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Research Article

**DEVELOPMENT AND VALIDATION OF UV  
SPECTROSCOPIC METHOD FOR THE ESTIMATION OF  
DAPAGLIFLOZIN IN BULK AND TABLET DOSAGE FORM****Kavana D. C<sup>\*1</sup>, Naveen Kumar G.S<sup>2</sup>, Sowmya H.G<sup>3</sup>**<sup>1</sup>2<sup>nd</sup> year M Pharma, Student of Department of Pharmaceutical Analysis, Bharathi College of Pharmacy, Bharathinagara, Mandya, Karnataka, India -571422<sup>2</sup> Professor and HOD of Department of pharmaceutical analysis, Bharathi college of Pharmacy, Bharathinagara, Mandya District, Karnataka, India -571422<sup>3</sup> Associate Professor, Department of Pharmaceutical Analysis, Bharathi college of Pharmacy, Bharathinagara, Mandya District, Karnataka, India -571422**Abstract:**

*The quantification of Dapagliflozin in pharmaceutical dosage forms and bulk medication has been accomplished through the development and validation of a new, precise, and effective Area under curve derivative UV spectroscopic approach. The absorbance of Dapagliflozin reaches its maximum at 224 nm in acetonitrile and ethanol (70:30), and the Area under curve in absorption spectra measured between wavelength range in 219nm and 229nm, its concentration falls between 3 and 18 µg/mL according to Beer's Law. A correlation value (R<sup>2</sup>) of 0.999 demonstrated the method's great linearity, demonstrating high consistency and dependability throughout the spectrum under study. While the limits of detection (LOD) and quantitation (LOQ) were determined to be 0.0707 µg/mL and 0.2142 µg/mL, respectively, recovery rates ranged from 98.15% to 100.09%. Additionally, the method's relative standard deviation (%RSD) values were less than 2%, indicating exceptional accuracy. The ICH recommendations were followed in evaluating the following validation parameters: linearity, accuracy, precision, robustness, ruggedness, LOD, and LOQ. For regular analysis of Dapagliflozin in different pharmaceutical formulations, this verified spectroscopic methodology proved to be a reliable and repeatable method.*

**KEYWORDS:** Dapagliflozin, Area under curve [AUC], Validation, Pharmaceutical formulation.**Corresponding author:****Kavana D. C,**

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## INTRODUCTION:

Dapagliflozin is a highly selective sodium-glucose cotransporter-2 inhibitor (SGLT2) used for the treatment of type 2 DM. Dapagliflozin is a new class of anti-diabetic agents that effectively reduce blood glucose levels, body weight, and systolic blood pressure. In addition to that, they have newly shown cardiovascular safety. The glucose-reducing effect of dapagliflozin has been approved in many randomized controlled clinical trials that showed notable reducing effects of Dapagliflozin in fasting blood glucose, glycosylated hemoglobin (HbA1c), and postprandial blood glucose levels. Furthermore, Dapagliflozin appeared to have a cardioprotective effect, by reducing blood pressure, lowering body weight, uric acid, and triglyceride, and enhance insulin resistance. Dapagliflozin is an oral, selective SGLT2 inhibitor that has displayed a significant improvement in glycemic control. Across universal clinical development programs including analysis of Phase IIB/III trial, treating with Dapagliflozin alone as monotherapy or in conjunction with pre-existing OADs was linked with a significant lowering in glycosylated hemoglobin (HbA1c), fasting blood glucose and also help in lower or stabilize the body weight and systolic blood pressure (SBP) in patients with T2 diabetes mellitus[1]. Dapagliflozin inhibits subtype 2 of the sodium-glucose transport proteins (SGLT2), which is responsible for at least 90% of the glucose reabsorption in the kidney. Blocking this transporter causes blood glucose to be eliminated through the urine. It also reduce the body weight, and systolic blood pressure. In addition to that, they have newly shown cardiovascular safety[2].

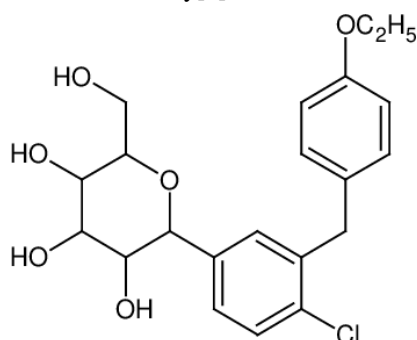


Fig1. Chemical Structure of Dapagliflozin.

Dapagliflozin is selected in order to assess the potency in pure and tablet dosage form. A thorough review of the literature reveals that only few spectrophotometric techniques [3-10], RP-HPLC [11-21], HPTLC [22] and UPLC [23] are effective for determining the presence of Dapagliflozin alone or in combination in a variety of pharmaceutical formulations and biological fluids, including stability studies. This information provides details about the analyte's synthesis, physical and chemical properties, solubility, and

pertinent analytical techniques. For the regular determination of dapagliflozin in pure and tablet form, newer, easier, more sensitive, quick, accurate, and reproducible spectrophotometric and chromatographical approaches are therefore required.

## MATERIALS AND METHODS:

**Instrument:** UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken in analytical balance.

**Chemicals:** Dapagliflozin pure drug was obtained as a gift sample from Althera Laboratories, Bengaluru and its pharmaceutical dosage Dapagliflozin 20 tablets (DAPANORM) labelled claim 10mg from local pharmacy manufactured by alkem laboratories ltd.

**Solvent:** Acetonitril and Ethanol (70:30) is used as a solvent

### Selection of analytical wavelength:

Appropriate dilutions of Dapagliflozin were prepared from standard stock solution and using spectrophotometer solution was scanned in the wavelength range 200-400 nm. Area under Curve[AUC] in absorption spectra were measured between the wavelength range 219nm and 229nm, as the wavelength for detection(Fig-2).

### Preparation of standard stock solution:

100mg of Dapagliflozin was weighed accurately transferred into 100 ml of volumetric flask and diluted in acetonitrile and ethanol (70:30) upto the mark. From this, the solution was further diluted into 100µg/ml and pipetted out 0.3, 0.6, 0.9, 1.2, 1.5 and 1.8 ml into 10 ml individual volumetric flask and diluted in acetonitrile and ethanol (70:30) upto the mark, this gives 3, 6, 9, 12, 15 and 18 µg/ml concentration.

### Preparation of sample solution:

20 tablets of Dapagliflozin marketed formulations was weighed and powdered. A quantity of tablet powder equivalent to 100mg of Dapagliflozin was transferred into 100ml volumetric flask then it was diluted with acetonitrile and ethanol (70:30) makes upto the mark.

## METHOD AND VALIDATION:

The method was validated according to the ICH guidelines<sup>[24-26]</sup>.

## RESULT AND DISCUSSION:

**Method : Area under curve spectroscopy.**

**Linearity:**

The linearity of an analytical method is its capacity to show the test results that are directly proportional to the concentration of the analyte in the sample within the range. The linearity was

established in the range of 3-18 $\mu$ g/ml and Area under curve [AUC] in absorption spectra were measured between the wavelength of 219nm and 229nm as absorbance values are shown in table-1(fig-3). The calibration curve was prepared by plotting graph against the concentration and absorbance and therefore the graph shown in (Fig-4). Statistical variables like slope, intercept, regression equation, correlation coefficient and sandell's sensitivity were determined and shown in( table-2).

#### Precision :

The precision of an analytical method express the closeness of series of individual analytical measurement obtained from the multiple sampling of equivalent sample. Precision was established by intra-day and inter-day was determined by analysing the same concentration for six times in a same day. Inter-day precision was analysing the same concentration daily for six days shown in (table-3).

#### Accuracy:

The accuracy of an analytical method says that closeness of test results obtained by that method of the true value .To assess the accuracy of the

developed method ,recovery studies were carried out at three different levels at 50% ,100% and 150% .In which the formulation concentration holds it constant and varied pure drug concentration Shown in (table -4).

#### Ruggedness:

The ruggedness is defined as the reliability of results when the method is performed under the variation in condition. This includes distinct analyst, laboratories, instruments , temperature etc. Ruggedness was determined between distinct analyst, the value of %RSD was found to be less than 2.(Table-5)

#### LOD and LOQ:

The limit of detection is an individual analytical method is the smallest amount of analyte in the sample which can be reliably detected by the analytical method. The limit of quantification is a discrete analytical procedure is the smallest amount of analyte in the sample which can be quantitatively determined. LOD and LOQ were calculated by using following formula  
 $LOD = 3.3(SD)/S$  and  $LOQ = 3(LOD)$   
 LOD and LOQ value of Dapagliflozin were found be 0.0707  $\mu$ g/mL and 0.2142  $\mu$ g/mL.

**Table 1: Results of calibration curve of Dapagliflozin at 219nm to 229nm by Area under curve.**

Sl No.	Concentration in $\mu$ g/ml	Absorbance $\pm$ Standard deviation
1	0	0
2	3	0.136 $\pm$ 0.0012
3	6	0.265 $\pm$ 0.0008
4	9	0.406 $\pm$ 0.0026
5	12	0.524 $\pm$ 0.0016
6	15	0.642 $\pm$ 0.0011
7	18	0.767 $\pm$ 0.0016

\*Average of six determinations

**Table 2:Regression parameters of Dapagliflozin at 219nm to 229nm by Area under curve**

Regression Parameter	Results
Range	3-18 $\mu$ g/ml
$\lambda_{max}$	219nm-229nm
Regression equation	$Y=0.042x-0.0008$
Slope(b)	0.042
Intercept (a)	0.0008
Correlation coefficient ( $r^2$ )	0.999
Sandell's sensitivity	0.022
Limit of detection ( $\mu$ g/ml)	0.098
Limit of quantification ( $\mu$ g/ml)	0.298

$$Y=bx+a^{**}$$

**Table 3: Determination of Precision results for Dapagliflozin at 219 nm to 229nm by Area under curve.**

Concentration (µg/ml)	Intra-day Absorbance ±Standard deviation*	%RSD**	Inter-day Absorbance ±Standard deviation*	%RSD**
3	0.136±0.0012	0.882	0.137±0.0011	0.802
6	0.265±0.0008	0.301	0.264±0.0016	0.606
9	0.406±0.0026	0.640	0.407±0.0013	0.319
12	0.524±0.0016	0.305	0.518±0.0010	0.193
15	0.642±0.0011	0.171	0.666±0.0012	0.180
18	0.767±0.0016	0.209	0.788±0.0015	0.190

\*Average of six determinations, \*\* Percentage relative standard deviation.

**Table 4: Determination of accuracy results for Dapagliflozin at 219nm to 229 by Area under curve**

Spiked levels	Amount of sample (µg/ml)	Amount of standard (µg/ml)	Amount recovered	%Recovery± Standard deviation*	%RSD**
50	9	4.5	13.51	100.09%±0.388	0.387
100	9	9	17.66	98.15%±0.381	0.388
150	9	13.5	22.46	99.87%±0.248	0.248

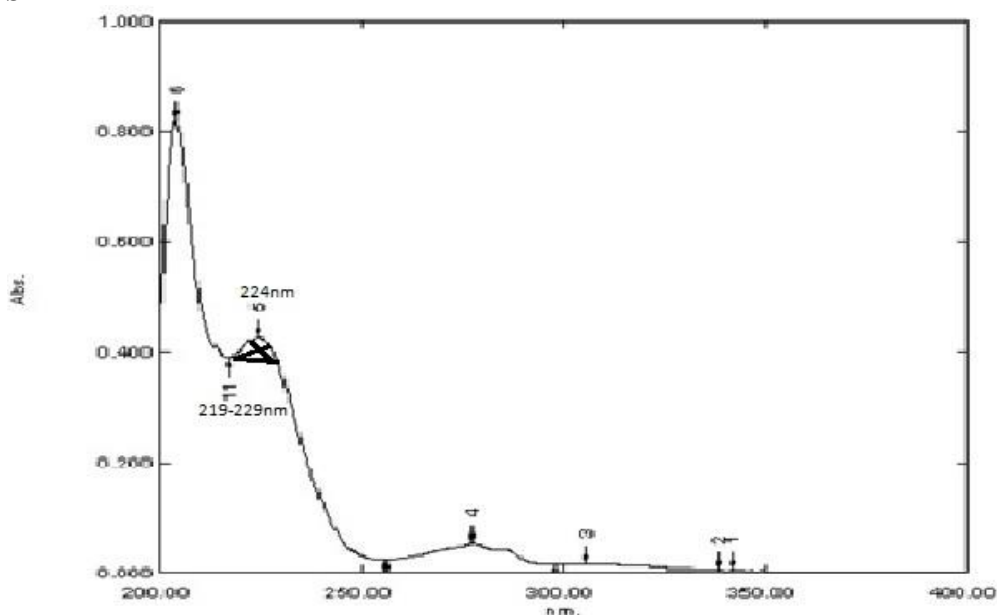
\*Average of six determinations, \*\* Percentage relative standard deviation.

**Table 5: Determination of ruggedness results of Dapagliflozin at 219nm to 229nm by Area under curve spectroscopy**

Analysts	Analyst 1	Analyst 2
Mean absorbance	0.407	0.406
± Standard deviation*	0.0010	0.0015
%RSD**	0.25	0.37

\*Average of six determinations, \*\* Percentage relative standard deviation.

## FIGURES

**Fig 2: Area Under Curve spectrum of Dapagliflozin at 219nm to 229nm.**

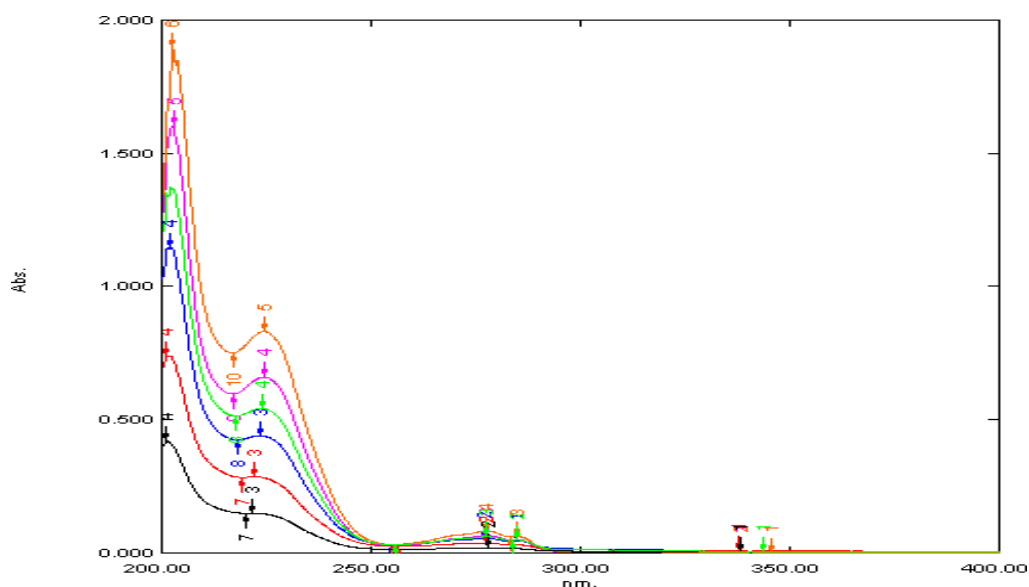


Fig 3: Area under curve overlain spectra of Dapagliflozin showing absorbance at 219nm to 229nm.

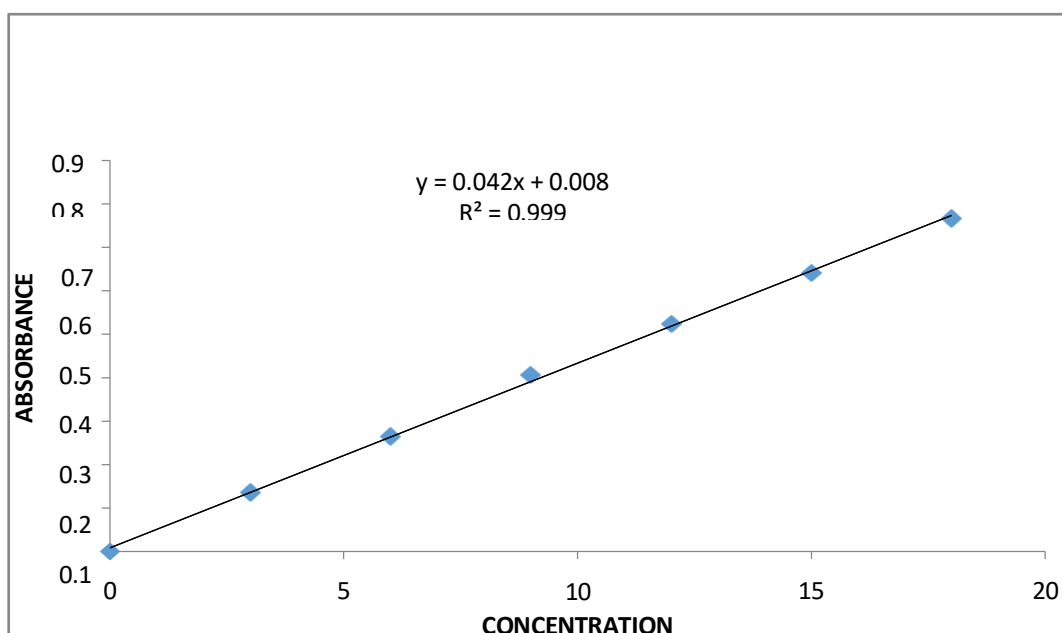


Fig 4: Calibration curve of Dapagliflozin by Area under curve.

### CONCLUSION:

The analytical method developed for Dapagliflozin was validated as per ICH guidelines demonstrating simplicity, specificity, accuracy, economy, and sensitivity. This method is suitable for regular analysis of Dapagliflozin in both bulk form and pharmaceutical preparations.

### REFERENCES:

1. Al-Arjani RA. Development and Validation of a New Combination: Dapagliflozin, Pioglitazone and Metformin Simultaneously in Tablets Dosage Form by HPLC . Master's thesis, University of Petra .Aug 2021:9-24.
2. Padmaja BR, Sivagami B, Chandrasekar R, Babu MN. A highly validated RP-HPLC method development for the simultaneous estimation of dapagliflozin and saxagliptin in tablet dosage forms. *Int J Pharm Sci Drug Res.* 2018 sep-oct;10(5):372-8.
3. Mante GV, Gupta KR, Hemke AT. Estimation of dapagliflozin from its tablet formulation by UV-spectrophotometry. *Pharm Methods.* 2017 Jul 1;8(2):102-7.
4. V.B. Tambe, P.S. Tajane, R. K. Godge. Analytical method Development and Validation of Dapagliflozin by UV-spectroscopy. *IJFANS Intl J of Food and Nutritional Sci.* 2022;11(11):709-716.
5. Yadav M, Chauhan R, Singh R, Tiwari N.

- UV-Spectrophotometric Approach for Concurrent Assessment of Sitagliptin and Dapagliflozin. *Afr.J.Bio.Sc.* 2024 Apr 22;6(9):1024-1032.
6. Suthar AM, Prajapati LM, Joshi AK, Patel JR, Kharodiya ML. Estimation of Saxagliptin hydrochloride and Dapagliflozin propendiol monohydrate in combined dosage form. *J. of Innv in Appl Pharm Sci (JIAPS)*. 2018 Jun 30;3(2):01-7.
  7. Patel A, Omray DL, Soni P. Method development for simultaneous estimation of Dapagliflozin and saxagliptin in fixed-dose combination and validation on UV spectroscopy. *J Pharm.* 2020;9(3):2536-43.
  8. Minal H, Sameer L, Valmik G, Vitthal C, Khomne A. Ultraviolet-spectrophotometric method for simultaneous estimation of Dapagliflozin propanediol and Metformin hydrochloride. *Intl Res J of Pharm.* 2019;10(4):90-4.
  9. Patel M, Vyas N, Shah H, Shah U, Patel A, Chokshi A. Analytical methods for simultaneous estimation of SGLT2 inhibitor and DPP-4 inhibitor in their combination for treatment of type 2 diabetes mellitus. *Lett Appl NanoBioScience.* 2020;10(1):1799-815.
  10. Mahabole S, Gajeli G, Kalshetti M. RP-HPLC and UV Spectroscopic Method Development and Validation for Estimation of Dapagliflozin in Bulk and Pharmaceutical Dosage Form. *Research Sqare.* 2024 jun12:2-15.
  11. Borse LB, Wagh MS, Borse SL, Ahire SP, Vaishnav IS, Naphade VD, Gulecha VS. RP-HPLC Method Development And Validation For Estimation Of Dapagliflozin In Tablet Formulation. *J of Pharm Negative Results.* 2022 Oct 15;13(5):364-72.
  12. Mante GV, Hemke AT, Umekar MJ. RP-HPLC method for estimation of dapagliflozin from its tablet. *Intl J of Chem Tech Res.* 2018;11(01):242-8.
  13. Gaikwad AV, Gawade AS, Hupparage Vrushabh B, Mantry S, Kale A, Kale J. Method Development and Validation of Dapagliflozin by RP-HPLC. *Jl of Pharm Negative Results.* 2022 Dec 31;13(6):4316-35.
  14. Sree VN, Bhavyasri DK, Sumakanth DM, Swethasri R. Estimation of Dapagliflozin in Pure and Marketed Formulation by Validated Reverse Phase-High Performance Liquid Chromatographic Method.(2020). *Int. J. Life Sci. Pharma Res.*;10(4):P70-84.
  15. Sravanthi S, Zarin N, Shruthi B, Krishna DR, Manjeera A. A New Analytical Method Development and Validation for the Estimation of Dapagliflozin by Using Reverse Phase- High Performance Liquid Chromatography. *Intl J of adv res in medical pharm sci:jul 2021*;6(4):13-20
  16. Debata J, Kumar S, Jha SK, Khan A. A New RP-HPLC method development and validation of dapagliflozin in bulk and tablet dosage form. *Int J Drug Dev Res.* 2017;9(2):48-51.
  17. Pal N, Mahtab T, Reddy PP, Rao AS. A new HPLC method development and validation for the determination of dapagliflozin in tablet dosage form. *World J of pharma res.* 2019;8(9):1156-1165.
  18. Urooj A, Sundar PS, Vasanthi R, Raja MA, Dutt KR, Rao KN, Ramana H. Development and validation of RP-HPLC method for simultaneous estimation of dapagliflozin and metformin in bulk and in synthetic mixture. *World J Pharm Pharm Sci.* 2017 May 20;6(7):2139-50.
  19. Rao BR, Rao VV, Venkateswarlu BS. RP-HPLC method for simultaneous estimation of dapagliflozin and saxagliptin in bulk samples. *J of Pharm Sci and Res.* 2019;11(1):254-7.
  20. Bhavyasri K, Surekha T, Begum S, Sumakanth M. RP-HPLC Method for Dapagliflozin and Metformin HCL in Bulk and Combined Formulation. *Archives of Pharmacy Practice.* 2021;12(4-2021):106-10.
  21. Kladi E, Zerva M, Dotsikas Y. A novel HPLC method for the simultaneous determination of empagliflozin and dapagliflozin: Development, validation, robustness testing and greenness assessment. *Archives of Pharmacy.* 2024 Apr 28;74(Notebook 2):267-80.
  22. Suma BV, Deveswaran R, Premnath SH. A new high-performance thin layer chromatographic method development and validation of dapagliflozin in bulk and tablet dosage form. *Int J Pharm Pharm Sci.* 2019 Aug 1;11(8):58-63.
  23. Madhavi S, Rani AP. Development and validation of a method for simultaneous determination of dapagliflozin and saxagliptin in a formulation by RP-UPLC. *World J Pharma Res.* 2017 Aug 11;6(12):904-16.
  24. ICH, Q2A text on validation of analytical procedures; 1994.
  25. ICH, Q2B validation of analytical methodology; 1996.
  26. ICH, Q2 (R1) validation of analytical procedures: text and methodology; 2005.