IJBPAS, July, 2026, 15(7): 3246-3258

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

# ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF DAPAGLIFLOZIN AND VILDAGLIPTIN IN BULK AND COMBINED DOSAGE FORM BY RP-HPLC

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**Received 20th April 2025; Revised 25th May 2025; Accepted 6th Aug. 2025; Available online 1st July 2026**

https://doi.org/10.31032/IJBPAS/2026/15.7.10325

## ABSTRACT

A rapid, simple, economical, accurate, and precise RP-HPLC approach for instantaneous evaluation of Dapagliflozin and Vildagliptin in the form of Combined &Bulk dosages has been validated and developed. The two drugs have also been separated by chromatography using an isocratic mode on a KinetexR C18 100A (250mm x 4.6mm x 5µm) column. The mobile phase has been supplied at a flow rate of 1ml per minute and contained $KH_2PO_4$ buffer with the pH adjusted to 3 utilizing Orthophosphoric acid and Acetonitrile in a 60:40 v/v ratio. Detection has been performed at 205nm. The retention time of Dapagliflozin & Vildagliptin has been observed to be 5.731 and 2.197 min, correspondingly. For both Dapagliflozin and Vildagliptin, the calibration curves showed a linear correlation coefficient of 0.993 and 0.99, respectively, within the concentration ranging from 10-80µg/mL & 10-80µg/mL, correspondingly. Additionally, the calibration curves have been precise, with % RSD<2.The technique could be utilized for regular quality control assessment and has been validated in accordance with ICH requirements.

**Keywords: Dapagliflozin, Vildagliptin, Simultaneous, RP-HPLC, Validation**

## INTRODUCTION

**Dapagliflozin (DAPA** Dapagliflozin is chemically (2s,3R,4R,5R, and 6R)2-4-[4-Chloro-3-[4-ethoxybenzyl] phenyl]-6-(hydroxyl methyl)tetrahydro-2H-pyran-

3,4,5-triol **[1]**. It is soluble in methanol, DMSO, and dimethyl formamide. It is barely soluble in water and aqueous buffer. Its primary goal for treating type-2 diabetes. It could also be used to treat heart failure. Positive benefits of dapagliflozin include decreased blood pressure, reduced body weight, elevated hemoglobin, and decreased high-sensitivity cardiac troponin.

**Vildagliptin (VILDA)** is chemically (S)-1-{2-[(3-hydroxyadamantan-1-yl) amino] acetyl} pyrrolidine-2-carbonitrile **[2]**. It is freely soluble in water, methanol, ethanol, DMSO, and dimethylformamide. Vildagliptin is the dipeptidyl peptidase-4 (DPP-4) inhibitor for treating type 2 diabetes mellitus (T2DM).

Reductions in blood pressure, body weight, hemoglobin levels, and high-sensitivity cardiac troponin are among the advantages of dapagliflozin **[3]**. Vildagliptin increased mean platelet volume but did not affect hemodynamic characteristics. Vildagliptin is a medication utilized for T2DM that reduces the enzyme DPP-4. The mechanism of inhibition of DPP-4 inhibitors is determined by their capacity to increase the incretin hormones levels, GLP-1("Glucagon-Like Peptide-1"), and GIP ("Glucose-Dependent Insulinotropic Polypeptide") **[4]** in systemic circulation. Dapagliflozin comes in tablet form and is a medication that can be used orally. Patients with T2DM respond very effectively to it both alone as well as in the combination with other medications of anti-diabetic. According to recent studies, dapagliflozin reduces fasting plasma glucose levels within a week of starting medication and has a quick onset effect **[5]**. An appealing strategy is provided by the FDC of sodium-glucose cotransporter type 2 inhibitor (SGT2i) and dipeptidyl peptidase-4 inhibitor (DPP-4i) **[6]**. This study evaluated the bioequivalence of individual tablet-based oral fixed-dose combination (FDC) of dapagliflozin 10mg and Vildagliptin SR 100mg. SGLT2 is preferentially blocked by dapagliflozin over SGLT1 **[5]**. By preventing the kidneys from reabsorbing glucose, it enhances glycemic control in persons with type 2 diabetes by causing the extra to be expelled in the urine. Pyrrolidine-2-carbonitrile. It is easily soluble in water, methanol, ethanol, DMSO, and dimethylformamide. Vildagliptin is a T2DM medication that blocks the DPP-4 enzyme. The mechanism by which DPP-4 inhibitors block DPP-4 is contingent upon their ability to elevate the systemic circulation levels of the incretin hormones, GIP&GLP-1 **[7]**. Vildagliptin thereby increases insulin secretion and decreases unnecessary glucagon release in T2DM patients. Additionally, it decreases HbA1c without causing weight gain or severe hypoglycemia when used with one of the

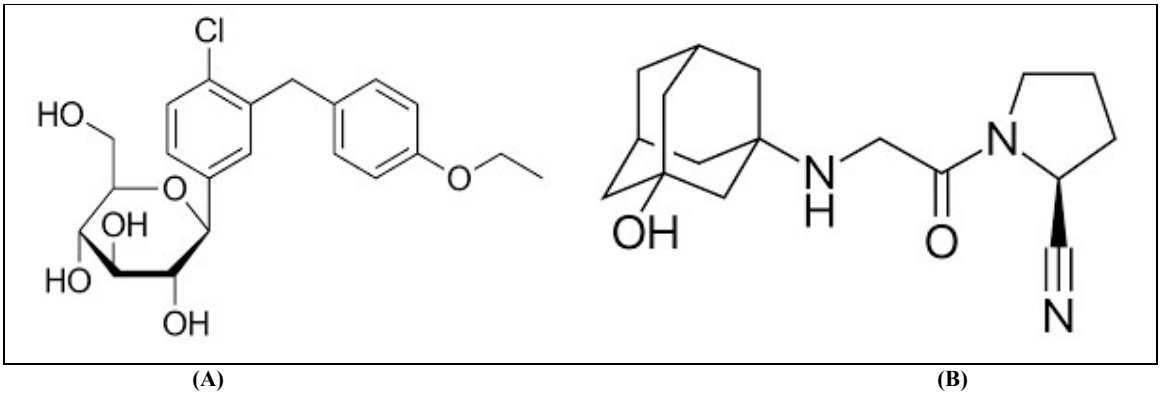
other commonly given classes of oral hypoglycemic drugs, such as sulfonylurea, insulin, or thiazolidinediones **[8]**. When used orally, vildagliptin is easily absorbed. Around 70% of vildagliptin metabolism occurs via hydrolysis, and 23% of oral dose is excreted in the urine unchanged. Renal excretion accounts for 85% of vildagliptin excretion. The pharmacokinetics of the medication are unaffected by food intake **[9]**. It neither induces nor inhibits the major P450 enzymes. The absorbance ratio method technique of analysis is based on the wavelength maxima of drug absorption for dapagliflozin and vildagliptin. 220nm and 195nm are the two wavelengths chosen for the construction of the absorbance ratio method **[10]**.

Through the literature survey, it was found that numerous analytical techniques are available for evaluation of Vildagliptin and Dapagliflozin alone, combination and other combinations in tablets, capsules, injections, etc. These techniques include UV Spectrophotometry **[11-16]** and HPLC **[17-26]**. The suggested method is appropriate and can be helpful for routinely analyzing Vildagliptin and Dapagliflozin in bulk and mixed dosage form, according to statistical analysis of the created method.

## MATERIALS AND METHODS

### Chemicals and Reagents:

The Dapagliflozin and Vildagliptin reference samples have been obtained from Dr. Reddys Labs, Hyderabad, India as gift samples. Daparyl-V tablets (Label claim: Dapagliflozin 10 mg and Vildagliptin 100 mg) were procured from the local drug store, Tarnaka, Hyderabad. $KH_2PO_4$ used was of Thomas Baker (Chemicals) Pvt Ltd, Mumbai, India. HPLC grade Acetonitrile used has been from Qualkems Life Sciences Pvt Ltd, Vadodara, India, HPLC grade Methanol has been attained from Avanto Performance Materials, Maharashtra, India, OPA was obtained from SD Fine Chem Limited, Mumbai, India, and Mili Q water.




**(A)** **(B)**

**Figure 1: Structures of (A) Dapagliflozin (B) Vildagliptin**

**Instrumentation and chromatographic conditions:**

The Proposed work has been carried out by utilizing HPLC (Waters), Pump (Binary), Manual with UV-Visible detector (UV-Detector), Column: Phenomenex C18 Kinetex 5µ column, data was recorded using Breeze software. Various combinations of mobile phases were screened and finally, the isocratic elution has been carried out with a mobile phase containing a mixture of $KH_2PO_4$ buffer (pH adjusted to 3 utilizing Orthophosphoric acid): Acetonitrile in ratio of 60:40v/v and the retention time of DAPA & VILDA was thoroughly investigated. The $KH_2PO_4$ Buffer concentrations: The ratio of 60:40v/v of Acetonitrile was tuned to produce a symmetric peak with a brief duration. Figure 2 illustrates the parameters of the experiment: the UV detection wavelength was set to 205 nm, the flow rate has been set to 1mL/min, the injection volume was 20µL, the runtime was set to 15 min, and the retention periods of DAPA & VILDA have been estimated to be 5.622 and 2.197min.

**Preparation of Buffer for mobile phase (20mm):**

1.36 grams of $KH_2PO_4$ were weighed, dissolved, and then diluted with Mili Q water to make 1000 ml in a beaker. After passing Orthophosphoric acid through a 0.2µm membrane filter and degassing, the pH has been adjusted to 3.

**Preparation of Mobile Phase:**

Mixed A mixture of $KH_2PO_4$ buffer 600ml (60percent) and 400ml of Acetonitrile HPLC grade (40percent) was degassed in the ultrasonic water bath until it was completely dissolved and filtered by a 0.2µm membrane filter.

**Diluent Preparation*:*** The mobile phase is being utilized as diluent.

**Preparation of Standard Solution:**

The drugs were found to be soluble in methanol. The preparation of the standard stock solution involved precisely weighing 100 mg of DAPA and VILDA separately, dissolving them in a small amount of methanol in a 100 ml volumetric flask, and then adding methanol to fill the remaining capacity. To attain a final concentration of 10µg/ml, 1ml of stock solution above was taken separately and diluted to 10ml using the mobile phase.

**Preparation of Sample Solution:**

10 tablets of Daparyl-V (Label claim: Dapagliflozin 10 mg and Vildagliptin 100 mg) were weighed accurately. Weighing out the powder, 0.1 mg of DAPA and 0.1 mg of VILDA were added to a 100ml clean, dry volumetric flask along with 25ml of methanol. To dissolve the components, the mixture was sonicated for 10 min. Subsequently, methanol was added to the volume while shaking the container

intermittently. A membrane filter having a pore size of 0.2µm has been utilized to filter the final solution. Furthermore, to acquire a concentration of 10µg/milliliter for DAPA and 100µg/mL for VILDA, 1 ml of the clear filtrate from the abovementioned stock solution has been transferred into a 10ml volumetric flask and then diluted to the appropriate level having the mobile phase.

**Selection of Analytical Wavelength:** The standard drug Dapagliflozin and Vildagliptin of 10µg/ml concentrations were scanned individually and overlay spectra of the two drugs showed the Isosbestic point at 205nm and was selected for the current method development.

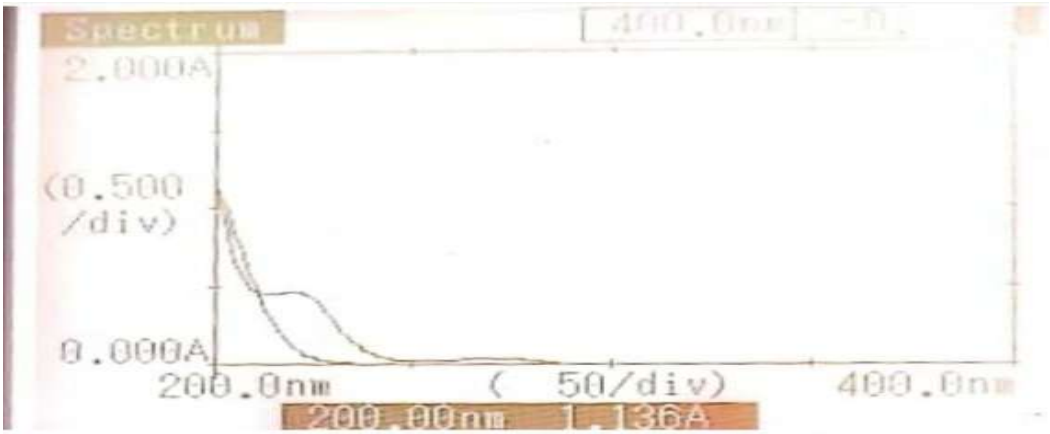



**Figure 2: Overlain Zero order spectra of Dapagliflozin (10 µg/ml) and Vildagliptin (50 µg/ml)**

**Method Validation:**

The method was validated for precision, linearity, robustness, specificity, sensitivity, accuracy, and parameters of system suitability by the following procedures by using the mentioned optimized chromatographic conditions as per ICH guidelines.

***Selectivity:***

The impact of excipients on the assay outcome is ascertained by the selectivity test. First, a standard sample of DAPA and VILDA was injected to ascertain the method's selectivity. Next, the device was used to run blank solutions and commercial items one after the other. The test results demonstrated that at the DAPA and VILDA retention times, the components other than medication did not provide a detectable signal.

***Accuracy:***

Recovery studies were conducted in triplicates at three various concentrations of 50%, 100%, and 15% for DAPA and VILDA, respectively, to assess the accuracy of the approach. The sample was mixed with known concentrations of standard drugs, and the peak area has been ascertained. The average recovery % values are displayed in **(Table 2)**.

***Linearity:***

Using the mobile phase, multiple aliquots of the standard stock solutions of DAPA & VILDA were taken and diluted to the desired final concentrations of 10-80µg/mL for DAPA & 10-80µg/mL for VILDA, respectively, in separate 10 ml volumetric flasks. Plotting the peak area vs. analyte concentration created calibration curves, as illustrated in **(Table 3)**.

**Precision:**

***Repeatability***

Six measurements of the same solution are the basis for the results about the repeatability of peak area measurement for Vildagliptin and Dapagliflozin. The % RSD for Vildagliptin & Dapagliflozin is displayed in **(Table 4)**.

***Inter-day and intra-day Precision***

In the intra-day investigations, the response factor of the drug peaks and the % RSD were computed after three consecutive injections of the standard solution. In inter-day variation investigations, the response of drug peaks and % RSD were computed after three consecutive days of standard solution injections. The %RSD for Dapagliflozin and Vildagliptin are shown in **(Tables 5, and 6)**.

***LOD and LOQ:***

This method's LOD and LOQ for DAPA and VILDA were assessed using the signal-to-noise ratio (SNR) approach outlined in ICH recommendations. In general, it is thought that a SNR of 3:1 to 2:1 is suitable for determining the detection limit. LOQ typically requires a SNR of 10:1.

***System suitability:***

Six replicates of samples containing DAPA and VILDA were given to assess equipment, analytical operations, electronics, and sample suitability. The % RSD of the retention time along with area, the theoretical plate number, and the Resolution were the parameters used to calculate the system suitability.

***Robustness:***

The degree of method robustness was assessed by purposefully and gradually adjusting chromatographic parameters, like column, wavelength, and flow rate ratio.

**RESULT AND DISCUSSION**

**Method development:**

An isocratic, rapid, and simple RP-HPLC approach was for the instantaneous estimation of DAPA & VILDA. Chromatographic conditions have been optimized for mobile phase proportion, pH, mobile phase composition, flow rate, and column oven temp. Optimized chromatographic conditions obtained consist of $KH_2PO_4$ buffer (pH adjusted to 3 with Orthophosphoric acid): Acetonitrile was used as the mobile phase on a Phenomenex C18 Kinetex (100A) 5µm column at a flow rate of 1 ml/min at a ratio of 60:40v/v. Eluents were detected at 205nm

by a UV detector. The temperature within the column compartment was kept at 25°C. According to **(Table 1)**, **(Figure 3)** the observed retention times for DAPA and VILDA are 5.731 and 2.188 minutes, respectively.

**Accuracy: Shown in Table 2**.

**Selectivity:**

The chromatogram of DAPA & VILDA in the mobile phase is displayed in **Figure 3**. The DAPA and VILDA retention times did not exhibit any interfering peaks.

**Linearity:**

The linearity of the developed HPLC approach has been studied by attaining the calibration curves of Dapagliflozin and Vildagliptin ranging from 10-80µg/ml for Dapagliflozin and 10-80 µg/ml for Vildagliptin each. The linearity regression co-efficient ($R^2$) values have been seen to be 0.993 for Dapagliflozin and 0.99 Vildagliptin **(Table 3)** shows linearity graphs for Dapagliflozin and Vildagliptin respectively.

**Precision: Shown in Table 4, 5**.

**LOD and LOQ:**

The calibration curve has been carried through three times, and the intercepts' SD was computed each time. The following was the calculation of LOD & LOQ:

LOQ = 10 * SD/slope of the calibration curve

LOD = 3.3* SD/slope of the calibration curve

Here, SD=Standard deviation of intercepts.

The outcomes have been displayed in **(Table 7)**.

**System suitability:** Six replicates of a sample containing 10-80µg/mL for Dapagliflozin and 10-80 µg/mL for Vildagliptin respectively were run and system suitability was tested for %RSD of areas, tailing factor, resolution, and a number of theoretical plates. Within allowable bounds, the outcomes are displayed in **Table 8**.

**Robustness:**

The results of the adjustments made to the flow rate and detecting wavelength were compiled in **(Table 9)**. % RSD of Dapagliflozin and Vildagliptin was found after variation in Flow rate to be 0.24 % – 1.08 % and 0.53% – 0.92 % respectively, whereas and % RSD of Dapagliflozin and Vildagliptin after variation in Mobile phase was found to be 0.62 % - 1.64 % and 1.68 % - 1.05% respectively and whereas % RSD of Dapagliflozin and Vildagliptin after variation in column changes was found to be 1.38 % - 1.68 % and 0.17% - 1.05%.

**Assay**

The proposed method was applied for the analysis of Tablet dosage form and the results of the assay were obtained within the specification limit **(Table 10)**. The % assay of Dapagliflozin and Vildagliptin were found to be 98.30% and 101.45 % respectively.

**Table 1: Optimized chromatographical condition**

| Parameters | Optimized condition |
|---|---|
| Stationary Phase | Kinetex C18 (250 mm x 4.6 mm x 5 µm) column |
| Mobile Phase(v/v) | 20mm $KH_2PO_4$ Buffer (pH adjusted to 3 by using Ortho Phosphoric Acid): Acetonitrile (60:40v/v) |
| Flow rate(mL/min) | 1 mL/min |
| Detection Wavelength(nm) | 205nm |
| Temperature | Ambient |
| Injection Volume(µL) | 20 µL |
| Run time(minute) | 15 minutes |
| Retention Time(minute) | Dapagliflozin (5.731min) and Vildagliptin (2.197 min.) |

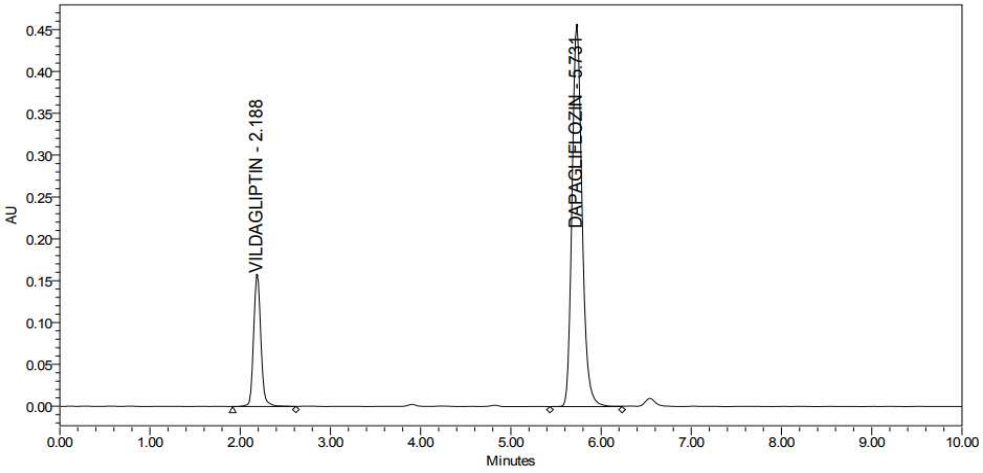



**Figure 3: Chromatogram of Dapagliflozin and Vildagliptin in mobile phase**

**Table 2: Recovery results for Dapagliflozin and Vildagliptin**

| Drugs | Concentration | Concentration of standard taken (µg/ml) | Concentration of sample added (µg/ml) | Final concentration in (µg/ml) | Area of Standard | Area of spiked | Area of Test | % Recovery ± SD (n=3) |
|---|---|---|---|---|---|---|---|---|
| DAPA | 50% | 3µg/ml | 1.5 µg/ml | 4.5 µg/ml | 1182930 | 2116237 | 357468 | 98.1 ± 0.1 |
| | 100% | 3µg/ml | 3 µg/ml | 6 µg/ml | 2286897 | 3250681 | 357468 | 100.2 ± 0.6 |
| | 150% | 3µg/ml | 4.5 µg/ml | 7.5 µg/ml | 3283440 | 4828834 | 357468 | 99.6 ± 0.10 |
| VILDA | 50% | 3µg/ml | 1.5 µg/ml | 4.5 µg/ml | 299008 | 1126052 | 721301 | 101.4 ± 0.11 |
| | 100% | 3µg/ml | 3µg/ml | 6 µg/ml | 538176 | 1464255 | 721301 | 100.8 ± 0.12 |
| | 150% | 3µg/ml | 4.5 µg/ml | 7.5 µg/ml | 820626 | 1753039 | 721301 | 101.3 ± 0.1 |

**Table 3: Linearity of Dapagliflozin and Vildagliptin**

| Dapagliflozin | | Vildagliptin. | |
|---|---|---|---|
| Concentration (µg/mL) | Peak area | Concentration (µg/mL) | Peak area |
| 10 | 984945 | 10 | 364525 |
| 20 | 1807347 | 20 | 492990 |
| 40 | 3194905 | 40 | 829738 |
| 60 | 5003537 | 60 | 1212121 |
| 80 | 6390867 | 80 | 1555527 |

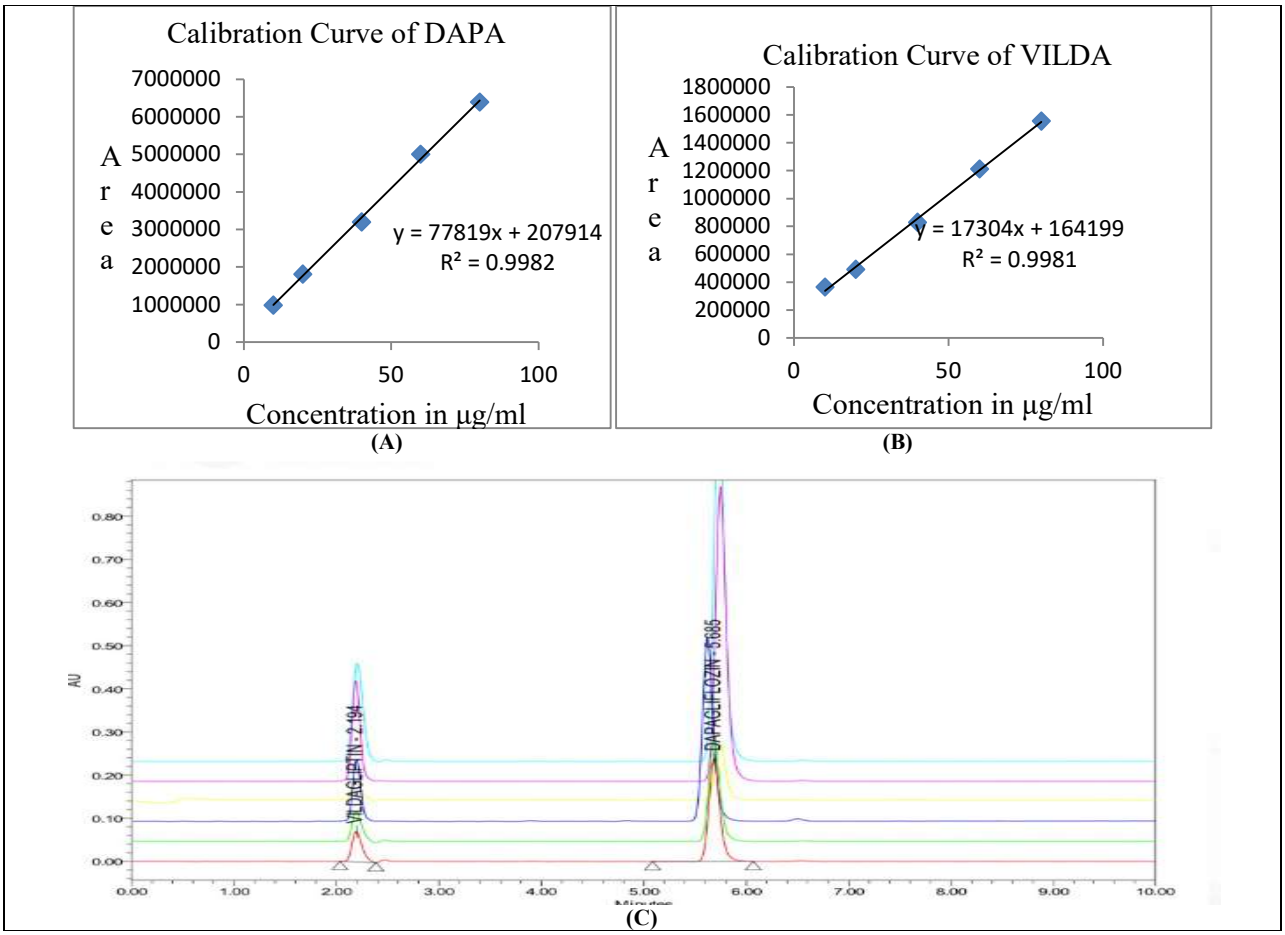



**Figure 4: (A) Calibration curve of Dapagliflozin (B) Calibration curve of Vildagliptin (C) Overlay in chromatogram for Linearity**

**Table 4: Repeatability study**

| Concentration of Dapagliflozin (µg/ml) | Dapagliflozin | | Concentration of Vildagliptin (µg/ml) | Vildagliptin | |
|---|---|---|---|---|---|
| | Mean ± SD (n=6) | % RSD | | Mean ± SD (n=6) | % RSD |
| 40 | 329661±4552.84 | 1.3811 | 40 | 642982± 6794.7 | 1.05675 |

**Table 5: Intraday & Inter-day precision study of Dapagliflozin**

| Drug | Conc. (µg/ml) | Intra-day precision | | Inter-day precision | |
|---|---|---|---|---|---|
| | | Mean ± SD(n=3) | % RSD | Mean ± SD (n=3) | % RSD |
| Dapagliflozin | 40 | 331992.33±2513.48 | 0.4 | 327329.66± 5403.50 | 1.65 |

**Table 6: Intraday & Inter-day precision study of Vildagliptin**

| Drug | Conc. (µg/ml) | Intra-day precision | | Inter-day precision | |
|---|---|---|---|---|---|
| | | Mean ± SD(n=3) | % RSD | Mean ± SD (n=3) | % RSD |
| Vildagliptin | 40 | 646813.66±3678.01 | 0.51 | 639150± 7605.48 | 1.18 |

**Table 7: LOD and LOQ of Dapagliflozin and Vildagliptin**

| Parameter | Dapagliflozin | Vildagliptin |
|---|---|---|
| LOD(µg/ml) | 0.285µg/mL | 0.231µg/mL |
| LOQ(µg/ml) | 0.940µg/mL | 0.764µg/mL |

**Table 8: System suitability results for Dapagliflozin and Vildagliptin**

| S. No. | System suitability parameters | Results | | Acceptance criteria |
|---|---|---|---|---|
| | | Dapagliflozin | Vildagliptin | |
| 1 | %RSD of peak Area (n=6) | 0.41 | 1.04 | ≤2 |
| 2 | Retention time($R_t$) | 5.731 | 2.19 | >2 |
| 3 | Theoretical plates(N) | 13457 | 3623 | ≥2000 |
| 4 | Tailing factor | 1.17866 | 1.200391 | ≤2 |
| 5 | Resolution ( R ) | 15.104 | | >2 |

**Table 9: Results of Robustness by variations in Flow rate, Mobile phase and Column**

| Para-meter | Value | Area ± S.D (n=3) | | % RSD | |
|---|---|---|---|---|---|
| | | Dapagliflozin | Vildagliptin | Dapagliflozin | Vildagliptin |
| Flow-rate | 0.8 mL/min | 1815397±4490.731 | 102681±551.1352 | 0.24 | 0.53 |
| | 1.0 mL/min | 230715±963.6917 | 304689.2±3178.52 | 0.41 | 1.04 |
| | 1.2 mL/ min | 2759810±30032.75 | 2758131±25543.8 | 1.08 | 0.92 |
| Mobile phase | 60:40 | 661024.5 ±4106.57 | 127166.7±2146.867 | 0.62 | 1.68 |
| | 58:42 | 3644005±67457.11 | 770237.2±11770.21 | 1.85 | 1.52 |
| | 62:38 | 3694561±60741.34 | 853119.7±9022.84 | 1.64 | 1.05 |
| Column | 1-C18 luna | 3423434±57571.66 | 830019±1455.588 | 1.68 | 0.17 |
| | 2-C18 kinetex | 329661±4552.83 | 642981.83±6794.70 | 1.38 | 1.05 |

**Table 10: Assay Data for Dapagliflozin and Vildagliptin**

| Name of Drug | Amount taken (µg/ml) | Amount Found (µg/ml) | %Assay± S.D (n=3) | % RSD |
|---|---|---|---|---|
| Dapagliflozin | 1 | 0.98 | 98.30 ± 0.722 | 0.734 |
| Vildagliptin | 10 | 10.35 | 101.45 ± 0.127 | 0.125 |

## CONCLUSION

The proposed HPLC method was found to be economical, simple, sensitive, accurate, precise, specific and robust and can be used for the routine quality control analysis of Dapagliflozin and Vildagliptin in single as well as in combined dosage forms.

**Acknowledgement:**

We are thankful to the authorities of Sarojini Naidu Vanita Pharmacy Mahavidyalaya for supporting and encouraging us to carry out the research.

**Conflicts Of Interest:**

The authors declare that there is no conflict of interests regarding the publication.

**Abbreviation Used:**

**API**: Active pharmaceutical ingredient, **RSD**: Relative standard deviation, **SD**: Standard deviations.

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