophotometer use :

Sheetal V. Mane et al (2022) : Development of UV-Visible spectrophotometric method for the estimation of vildagliptin in different medium. A simple, accurate, precise, cost effective, rapid and sensitive UV/visible spectrophotometric method was developed for the determination of Vildagliptin in active pharmaceutical dosage form. The developed method was validated as per ICH guidelines. The drug was analyzed using UV/visible spectrophotometric method was validated in terms of linearity and range. The solvents used was water, 0.1 N HCl and the wavelength corresponding to maximum absorbance of the drug were found at 210 nm.The drug was confirmed by interpretation of UV spectra. Hence, proposed method stands out validated and shows a linear relationship and thus may be used for routine analysis of Vildagliptin in pharmaceutical dosage forms14.

Evaluation parameters :

Nayak AK, et.al. (2010) –

Comparative in vitro Bioequivalence Analysis of Generic Tablets. The dissolution test was undertaken using Tablet Dissolution Tester (TDT-08L, Electrolab, India) in 6 replicates for each brand. The dissolution medium was 900 ml of 0.1N HCl which was maintained at 37 ± 0.5 °C. In all the experiments, 5 ml of dissolution sample was withdrawn at 0, 15, 30, 45, 60, 75, 90 min and replaced with equal volume to maintain sink condition. Samples were filtered and assayed by UV-VIS spectrophotometer (UV-1700, Shimadzu, Japan) at 210 nm. The concentration of each sample was determined from a ten point calibration curve obtained from standard samples5.

Ghimire Prakash et al. (2020) :

Pharmacopoeial comparison of in-process and finished product quality control test for pharmaceutical tablets Pharmaceutical industries aim to generate high-quality products using in-process and completed product quality control measures. In-process quality control encompasses all steps of production, including specification establishment, sampling, testing, and analytical

clearance, to ensure that intermediates, packaging materials, and finished pharmaceutical tablets fulfill approved specifications for efficacy, safety, and elegance. This ensures consistent and elegant product performance for consumers8.

Daniela Silva et al (2018):

Disintegration is a physical process related to the mechanical breakdown of a tablet or granulate particle into smaller particles. This review investigates disintegration mechanisms, pharmacopeial use of the disintegration test and scientific studies showing its utility and potential as a pharmaceutical performance test. With a proper dosage form understanding and demonstration/justification of the mechanistic details of drug dissolution from a dosage form, dissolution testing might be replaced by disintegration testing as a performance test11.

MATERIALS AND METHODS

Materials used :

Legally registered two brands & four generics brands of marketed tablets obtained from local medicine shop sampled as A, B, C, D, E and F were used during this study. All others research grade chemical reagents and logistical supports were provided by SVPM's COP, Baramati. Working standard, Indian pharmacopoeia, United State Pharmacopeia & British Pharmacopoeia were used as a reference for the experiment.

Label information & comparison of Vildagliptin 50 mg tablet6,18.

Table no. 2

Tablet marketed name	Type	Batch no.	MFG date	EXP. date
Vylda (Emcure)	Brand	E16KN23022	OCT-23	MAR-26
Vildagliptin (Skyogen)	Generic	T222838	FEB -23	JAN -25
Agivilda (Medplus+)	Branded	MVA230703	JUL -23	JAN -25
Vildagliptin (PMBI)	Generic	VDA4002	OCT - 22	SEP -24
Vildax (Daxia)	Generic	MT-221325	NOV-22	OCT-24
Vildagliptin (Prevego)	Generic	VDT -23587	JUL -23	JUN -25

Fig no. 3

Fig. no. 4

Fig. no. 5

Methods:

Universal test for the pharmaceutical tablets dosage form

Description :

This test is a qualitative description of the appearance of tablets depicts on a specification. For example, specification illustrates the tablets as an: white, round, biconvex, uncoated & film-coated tablet, embossed with "drug strength (Rx)" on the single side8,16.

Identification :

The objective of an identification or identity test is to substantiate the identity of the active pharmaceutical ingredient(s) (API) and to

distinguish the compound(s) that is closely related in structure as that of compounds that are likely to be present in pharmaceutical tablets8,16.

Assay :

This tests also known as a content test and is used to conclude the strength or content of the active pharmaceutical ingredients (API) present in the tablets8. This method is specific and quantitative to detect chemical changes over time and thus taken as a stability-indicating test. In many cases, it needs to apply the same method (for example, UV/HPLC are shown in Fig. 1) for both the drug substance and the number of impurities.12,16,23.

Quality control test for tablets: non-compendial standards

There are frequent numbers of tests applied to tablets which are not included in official pharmacopoeias and will be based on the manufacturer's own product specification.

General appearance test :

The general appearance of the tablet can be controlled by assessment of a number of features such as tablet's dimensions (size and shape), colour, odour, taste, texture, readability of any identifying markings. Unique identification marking Pharmaceutical industries exploit some type of embossing, engraving or printing as some forms of unique marks apart from the addition of colour. These markings embrace company name or logo, product code, drug strength, product name etc. on tablets8.

Hardness test :

Hardness may be important criterion, it affects the friability, disintegration, and dissolution of tablets. Tablet entails a certain amount of hardness and resistance to friability to withstand abrasion & breakage of tablets in handling, packaging, and transportation. The extent of pressure during compression, characteristic of granulation affects the hardness of tablets. Thus, to control a tablet's hardness, it's important to control pressure. Hardness is measured by hardness tester-the Monsanto tester, the Pfizer tester, the Erweka tester, the Schleuniger tester; or a multifunctional system. The tablets are typically positioned between two platens, where one is constant, and other moves apply ample power to cause fracture of a tablet8. Therefore, adequate tablet hardness and resistance to powdering are essential requisites for quality products. This test measures the ability of tablets to withstand pressure or stress during handling, packaging, and transportation16,18.

Fig no 6

Thickness and diameter test :

The thickness of the tablets was determined using vernier caliper and the results were expressed as mean values of 20 determinations, with standard deviations. The tablet put between the sliding jaw of vernier calliper is then moved until the object is gripped firmly between the jaws. Reading is shown on digital screen. The thickness of the tablet should be controlled within a range of ±5 % deviation of a standard limits. Which is expressed in millimeter (mm)8.

Fig. no.7

Quality control test for tablets dosage form – pharmacopoeial standards

Friability:

A compressed and uncoated tablets strength and durability may be determined through the use of friabilator mostly by Roche friabilator. For this test, tablets with an average weight of ≤ 50 mg and greater than 50 mg, sample of entire tablets equivalent to about 5 g and a sample of 10 whole tablets respectively are weighed, dedusted and placed in drum of friabilator where it is rotated for 100 times. The friability value is expressed in percentage, which is calculated by using the subsequent formula8:

$$\textbf{Friability} = (Wi - Wf)/ Wi \times 100$$

Where,

Wi = Total initial mass of tablets;

Wf = Total final mass of tablets.

Generally, the test is run only once but in case of difficulty in interpretation of the result, or if final weight loss is higher than the targeted value, the test can be replicated twice, and the result is expressed as a mean of the three tests. Apart from cracked, chipped, broken of tablets, if weight loss of rolled (after 100 times revolution) tablets is more than 1% then the test is not acceptable8,16,23.

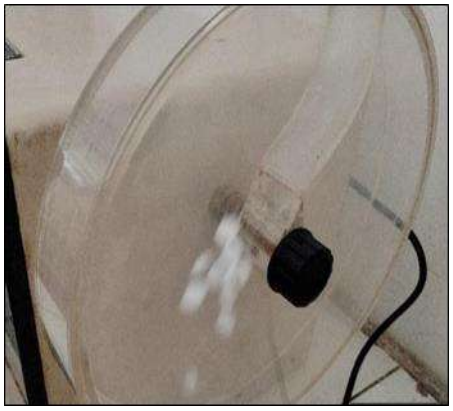


Fig.no.8

Fig. no. 9

Weight variation test :

This test is applicable to both coated and uncoated tablets, involving the individual weighing of 20 tablets and the determination of their average mass. If the weight of no more than two of them deviates from the average, the standards for weight variation are satisfied. weight by more than the proportion shown in tables 3 and 4, and no tablet's weight varies by more than twice that amount8.

The result of this test is expressed in percentage and calculated from the given formula8,16,23:

$$\textbf{Weight Variation} = (WI - WA)/WA \times 100$$

Where,

WI = Individual tablet's weight;

WA = Average tablet's weight

Weight variation tolerance for uncoated and film coated tablets as per IP, BP and USP8.

IP/BP	Percentage Deviation (%)	USP
80 mg or less	10	130 mg or less
More than 80 mg and less than 250 mg.	7.5	More than 130 mg and less than 325 mg

250 mg or more	5	325 mg or more

Fig. no. 10

Disintegration test :

Disintegration is a physical process associated with tablets are mechanically broken down into smaller particles/granules due to inter-particle interactions during compaction of active pharmaceutical ingredients (API) and excipients.

Disintegration involves two steps: first, tablet disintegration into minute granules, followed by disaggregation or granule disintegration. The first step determines the pace of initial drug release from the tablet. Disintegration process increase the surface area compared to the intact tablet yields a higher dissolution rate. As per IP disintegration apparatus consists of six open-ended clear tubes measuring 77.5±2.5 mm length, 21.5 mm internal diameter, and 2.0 mm wall thickness. The seamless tube was secured to a 10-mesh screen at the bottom of the basket rack assembly8. To determine the time of disintegration, a single disc is placed in each tube, and the basket rack. Place the assembly in a vessel, preferably a 1-litre beaker, at a temperature of 37 ± 2 °C (unless otherwise specified in the individual monograph). The wire mesh should be at least 15 mm beneath the liquid surface when in the outmost position, and at the lowest position. The top of the basket rack assembly should not be immersed in medium. A motor-driven tool moves the tablet basket assembly 5.5±0.2 cm up and down at 28 to 32 cycles per minute. Perforated plastic discs could also be used in the test. Introduce one. In the test, one tablet is placed in each of the basket's six tubes, and perforated plastic discs may be used if necessary8,16.

Fig.no.11

Preparation of calibration curve:

Calibration curve of Vildagliptin was prepared with the help of UV spectroscopy.

Weight accurately 10 mg of Vildagliptin drug dissolve in 100 ml volumetric flask with 0.1N HCL. Then pipette out 10 ml of this solution and dilute to 100 ml with 0.1 N HCL. This is the preparation of stock solution. Then pipette out 1 ml of above stock solution and dilute to 10 ml with 0.1 N HCL this is the working solution to form the 1 ug/ml concentration. (1,2,3...10 ug/ml) respectively12.

UV method validation :

The ultraviolet spectrophotometric method was validated for different parameters like linearity and range14,16. Linearity : The linearity was evaluated by analysing the different concentration of standard solution of vildagliptin. Calibration curves were constructed by plotting a graph by taking concentration (µg/ml) on X-axis and

absorbance on Y-axis. This plot gives a straight line and the linearity can be determined using y = mx + C formula regression equation was calculated14.

Determination of λ max by UV spectroscopy

The λ max of Vildagliptin was found to be 210 nm as can be seen from the scan14.

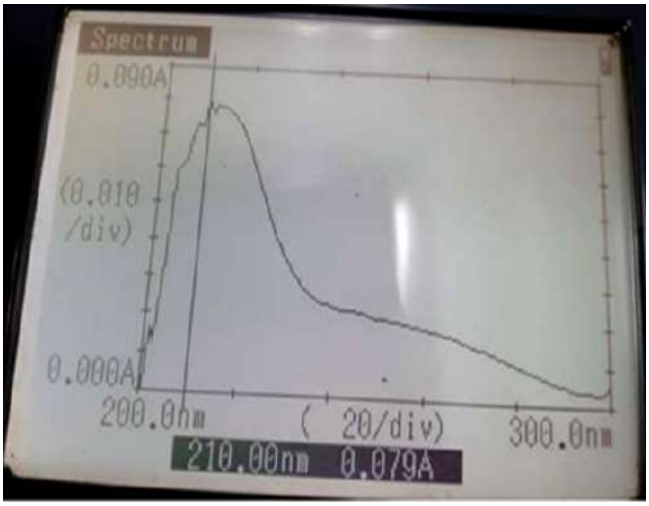


Fig. no. 12

Uniformity of Content :

To evaluate tablet potential for efficacy, it is necessary to monitor the amount of drug per tablet, from tablet to tablet, and from batch to batch. For this test according to BP using the appropriate experimental analysis method, determine the individual content of active substance of 10 tablets taken at random. The tablet complies with BP-based testing, if the average content of each individual content is 85 % to 115 %. If the tablet fails to comply with the test, more than one distinct content is out of range or if one individual content is out of the range the average content is 125 % to 75 %. If an individual content exceeds the 85 % to 115 % limit, set the individual content of the other 20 tablets taken randomly, in the range of 75 % to 125 % 16. Standard limit 90-105%.

Procedure25 :

- Weigh 20 tablets (as per monograph) and then grind them using a mortar and a pestle.
- From this powder, take equivalent amount containing API and dissolved in suitable solvent (as per monograph).
- The solution is further diluted and filtered.
- The absorbance of filtrate is measured by to using UV Spectrophotometer.

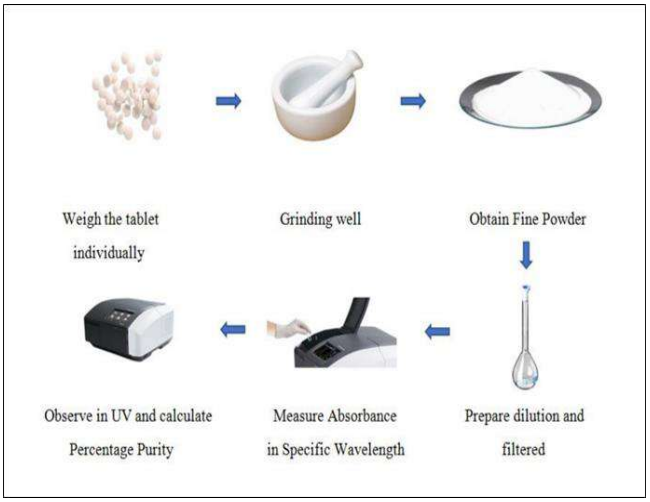


Fig.no. 13

Dissolution test :

The dissolution test of six vildagliptin tablets from each brand was conducted using the dissolution apparatus USP II (Paddle apparatus) (Electrolab, Mumbai, India) at 50 rpm. A total of 900 mL 0.1N HCl was used as a dissolution medium at 37±0.5°C. The 2 mL of the dissolution sample were withdrawn at 0, 15, 30, 45, 60, 75 &90 min and replaced with an equal fresh medium to maintain sink condition. Samples were filtered and assayed by an UV-VIS spectrophotometer (Shimadzu) spectrophotometer at 210 nm. We determined the concentration of each solution using the calibration curve obtained from the standard vildagliptin1,8,16.

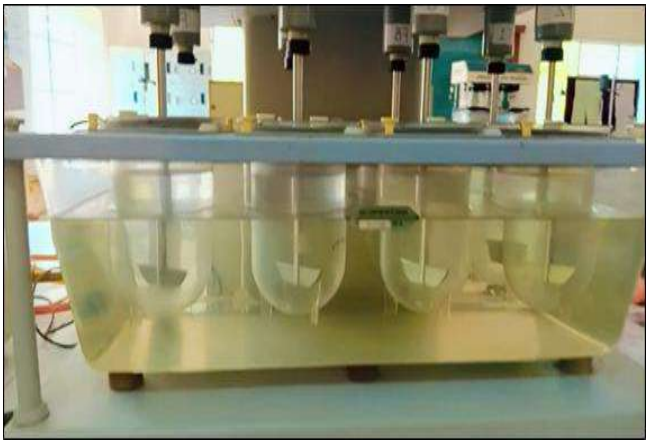


Fig. no. 14

Statistical Analysis

All statistical analysis was performed by MS Office Excel 2011 and Graph Pad Prism software version . Results generated were presented as Mean ± Standard Deviation.

RESULTS AND DISCUSSION

Hardness test :

Tests Hardness has impact on disintegration. The results of the hardness test are displayed in Table. All brands represented hardness value of < 4kg/cm2 thus, all products conformed to fulfill the requirement for hardness test. However, the average hardness of the products is different from each other, and it is observed that tablet hardness ranged from 2 Kg/cm2 to 4 Kg/cm2 for different brands The reason for this variability between brands may have been related to pharmaceutical manufacturer's formulation conditions such as alteration in machine speed, granulation techniques, and amount of lubricants added during manufacturing processes8,16,18.

Tablet name	Hardness in kg/cm2
Vylda (Emcure)	2.3
Vildagliptin (Skyogen)	2.5
Agivilda (Medplus+)	4
Vildagliptin (PMBI)	3.2
Vildax (Daxia)	2.5
Vildagliptin (Prevego)	3

Thickness and Diameter test :

The thickness of the tablets was determined using vernier caliper and the results were expressed as mean values of 20 determinations, with standard deviations. The tablet put between the sliding jaw of vernier calliper is then moved until the object is gripped firmly between the jaws. Reading is shown on digital screen8.

Tablet name	Thickness (mm)	Diameter (mm)
Vylda (Emcure)	3.20	8.04
Vildagliptin (Skyogen)	3.07	8.07
Agivilda (Medplus+)	3.52	8.01
Vildagliptin (PMBI)	3.46	8.01
Vildax (Daxia)	3.80	8.14
Vildagliptin (Prevego)	4.86	12.92

Friability test:

Friability reveals good mechanical strength of the tablets. A compressed and uncoated tablets strength and durability may be determined through the use of friabilator mostly by Roche friabilator The result of friability test as shown in table. Two brands (Emcure, Medplus) and two generics (PMBI,Prevego) had percent friability below 1%. Two generics (Skyogen, Vildax) which indicates more than 1% friability may face difficulty during storage or transportation. This result of friability ensures that all the tablets of each brand were mechanically stable8,19.

Tablet name	% Friability
Vylda (Emcure)	0.09
Vildagliptin (Skyogen)	0.121
Agivilda (Medplus+)	0.09
Vildagliptin (PMBI)	0.1

Vildax (Daxia)	1.5
Vildagliptin (Prevego)	0.005

Weight Variation test:

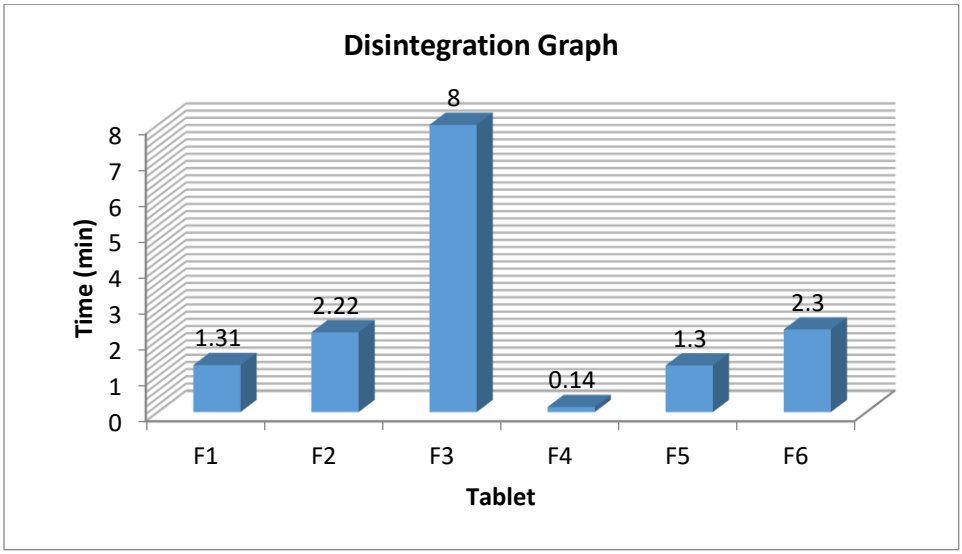
Weight variation functions as a pointer for good manufacturing practices (GMP) that is maintained by the manufacturers as well as amount of active pharmaceutical ingredient (API) contained in the formulation. According to USP not more than two tablets should cross the single limit and none of them should cross the double of the limit. The weight variation for all the tablets used in this study showed compliance with the official specifications of USP18,23,25.

Tablet name	Individual Wt	Wt of 20 tablets	Average wt	% deviation
Vylda (Emcure)	0.199	4.01	0.200	0.40
Vildagliptin (Skyogen)	0.163	3.29	0.164	0.39
Agivilda (Medplus+)	0.198	3.98	0.198	0.20
Vildagliptin (PMBI)	0.198	3.95	0.197	0.45
Vildax (Daxia)	0.194	3.93	0.196	0.37
Vildagliptin (Prevego)	0.556	11.22	0.561	0.026

Disintegration test:

Tablet disintegration into minute granules, followed by disaggregation or granule disintegration. The pharmacopoeias limits for disintegration according to IP/BP times is 15 min8,18. which 30 min as per USP frame of tablets along with the liquid medium and the operating temperature are 37±2°C for uncoated tablets. Following table shows that all the brands met the requirement of official criteria23,25.

Tablet name	Disintegration time (min)
Vylda (Emcure)	1.31
Vildagliptin (Skyogen)	2.22
Agivilda (Medplus+)	8
Vildagliptin (PMBI)	0.14
Vildax (Daxia)	1.30
Vildagliptin (Prevego)	2.30

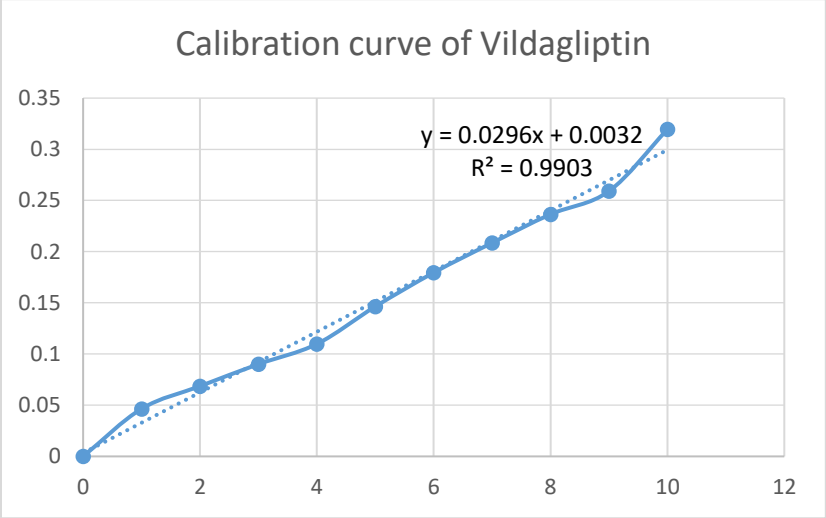


Preparation of calibration curve:

Calibration curve of Vildagliptin was prepared with the help of UV spectroscopy.

Weight accurately 10 mg of Vildagliptin drug dissolve in 100 ml volumetric flask with 0.1N HCL. Then pipette out 10 ml of this solution and dilute to 100 ml with 0.1 N HCL. This is the preparation of stock solution. Then pipette out 1 ml of above stock solution and dilute to 10 ml with 0.1 N HCL this is the working solution to form the 1 ug/ml concentration. (1, 2,3...10 ug/ml) respectively12,16,18.

Concentration ug/ml	Absorbance ($L\ mol^{-1}cm^{-1}$)
0	0
1	0.0465
2	0.0686
3	0.0901
4	0.1098
5	0.1464
6	0.1795
7	0.2086
8	0.2365
9	0.2591
10	0.3195



Drug content uniformity :

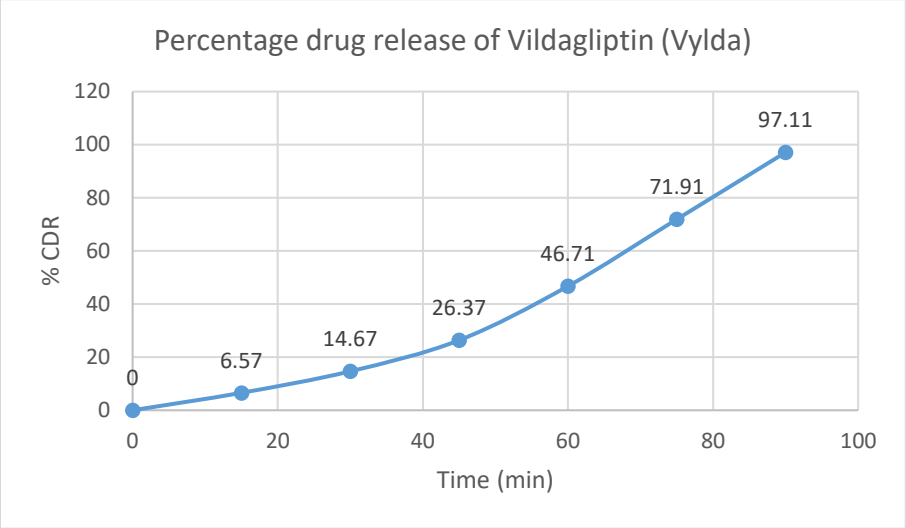
The 10 tablets were powdered and powdered tablet equivalent to 50 mg of drug was added in 100 ml of 0.1 N HCL and stirred to dissolve the vildagliptin. Prepare the dilution and analyzed spectrophotometrically against blank solution (0.1N HCL) for the determination of drug content at 210 nm16,20. The tablet complies with BP-based testing, if the average content of each individual content is 85 % to 115 %. If the tablet fails to comply with the test, more than one distinct content is out of range or if one individual content is out of the range the average content is 125 % to 75 %. The following all vildagliptin tablets pass the test between 85-115 % limit21,22,25.

Tablet name	% Drug content
Vylda (Emcure)	104
Vildagliptin (Skyogen)	91
Agivilda (Medplus+)	99
Vildagliptin (PMBI)	86.14
Vildax (Daxia)	96.95
Vildagliptin (Prevego)	98.92

Dissolution test :

The dissolution test of six vildagliptin tablets from each brand was conducted using the dissolution apparatus USP II (Paddle apparatus) (Electrolab, Mumbai, India) at 50 rpm. A total of 900 mL 0.1N HCl was used as a dissolution medium at 37±0.5°C16,18.Dissolution is another very important quality control parameters that is directly interconnected to the absorption and bioavailability of drug. The present study exposed that at different time intervals drug release rate is better in Vildagliptin tablets23,25.

Time (min)	Absorbance (L $mol^{-1}cm^{-1}$)	Conc. ug/ml	Conc. ug/ml ×10 DF	Conc. mg/ml	Conc. mg/ml × 900ml	CDR	% CDR
0	0	0	0	0	0	0	0
15	0.0465	1.46	14.6	0.0146	13.14	13.14	6.57
30	0.0570	1.81	18.1	0.018	16.2	29.34	14.67
45	0.0819	2.65	26.5	0.026	23.4	52.74	26.37
60	0.1372	4.52	45.2	0.0452	40.68	93.42	46.71
75	0.1698	5.62	56.2	0.0562	50.4	143.82	71.91
90	0.1699	5.63	56.3	0.0563	50.4	194.22	97.11



Comparison of % CDR of Vildagliptin tablets

Time (min)	Vylda	Skyogen	Agivilda	PMBI	Vildax	Prevego
0	0	0	0	0	0	0
15	6.57	4.86	12.55	9.18	10.03	8.46
30	14.67	15.66	26.95	16.74	22.14	21.1
45	26.37	31.59	43.2	30.06	35.04	35
60	46.71	51.66	61.65	46.57	50	53
75	71.91	72.01	81.22	64.44	70	74
90	97.11	98.46	99.8	84.65	92.74	97.8

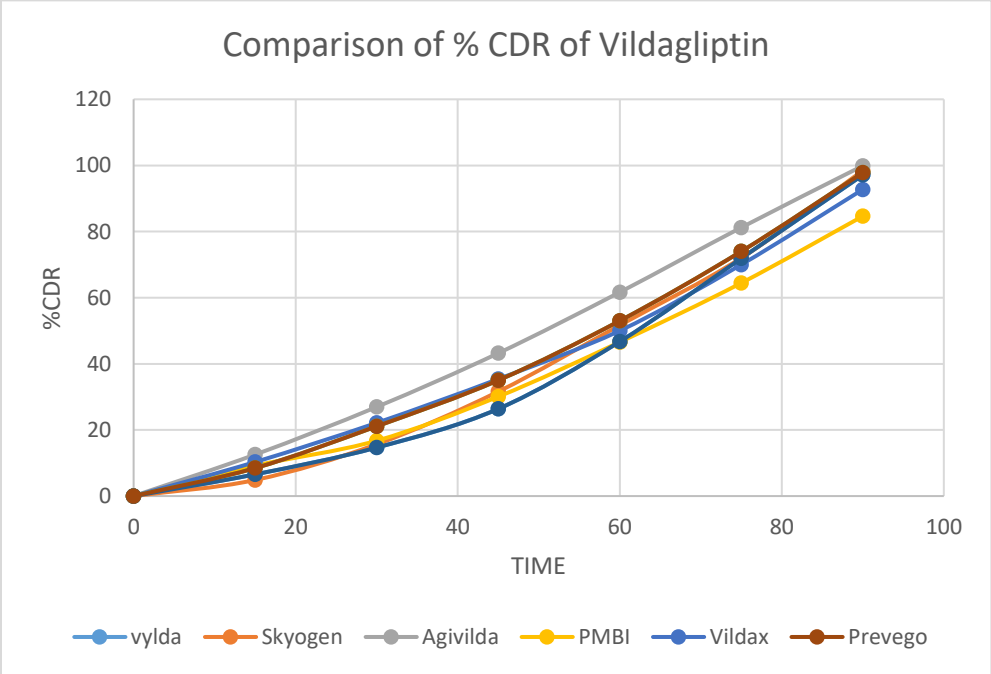


Fig. no. 18 Percent of drug release after 90 min in 0.1 N HCL . All the brands meet the specification of the U.S.P/IP.

CONCLUSION:

The current research study was performed to identify the finished product quality control tests of branded and generic drugs of Vildagliptin, an antidiabetic medication based on different compendial and non-compendial standards concerning quality attributes prior to their release into the market8. All tablets pass the quality control evaluation such as weight variation, hardness, thickness, diameter, friability testing, disintegration and dissolution study of two different branded and four generic dispensed tablets of Vildagliptin sold in pharmacies across India are assessed within standard limits6,8. Purity determination of drug is done by performing calibration curve of pure drug at 210 nm wavelength12,14. All of the tablets in this study which showing more than 90% of the drug release and one brand of vildagliptin (PMBI) which shows slightly less drug release In the present manufacturing practice, in-vitro quality control parameters test plays an important role to compare with various brand and generic molecules and to provide enough therapeutic activity of the dosage form25,26,27. Therefore, based on the objectives of this research, it has been proven that the six brands of Vildagliptin used in this study are suitable for human consumption and can be administer at their recommended dosage by a health practitioner. The data collected and calculated in chapter 4, it has indicates that all of the brands of Vildagliptin used in this study passed/meet the quality testing specification by different pharmacopoeia (USP/IP).This study underscores the necessity for constant surveillance of marketed drugs by the regulatory bodies to ensure the circulation of high quality pharmaceutical products from different manufacturers. Although in vivo testing is required for final remarks regarding the quality of marketed brands of Vildagliptin, the findings from this study confirm that the tested brands meet the required quality standards.

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