WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.632
Volume 12, Issue 8, 1059-1076 Research Article ISSN 2278 – 4357

INVITRO COMPARATIVE DISSOLUTION STUDY FOR DIFFERENT BRANDS OF SAXAGLIPTIN AND VILDAGLIPTIN TABLETS USING UV SPECTROSCOPY AND THEIR VALIDATION AS PER ICH GUIDELINES

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Article Received on
31 May 2023,

Revised on 20 June 2023,
Accepted on 10 July 2023

DOI: 10.20959/wjpps20238-25448

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ABSTRACT

Invitro drug dissolution is an important Quality control parameter in Pharmaceutical discipline used to evaluate the release of drug from tablet dosage form under standard conditions. The present research proposal is a comparative dissolution study for two different brands of majorly used antidiabetic drugs, Saxagliptin and Vildagliptin both belonging to the gliptin category of anti diabetics. Pharmacologically, their anti- diabetic action is attributed to inhibiting DPP- 4 Enzyme to deal with type 2 Diabetes. The aim of this study is to perform *Invitro* comparative dissolution study for different brands of Saxagliptin and Vildagliptin tablets using UV spectroscopy as the chief analytical technique. The aim of the present research work is to investigate the most preferable dissolution media for drug evaluation. Phosphate buffer of pH 6.8 was selected, prepared and maintained at a temperature of 37±0.5°C and the paddle type II USP apparatus was set at 100 rpm, and aliquots were withdrawn at an interval of 15, 30,45 and 60 minutes. The absorbance maxima (lamda max) of Saxagliptin tablet was 266 and 264 nm and Vildagliptin tablet was 265 and 263nm. The analytical method was evaluated as perICH guidelines on accuracy and precision parameters. The intraday precision of Saxagliptin was 0.243061% and for Vildagliptin was 0.17432% RSD respectively. The result of the percentage recoveries was found to be98%, 99.5% and 101.6% for Saxagliptin and for Vildagliptin 99.2%, 98.7%, and 99.9%. The effective dissolution method was developed and validated by UV spectrophotometer which is convenient, cost effective, sensitive and rugged for major applications in various pharmaceutical industries.

KEYWORDS: Dissolution; Saxagliptin and Vildagliptin; ICH Guidelines; UV spectrophotometric method.

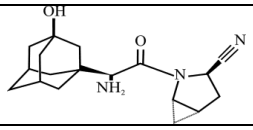
ROLE OF UV SPECTROSCOPY FOR DISSOLUTION STUDIES

UV Spectroscopy is the preferred analytical choice for drug analysts throughout the quality Control domain. Preformulation and formulation development involve dissolution testing, a natural bondhas been established between dissolution and spectroscopy.

- ✓ **Simplicity and Reliability**: Dissolution testing is especially reliant on UV spectroscopy fordetecting the amount of drug released in the medium.
- ✓ **Evaluation of Therapeutic effectiveness**: Optimizing a drug product's Therapeutic effectiveness**.** While some would think that analysis of dissolution samples by high-performance liquid chromatography (HPLC) would always be the most efficient and effective method, analysis by UV spectroscopy does provide for immediate data and trending, as well as significant cost savings.
- ✓ **UV Imaging has advantages:** Which compared with the other spectroscopic imaging technologies being applied to dissolution testing.
- ✓ **UV imaging provides simple quantification of:** Drug release and bulk concentration calculation is simplified and convenient because UV spectroscopy obeys Beer's Law.
- ✓ **UV Spectroscopic Calculations**: Calculations involving drug release is simplified with helpof Calibration Curve methods.

DRUG PROFILE

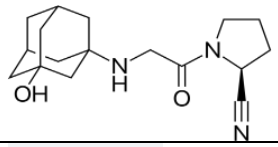
1. SAXAGLIPTIN

Name of drug	**SAXAGLIPTIN**
Chemical structure	
Synonym	Onglyza
IUPAC name	(1S,3S,5S)-2-[(2S)-2-amino-2-(3-hydroxy-1-adamantyl)acetyl]-2-azabicyclo[3.1.0]hexane-3-carbonitrile
Chemical formula	C18H25N3O2
CAS registry number	HCl: 709031-78-7
Molecular weight	333.432 g/mol
State and colour	White Solid
Solubility	soluble in water, and very soluble at low pH showing a minimum solubility of 17.6 mg/ml over the pH range 1.2 to 8.7
Melting point	96 - 102 °C
PKa value	7.3
Lambda Max	266nm

Pharmacological data

Therapeuticcategory	**Dipeptidyl peptidase-4 (DPP-4) inhibitors.**
Pharmacological use	Saxagliptin is used along with diet and exercise to lower blood sugar levels in patients with type 2 diabetes. Saxagliptin is in a class of medications called dipeptidyl peptidase-4 (DPP-4) inhibitors.
Mechanism of action	Saxagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor antidiabetic for thetreatment of type 2 diabetes. DPP-4 has two main mechanisms of action, an enzymatic function and another mechanism where DPP-4 binds adenosine deaminase, which conveys intracellular signals via dimerization when activated. Saxagliptin forms a reversible, histidine-assisted covalent bond between its nitrile group and the S630 hydroxyl oxygen on DPP-4. The inhibition of DPP-4 increases levels active of glucagon like peptide 1 (GLP- 1), which inhibits glucagon production from pancreatic alpha cells and increases production of insulin from pancreatic beta cell.
Dose	(5mg) once a day
Stability	24 Months for 5mg
Storage	Store below 30 C

2. VILDAGLIPTIN

Name of drug	**Vildagliptin**
Chemical structure	
Synonym	Vildagliptin
IUPAC name	(S)-1-[2-(3-Hydroxyadamantan-1-ylamino) acetyl]pyrrolidine-2-carbonitrile
Chemical formula	C17H25N3O2
CAS registry number	
Molecular weight	303.399 g/mol

Physicochemical properties of drug

State	White solid
Solubility	freely soluble in water
Melting point	149- 155^0 C
Flash point	
PKa value	9.03
Max	

Pharmacological data

Therapeutic category	oral anti-hyperglycemic agent (anti-diabetic drug) of the dipeptidylpeptidase-4 (DPP-4) inhibitor
Pharmacological use	Vildagliptin (LAF237) is an orally active antihyperglycemic agent that selectively inhibits the dipeptidyl peptidase-4 (DPP-4) enzyme. It is used to manage type II diabetes mellitus, where GLP-1 secretion and insulinotropic effects are impaired.

Mechanism of action	Vildagliptin exerts its blood glucose-lowering effects by selectively inhibiting dipeptidyl peptidase-4 (DPP-4), an enzyme that rapidly truncates and inactivates GLP-1 and GIP upon their release from the intestinal cells. DPP-4 cleaves oligopeptides after the second amino acid from the N-terminal end. Inhibition of DPP-4 substantially prolongs the half-life of GLP-1 and GIP, increasing the levels of active circulating incretin hormones. The duration of DPP-4 inhibition by vildagliptin is dose-dependent. Vildagliptin reduces fasting and prandial glucose and HbA1c. It enhances the glucose sensitivity of alpha- and beta-cells and augments glucose-dependent insulin secretion. Fasting and postprandial glucose levels are decreased, and postprandial lipid and lipoprotein metabolism are also improved.
Dose	Once in a day
Stability	24 Months For 50mg
Storage	Store in dry place temperature not exceeding 25 C

MATERIALS AND METHODS

The dissolution studies were carried out by using UV Spectrophotometric method.

- **The Drugs that were selected for dissolution studies are.**
- Saxagliptin
- Vildagliptin

■ Materials

Drugs: Saxagliptin tablets of two different brands i.e. Astra Zeneca Pharmaceuticals (Onglyn 5 mg) and Steris Healthcare Pvt.Ltd (Saxaglyn 5 mg) were utilized and procured from local marketand Vildagliptin of two different brands i.e.Zydus Cardiva (Vinglyn 50 mg) and Primus Remedies Pvt.Ltd (Vildaprime 50 mg) were procured from local market.

Chemicals: Disodium Hydrogen phosphate and Potassium dihydrogen phosphate

■ Instrument

- Digital weighing balance– WENDZAR company
- UV-Visible Spectrophotometer- PG INSTRUMENTS- model number T 60 Spectrophotometer.
- Paddle Type Apparatus – LABINDIA DS 8000.

Glass apparatus

- Pipette: Borosil pipettes of 1, 2, 5 and 10 ml capacity.
- Volumetric flask: Borosil volumetric flask 25, 100 and 1000 ml capacity.

■ **Preparation of Dissolution Media (6.8 pH phosphate buffer)**

Dissolve 28.80 grams of disodium hydrogen phosphate and 11.45 grams of potassium dihydrogen phosphate insufficient water to produce 1000 ml.

■ **Preparation of Standard Stock Solution**

Saxagliptin

Standard stock solution was prepared by dissolving 10 mg of drug (Saxagliptin) in 15 ml of methanol in 100 ml of standard volumetric flask and then it was made up to the volume with 6.8 pH phosphate buffer to give the solution containing 100 mcg/ ml of Saxagliptin.

Vildagliptin

Standard stock solution was prepared by dissolving 10 mg of drug(Vildagliptin) in 15 ml of methanol in 100 ml of standard volumetric flask and then it was made up to the volume with 6.8 pH phosphate buffer to give the solution containing 100 mcg/ml of Vildagliptin.

■ **Preparation of the Sample solution**

Saxagliptin

1. Aliquots of standard stock solution of both the brands of Saxagliptin i.e. Onglyn and Saxaglyn were pipetted out individually and suitably diluted with 6.8 pH phosphate buffer to get the final concentrations of 5,10,15,20,25 and 4,8, 12, 16 and 20 mcg/ml of standard solutions.
2. The solutions were scanned in the spectrum mode from 200-400 nm wavelength range.
3. The maximum absorbance of Saxagliptin (Onglyn) was observed at 266nm and Saxagliptin (Saxaglyn) was observed at 264nm.
4. The drug followed the Beer-Lambert's law in the concentration range of 5- 25 and 4-20 mcg/ml.
5. The calibration curve was plotted as absorbance against concentration of Saxagliptin.
6. The concentrations of sample solutions were determined from the calibration curve.

Vildagliptin

1. Aliquots of standard stock solution of both the brands of Vildagliptin i.e. Vildaprime and Vinglyn were pipetted out individually and suitably diluted with 6.8 pH phosphate buffer to get the final concentrations of 4,6,10,12,20 mcg/ ml and 4,6,8,10,20 mcg/ml of standard solutions respectively.
2. The solutions were scanned in the spectrum mode from 200-400 nm wavelength range.

3. The maximum absorbance of Vildagliptin (Primus) was observed at 265nm and Vildagliptin (Zydus) was observed at 263nm.
4. The drug followed the Beer-Lambert's law in the concentration range of 4-20 mcg/ml.
5. The calibration curve was plotted as absorbance against concentration of Saxagliptin.
6. The concentrations of sample solutions were determined from the calibration curve.

PHYSICOCHEMICAL TESTS FOR TABLETS

EVALUATION OF TABLETS – POST COMPRESSION PARAMETERS

Tablets were evaluated for weight variation, tablet hardness, friability, and thickness.

1. Weight Variation

20 tablets were selected randomly and average weight was determined. The individual tablets were weighted and compared with average weight to determine weight variation. The deviation if any in the weight of individual tablets from the average weight was checked. This test highly describesthat all the tablets of a particular batch should be uniform in weight. If any weight variation is therehere, that should be within IP limits. The test was considered correct if not more than two tablets fall outside the IP limits out of twenty tablets taken for the test.

2. Tablet hardness

The resistance of tablets to shipping or breakage, beneath conditions of storage, transportation and taking care of sometime recently utilization depends on its hardness. Hardness of tablet crushing strength is the force required to break a tablet in a diametric dimension was measured using Monsanto hardness tester.

3. Friability

Friability of tablets was determined using Roche friabilator (Electrolab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. 10 tablets were randomly selected, weighed (W_{1}) and were placed in the friabilator and were subjected to 100 revolutions. The tablets were de dusted using a soft muslin cloth and reweighed (W_{2}) The friability (f) iscalculated by following formula.

f = (1 – W1/ W2) x 100

Where, W1 is weight of the tablets before revolutions and W2 is the weight of the tablets after revolutions.

4. Thickness

Thickness of tablet is vital for consistency of tablet estimate. Thickness was measured by utilizing Vernier Calipers.

SOLUBILITY STUDIES

Drug	Methanol	Water	0.1N HCl	PhosphateBuffer
Saxagliptin	Soluble	SparinglySoluble	Soluble	Soluble
Vildagliptin	Soluble	Soluble	Soluble	Soluble

A Table of Different Brands with their Mfg. Date and Exp. Date

DRUGS	MANUFACTURE DDATE	EXPIRY DATE
Onglyn(5mg) Astra ZenecaPharmaceuticals	01/2022	12/2024
Saxaglyn(5mg) SterisHealthcare Pvt.Ltd	05/2022	04/2024
Vildaprime(50mg) PrimusRemedies Pvt.Ltd	03/2022	02/2024
Vinglyn (5mg) ZydusCardiva	07/2022	06/2024

A Table of Different Brands with their Average Weight

DRUG	AVERAGE WEIGHT
Onglyn(5mg)	0.2391g
Saxaglyn(5mg)	0.2062g
Vildaprime(50mg)	0.2813g
Vinglyn (5mg)	0.2002g

VALIDATING THE DISSOLUTION STUDIES USING UVSPECTROSCOPY AS PER ICH GUIDELINES

1. *Linearity*

- Linearity is the property of a mathematical relationship or function which means that it can be graphically represented as a straight line. Linearity expresses that concentration is directlyproportional to absorbance. The 5 concentrations are taken from the stock solution and diluted to final volume with solvent. These concentrations are scanned at respective λ max in photometric mode and the absorbance was noted for each concentration. The calibration curve is plotted by taking concentration on x-axis and absorbance on y-axis. The correlation coefficient and slope arecalculated.
- The linearity for Vildagliptin was determined by taking the concentration from 2-12 µg/ml for eachsolvent. The regression equation for water as solvent was found to be y = 0.0054x + 0.0505, R2 =0.9998, for 0.1 N HCl as solvent was found to be y = 0.004x + 0.0385, R2 = 0.9994 and for phosphate buffer pH 6.8 as solvent the regression equation is y = 0.0112x + 0.0034, R2 = 0.9991.

- And For Saxagliptin concentrations are taken 2, 4, 6, 8, 10 µg/ml. Calibration curves were constructed by plotting absorbance versus concentrations and regression equations were for water y= 0.0044x + 0.0605, R2 = 0.9998, for 0.1 N HCl y = 0.044x + 0.0685, R2 = 0.9997 and for phosphate buffer pH 6.8 0.0122x + 0.0334, R2 = 0.9993.

2. *Specificity*

- The specificity was intended to evaluate if any compound present in the formulation or the dissolution medium showed any signal or interference that could affect the quantification of theanalyte. The discriminatory capacity was confirmed by comparing of the scans in a range of 200 nm to 400 nm obtained from references standards, tablets samples, placebos (mixture of excipients), and diluents (buffers pH 1.2, pH 4.5, and pH 6.8).
- The interference should not exceed 2%, if it exceeds the value, it is necessary to modify themethod.
- Samples were prepared by mixing known amounts (5 mg SAX/50 mg VDG) with various amounts of the common excipients: starch (50 mg), glucose (10 mg), lactose (10 mg), talc (5 mg) and magnesium stearate (10 mg). These laboratory pre- pared samples were analyzed by the proposed methods applying the general recommended procedures previously mentioned. The recoveries of both drugs ranging from 99% to 101% with RSD % ranging from 0.5% to 0.9% were obtained. This confirmed the absence of interference from any of the common excipients with the determination of SAX/ VDG by the proposed methods.

3. *Precision*

- Precision was determined by using data from the interday repeatability studies. Same level of concentration, prepared from independent stock solution was used for both the studies. The solutions of saxagliptin and vildagliptin were prepared at two different times in a day and studied for intraday variation. was followed The method precision was evaluated by calculating relative standard deviation (RSD%).

4. *Accuracy*

- Accuracy refers to the closeness of measurement to the true value. Accuracy is also defined as the extent to which a given measurement agrees with the standard value for that measurement. To determine the accuracy of the proposed method, standard addition

method was performed. In this study, different concentrations of drug were added to a known quantity of sample and the total concentration was determined using the proposed methods. The percent recovery (%R) of the added pure drug was calculated as shown in the equation.

% Recovery = amount found/amount added ×100.

DISSOLUTION STUDIES

- The selection of the dissolution medium was made by considering the solubility of Vildagliptinand Saxagliptin in order to ensure sink conditions. The solubility was checked in Methanol, Water, 0.1N HCl and 6.8 pH phosphate buffer.
- The dissolution profiles for different brands of Saxagliptin and Vildagliptin tablets were carried out in 6.8 pH phosphate buffer media.
- For dissolution tests, 900 mL of the medium were deaerated, by stirring and heating, and maintained at 37 ± 0.5 ºC and the USP type 2 paddle type apparatus was set at 100 rpm, and aliquots were withdrawn at an interval of 15, 30, 45 and 60 minutes.
- The samples were analysed by UV- Visible Spectrophotometer.
- The average percentage of drug released within 60 min as determined by the proposed spectrophotometric method after in vitro dissolution of tablets. With the increase in time, therewas also an increase in the release profile of the tablets.
- The dissolution profile complies with the FDA guidance, indicating suitability of the proposed method for the Dissolution testing of both the brands of Saxagliptin and Vildagliptin tablets.

PREPARATION OF STANDARD CALIBRATION CURVE

Saxagliptin

Aliquots of standard stock solution were further diluted with 6.8 pH phosphate buffer to get the solutions of concentrations 5,10,15,20,25 and 4,8,12,16 and 20 mcg/ml. The absorbance was measured at 266nm against 6.8 pH phosphate buffer as blank. All measurements were repeated three times for each concentration. The calibration curve was constructed by plotting mean of absorbance against corresponding concentration.

Preparation of Standard Calibration Curve

Vildagliptin

Aliquots of standard stock solution were further diluted with 6.8 pH phosphate buffer to get the solutions of concentrations 4,6,10,12,20 and 4,6,8,10 and 20 mcg/ml. The absorbance was measured at 265 nm against 6.8 pH phosphate buffer as blank. The calibration curve was constructed by plotting mean of absorbance against corresponding concentration.

RESULTS AND DISCUSSION

Evaluation Parameters

Drugs	Weight Variations (mg)	Thickness (mm)	Hardness Kg/cm2	%Friability
Saxagliptin (Onglyn 5 mg)	4.8 mg	4.92±0.03	6.6±0.02	0.19±0.02
Saxagliptin (Onglyn 5 mg)	4.76 mg	4.92±0.02	6.2±0.05	0.22±0.03
Saxagliptin (Onglyn 5 mg)	4.9 mg	4.94±0.02	6.3±0.05	0.22±0.02
Saxagliptin (Onglyn 5mg)	5.0 mg	4.95±0.03	6.4±0.05	0.23±0.03
Saxagliptin (Onglyn 5mg)	5.0 mg	4.98±0.02	6.7±0.05	0.17±0.02
Vildagliptin (Vinglyn 50 mg)	46.65 mg	4.06±0.03	6.2±0.02	0.27±0.02
Vildagliptin (Vinglyn 50 mg)	49.53 mg	4.94±0.02	6.3±0.05	0.27±0.03
Vildagliptin (Vinglyn 50 mg)	48.62 mg	4.95±0.03	6.4±0.02	0.33±0.03
Vildagliptin (Vinglyn 50mg)	49.45 mg	4.97±0.02	6.4±0.02	0.23±0.02
Vildagliptin (Vinglyn 50mg)	49.68 mg	4.97±0.02	6.4±0.02	0.23±0.02

Validation Parameters Linearity

- The linearity for Vildagliptin was determined by taking the concentration from 2-12 µg/ml for eachsolvent. The regression equation for water as solvent was found to be y = 0.0054x + 0.0505, R2 =0.9998, for 0.1 N HCl as solvent was found to be y = 0.004x + 0.0385, R2 = 0.9994 and for phosphate buffer pH 6.8 as solvent the regression equation is y = 0.0112x + 0.0034, R2 = 0.9991.
- And For Saxagliptin concentrations are taken 2, 4, 6, 8, 10 µg/ml. Calibration curves were constructed by plotting absorbance versus concentrations and regression equations were for water y= 0.0044x + 0.0605, R2 = 0.9998, for 0.1 N HCl y = 0.044x + 0.0685, R2 = 0.9997 and for phosphate buffer pH 6.8 0.0122x + 0.0334, R2 = 0.9993.

Data for Standard Calibration Curve of Saxagliptin (Saxaglyn 5mg)

Concentration	Absorbance
5 mcg	0.185
10 mcg	0.325
15 mcg	0.473
20 mcg	0.637
25 mcg	0.781

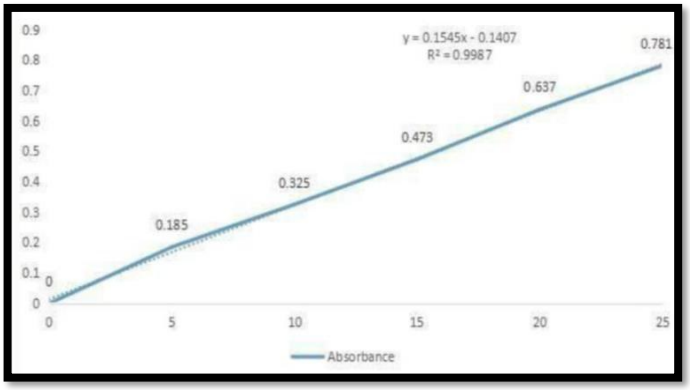


Figure number-4.

Calibration curve of Saxagliptin (Saxaglyn 5mg)

Data for Standard Calibration Curve of Saxagliptin (Onglyza 5 mg)

Concentration	Absorbance
0	0
4 mcg	0.53
8 mcg	0.7
12 mcg	1.1
16 mcg	1.5
20 mcg	1.75

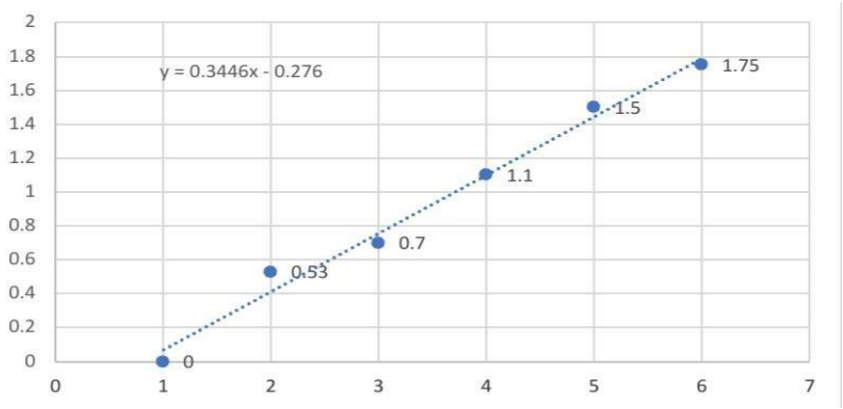


Figure number-5

Calibration Curve of Saxagliptin (Onglyza 5 mg)

Data for Standard Calibration Curve of Vildagliptin (Vinglyn 50mg)

Concentration	Absorbance
0	0
4 mcg	0.295
6 mcg	0.39
8 mcg	0.457
10 mcg	0.515
20 mcg	0.773

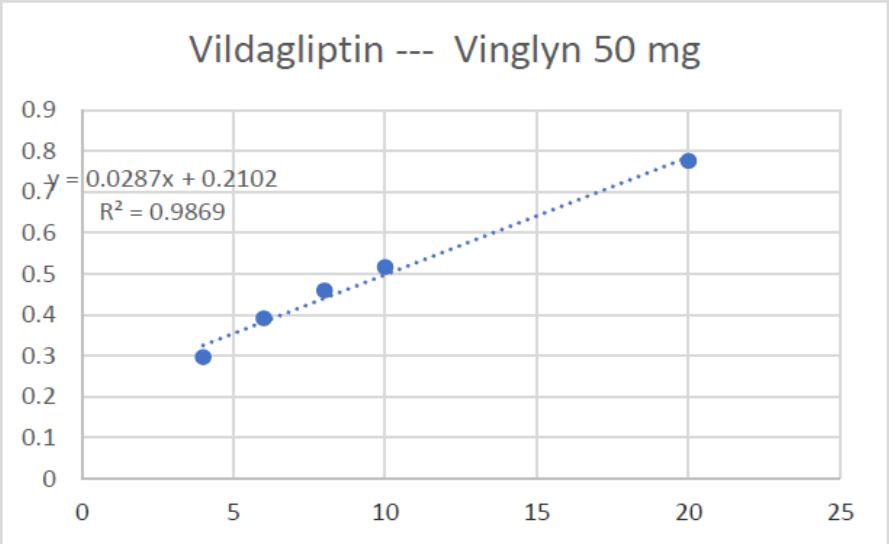


Figure number-6

Calibration Curve of Vildagliptin (Vinglyn 50mg)

Data for Standard Calibration Curve of Vildagliptin (Vildaprime 50 mg)

Concentration	Absorbance
0	0
4 mcg	0.196
6 mcg	0.298
10 mcg	0.46
12 mcg	0.523
20 mcg	0.793

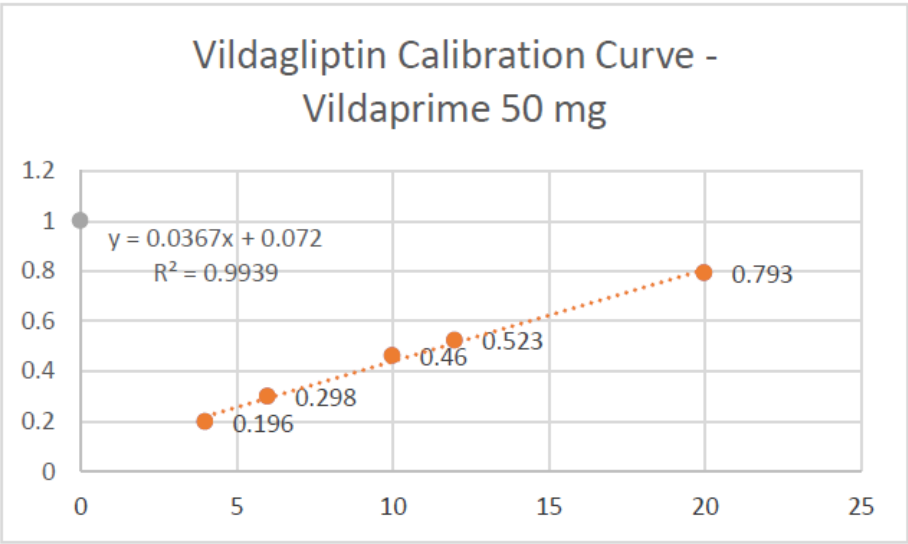


Figure number-7

Calibration Curve of Vildagliptin (Vildaprime 50 mg)

Precision

Drug	Concentration (µg/ml)	Absorbance	SD	%RSD
Saxagliptin	40 40 40 40 40 40	0.431 0.430 0.432 0.431 0.433 0.433	0.001049	0.243061
Vildagliptin	40 40 40 40 40 40	0.432 0.431 0.434 0.432 0.433 0.431	0.000753	0.17432

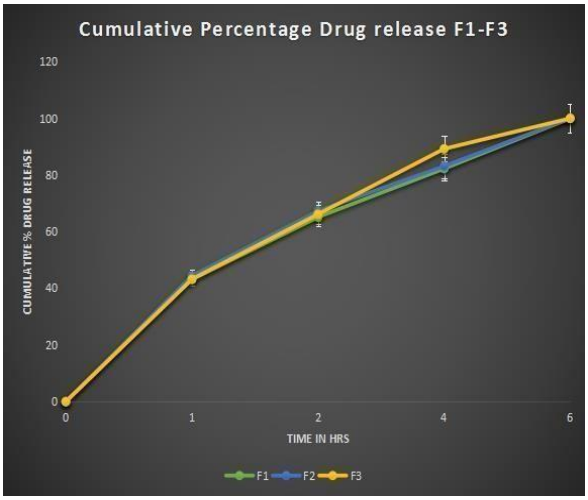
Accuracy

Drug	Level (%)	Added (µg/ml)	Found(µg/ml)	% Recovery	%RSD
Saxagliptin	80 100 120	8.1 10 12.53	7.94 9.94 12.73	98 99.5 101.6	1.37
Vildagliptin	80 100 120	7.9 10.2 12.46	7.8 10 12.52	99.2 98.7 99.9	0.98

DISSOLUTION PROFILE

Vildagliptin

Time	Cumulative Percentage Drug release								
(min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
15	43.11 ± 0.02	44.45 ±0.03	43.23 ±0.03	33.04 ±0.05	30.33 ±0.05	38.56 ±0.05	22.66 ±0.04	21.17 ±0.04	20.26 ±0.04
30	65.13 ±0.02	67.33 ±0.03	66.14 ±0.03	44.18 ±0.05	42.32 ±0.05	40.44 ±0.05	35.15 ±0.04	33.46 ±0.04	32.63 ±0.04
45	82.22 ±0.02	83.12 ±0.03	89.22 ±0.03	59.27 ±0.05	58.77 ±0.05	54.06 ±0.05	49.32 ±0.04	48.28 ±0.04	45.35 ±0.04
60	100 ±0.02	100 ±0.03	100 ±0.03	70.46 ±0.05	72.56 ±0.05	70.17 ±0.05	64.46 ±0.04	62.64 ±0.04	61.73 ±0.04



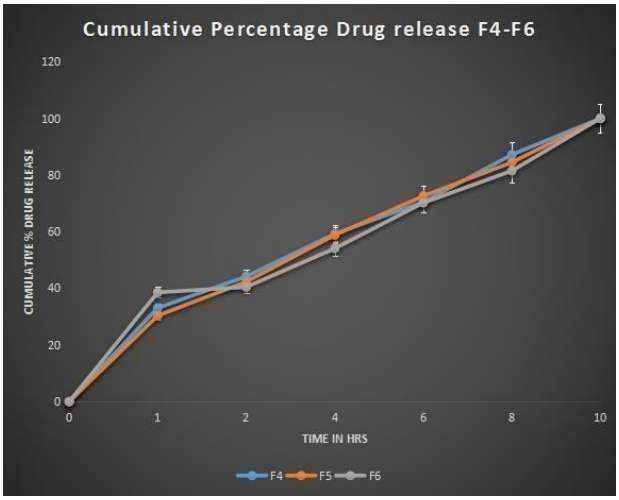
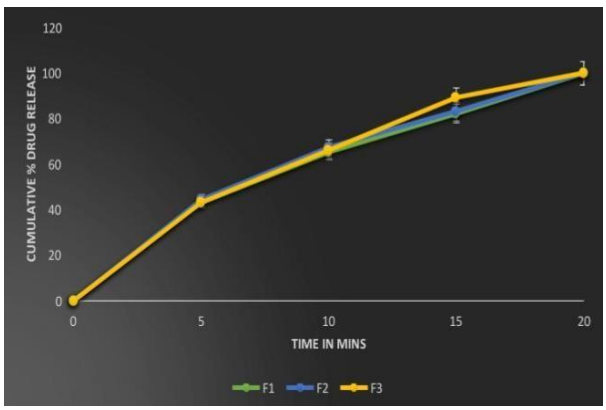


Figure number-8 Figure number-9

% drug release of Vinglyn 50 mg % drug release of Vildaprime50 mg

Saxagliptin

Time	Cumulative Percentage Drug release								
(Mins.)	F1	F2	F3	F4	F5	F6	F7	F8	F9
15	43.11 ±0.02	44.45 ±0.03	43.23 ±0.03	33.04 ±0.05	30.33 ±0.05	38.56 ±0.05	22.66 ±0.04	21.17 ±0.04	20.26 ±0.04
30	65.13 ±0.02	67.33 ±0.03	66.14 ±0.03	54.18 ±0.05	52.32 ±0.05	50.44 ±0.05	65.15 ±0.04	63.46 ±0.04	62.63 ±0.04
45	82.22 ±0.02	83.12 ±0.03	89.22 ±0.03	79.27 ±0.05	78.77 ±0.05	74.06 ±0.05	89.32 ±0.04	88.28 ±0.04	85.35 ±0.04
60	100 ±0.02	100 ±0.03	100 ±0.03	100 ±0.05	100 ±0.05	100 ±0.05	100 ±0.05	100 ±0.05	100 ±0.05



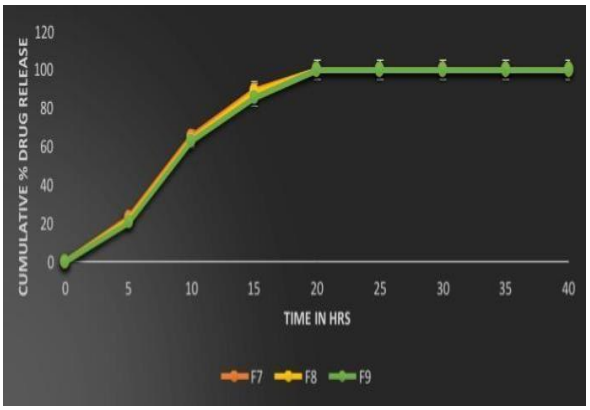


Figure number-10 Figure number-11

% drug release of Saxaglyn 5 mg % drug release of Onglyza 5 mg

Combination Spectra of Saxagliptin

Time (minutes)	% drug release
15	43.11 ± 0.02
30	65.13 ± 0.02
45	82.22 ± 0.02
60	100 ± 0.02

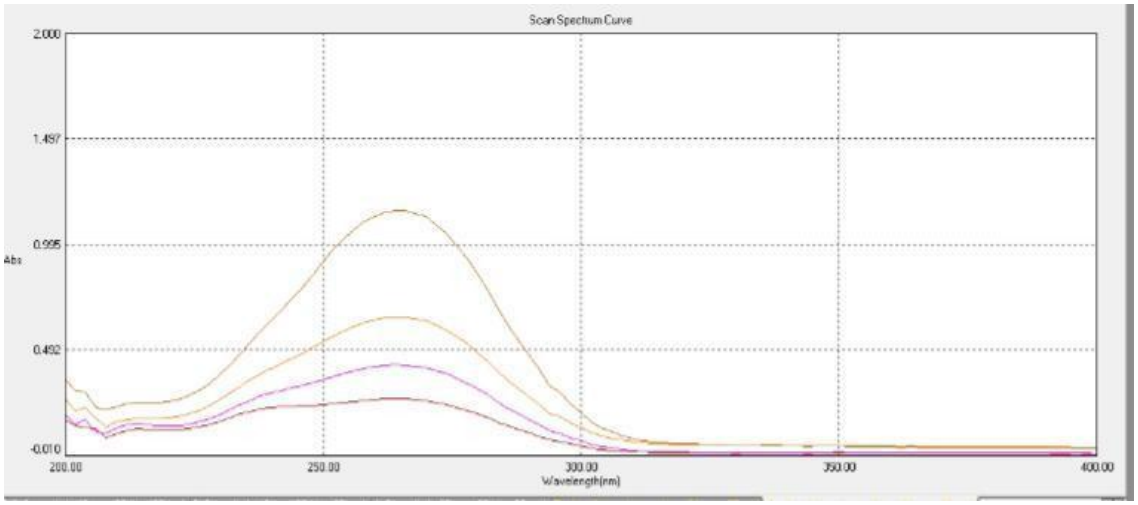


Figure number-12

Combination Spectra of Vildagliptin

Time (minutes)	% drug release
15	43.11 ± 0.02
30	65.13 ± 0.02
45	82.22 ± 0.02
60	100 ± 0.02

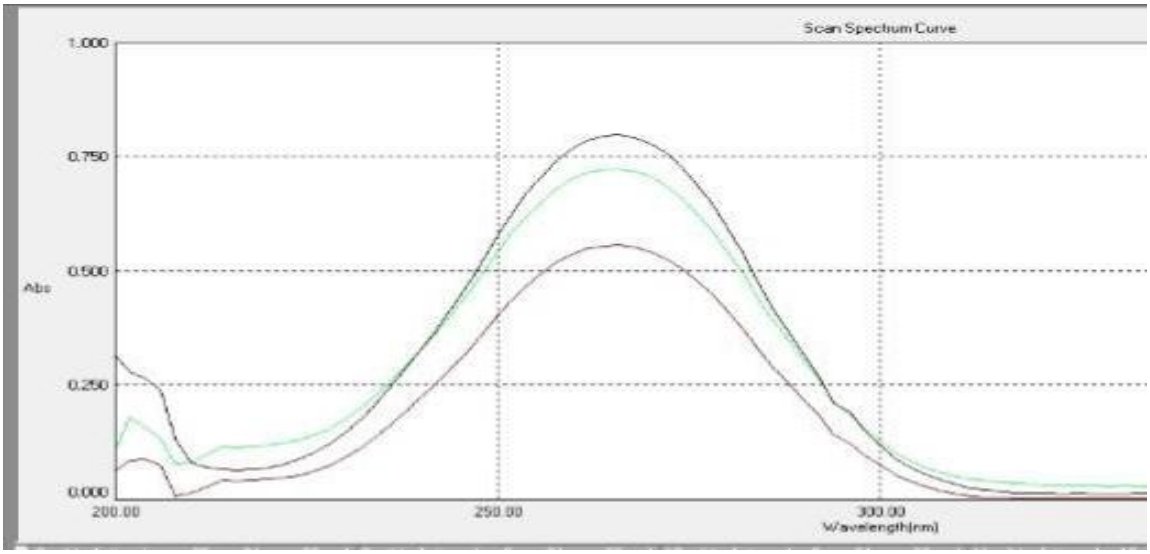


Figure number-13.

➢ CONCLUSION

- The developed UV-Visible Spectrophotometric method is used for the estimation of dissolution of saxagliptin and vildagliptin tablets .
- UV Spectroscopy is a versatile analytical technique for drug estimation and has proven to be a suitable technique for the routine analysis of commercial formulations containing drugs.
- The proposed dissolution test method was developed and validated as per the ICH guidelines for Saxagliptin and Vildagliptin by using UV spectrophotometer method.
- The results obtained by proposed methods were found to be reliable, accurate and precise.
- The suitable conditions of dissolution test for Saxagliptin and Vildagliptin tablet was pH 6.4phosphate buffer, USP types II apparatus, speed 100 rpm at 60 min.
- The results of the comparative dissolution studies were validated and are were within the limits.
- It is concluded that as the time increases, the rate of drug release also increases.
- Comparative dissolution study for different brands of Saxagliptin and Vildagliptin have released the drug in the same proportion.

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