

**UV METHODS FOR THE SIMULTANEOUS DETERMINATION OF DAPAGLIFLOZIN
PROPANEDIOL MONOHYDRATE AND BISOPROLOL FUMARATE IN COMBINED
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603319, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai 600032, Tamil Nadu, India.**DOI:** <https://doi.org/10.5281/zenodo.23830119>**How to cite this Article:** S. Arunprasath^{1*}, Dr. T. Vetrichelvan², Dr. S. M. Murugan³. (2026). Uv Methods For The
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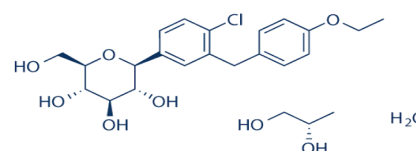
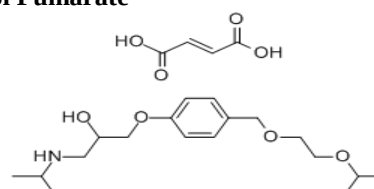
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ABSTRACT

A simple, rapid, accurate, precise, and economical UV spectrophotometric “simultaneous equation method (Vierordt’s Method)” for the determination of **Dapagliflozin Propanediol Monohydrate (DAPA)** and **Bisoprolol Fumarate (BISO)** in a combined tablet dosage form using the simultaneous equation method has been developed. **Materials and Methods:** The method is based on the simultaneous equations for analysis of both the drugs using 0.1N HCl and further diluted with methanol as a solvent. DAPA has absorbance maxima at 224 nm and BISO has absorbance maxima at 264 nm in Methanol. **Results:** The linearity was obtained in the concentration range of 4–20 µg/ml and 2–10 µg/ml for DAPA and BISO, respectively. The concentrations of the drugs were determined by using the simultaneous equations method. The mean recovery was 99.97 and 99.92 for DAPA and BISO, respectively. **Conclusion:** The method was found to be simple, accurate, and precise and was applicable for the simultaneous determination of DAPA and BISO in the pharmaceutical tablet dosage form. The results of analysis have been validated statistically and by recovery studies.

KEYWORDS: Methanol, Dapagliflozin Propanediol Monohydrate, Bisoprolol Fumarate, recovery, simultaneous equations, validation.**1. INTRODUCTION**

Dapagliflozin propanediol monohydrate (DAPA), a sodium-glucose co-transporter-2 (SGLT2) inhibitor, and bisoprolol fumarate (BISO), a β 1-selective adrenergic blocker, represent a pharmacologically complementary fixed-dose combination (FDC). Clinical evidence shows SGLT2 inhibitors such as dapagliflozin in heart failure with reduced ejection fraction (HFrEF), where dapagliflozin 10 mg/day reduced the composite of cardiovascular death and worsening heart failure compared with placebo in the DAPA-HF trial.

Dapagliflozin Propanediol Monohydrate^[18]**Bisoprolol Fumarate^[19]**

1.1 Simultaneous Equation Method (Vierordt's Method).^[4]

1.1.1 Absorbance Relationships at Two Wavelengths (λ_1 and λ_2)

According to the Beer-Lambert law, the total absorbance of a mixture containing two absorbing species (X and Y) at a specific wavelength is the sum of the individual absorbances of each component.

At wavelength λ_1

$$A_1 = a_{x1}c_x + a_{y1}c_y \quad (1)$$

At wavelength λ_2

$$A_2 = a_{x2}c_x + a_{y2}c_y \quad (2)$$

1.1.2. Path Length Simplification

- For standard measurements performed in 1 cm cuvettes, the optical path length $b = 1$, which simplifies the equations to:
 - $A_1 = a_{x1}c_x + a_{y1}c_y$
 - $A_2 = a_{x2}c_x + a_{y2}c_y$

1.1.3. Rearranging and Solving for Concentration (C_x and C_y)

By rearranging the equation for A_2 to isolate C_y and substituting it back into the equation for A_1 , simultaneous linear equations are solved to yield the final concentration formulas for each component:

- Concentration of Component X (C_x)

$$C_x = \frac{A_2 a_{y1} - A_1 a_{y2}}{a_{x2} a_{y1} - a_{x1} a_{y2}}$$

- Concentration of Component Y (C_y)

$$C_y = \frac{A_1 a_{x2} - A_2 a_{x1}}{a_{x2} a_{y1} - a_{x1} a_{y2}}$$

If a sample contains two absorbing drugs (X and Y) each of which absorbs at the $\lambda_{\max}$ of the other it may be possible to determine both the drugs by the technique of simultaneous Equation (Vierordt's method)

The information required is

- The absorptivities of X at λ_1 and λ_2 , a_{x1} and a_{x2} respectively
- The absorptivities of Y at λ_1 and λ_2 , a_{y1} and a_{y2} respectively
- The absorbances of the diluted sample at λ_1 and λ_2 , A_1 and A_2 respectively.

Let C_x and C_y be the concentration of X and Y respectively in the diluted Sample.

Two equations are constructed based upon the fact that at λ_1 and λ_2 the absorbances of the mixture is the sum of the individual absorbances at X and Y.

2. MATERIALS AND METHOD

Apparatus

A Shimadzu model 1700 (Japan) double beam UV/Visible spectrophotometer with a spectral width of 2 nm, a wavelength accuracy of 0.5 nm, and a pair of 10 mm matched quartz cell was used to measure absorbance of all the solutions. A AUX-220 electronic weighing analytical balance and a Sonicator-sonica ultrasonic cleaner-model 12200MH specification. Have been used in the study.

Reagents and materials

BISO and DAPA bulk powders were Purchased. The commercial fixed dose combination carbis D 10/5 mg was procured from the local market. All other chemicals used were of analytical grade. Calibrated glasswares were employed throughout the work.

Preparation of standard stock solutions

Weighed 10 mg of **Dapagliflozin Propanediol Monohydrate** and 50 mg of **Bisoprolol Fumarate** in 10 ml volumetric flask in individual and made to volume with 0.1N HCl DAPA (1000 $\mu\text{g/ml}$) & BISO (5000 $\mu\text{g/ml}$).

From the above solution pipetted out 1 ml into a 25 ml volumetric flask made up to the volume with Methanol (40 $\mu\text{g/ml}$) of **Dapagliflozin Propanediol Monohydrate** and 10 ml volumetric flask made up to the volume with Methanol **Bisoprolol Fumarate** (500 $\mu\text{g/ml}$).

From the working standard solution of **Dapagliflozin Propanediol Monohydrate** (40 $\mu\text{g/ml}$) and **Bisoprolol Fumarate** (500 $\mu\text{g/ml}$) 1-5 ml were transferred into 10 ml volumetric flasks for **Dapagliflozin Propanediol Monohydrate** for **Bisoprolol Fumarate** were transferred into 25 ml and made up to the volume to get 4,8,12,16,20 $\mu\text{g/ml}$ of **Dapagliflozin Propanediol Monohydrate** & 2,4,6,8,10 $\mu\text{g/ml}$ of **Bisoprolol Fumarate** concentrations with methanol.

3. Validation of the proposed method^[8]

The proposed method was validated according to the International Conference on Harmonization (ICH) guidelines.

Linearity (calibration curve)

Weighed 10 mg of **Dapagliflozin Propanediol Monohydrate** and 50 mg of **Bisoprolol Fumarate** in 10 ml volumetric flask in individual and made to volume with 0.1N HCl DAPA (1000 $\mu\text{g/ml}$) & BISO (5000 $\mu\text{g/ml}$).

From the above solution pipetted out 1 ml into a 25 ml volumetric flask made up to the volume with Methanol (40 $\mu\text{g/ml}$) of **Dapagliflozin Propanediol Monohydrate**

and 10 ml volumetric flask made up to the volume with Methanol **Bisoprolol Fumarate** (500 µg/ml).

From the working standard solution of **Dapagliflozin Propanediol Monohydrate** (40 µg/ml) and **Bisoprolol Fumarate** (500 µg/ml) 1-5 ml were transferred into 10 ml volumetric flasks for **Dapagliflozin Propanediol Monohydrate for Bisoprolol Fumarate** were transferred into 25 ml and made up to the volume to get 4,8,12,16,20 µg/ml of **Dapagliflozin Propanediol Monohydrate** & 2,4,6,8,10 µg/ml of **Bisoprolol Fumarate** concentrations with methanol.

The absorbance of resulting solutions was measured at 224 nm and 264 nm, and the calibration curves were plotted at these wavelengths. The absorptivity coefficients of these two drugs were determined using the calibration curve equations. The concentration of DAPA and BISO in the sample solution was determined by solving the respective simultaneous equations generated by using absorptivity coefficients and absorbance values of DAPA and BISO at these wavelengths.

Method precision (repeatability)

The precision of the instrument was checked by repeated scanning and measurement of absorbance of solutions ($n = 6$) for DAPA and BISO (4 µg/ml for BISO and DAPA 8 µg/ml) without changing the parameter of the proposed spectrophotometry method.

Intermediate precision (reproducibility)

The intra-day and inter-day precision of the proposed method was determined by analysing the corresponding responses three times on the same day and on three different days same concentrations of standard solutions of BISO and DAPA.

Accuracy (recovery study)

The accuracy of the method was determined by calculating recovery of DAPA and BISO. By the standard addition method. Known amounts of standard solutions of DAPA and BISO were added at 50, 100, and 150% level to pre-quantified sample solutions of DAPA and BISO (8 µg/ml for DAPA and 4 µg/ml for BISO). The amounts of DAPA and BISO were estimated by applying obtained values to the respective regression line equations. The experiment was repeated for three times.

Limit of detection and limit of quantification

The limit of detection (LOD) and the limit of quantification (LOQ) of the drug were derived by calculating the signal-to-noise ratio (S/N) using the following equations designated by International Conference on Harmonization (ICH) guidelines.

$$\text{LOD} = 3.3 \times \sigma/S$$

$$\text{LOQ} = 10 \times \sigma/S$$

Where,

σ is the standard deviation of the response and S is the slope of the calibration curve.

Analysis of DAPA and BISO in a combined tablet dosage form

15 Tablets of formulation containing 10 mg of **Dapagliflozin Propanediol Monohydrate** and 5 mg of **Bisoprolol Fumarate** were weighed accurately. The average weight of tablets was found and powdered. The tablet powder equivalents to 10 mg of **Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate** was weighed and transferred into 10 ml clean and dry volumetric flask containing 10 ml of diluent. The contents of flask were sonicated for 15 minutes and methanol was added to made up to mark to get a sample stock concentration of **Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate**. The content was filtered through the Whatmann filter paper No.41. From the filtrate 1 ml taken in a 25 ml volumetric flask made up to the volume with methanol to get 40 µg/ml of DAPA and 20 µg/ml of BISO. From the above solution transfer 2 ml into 10 ml volumetric flask made up to the volume with methanol to get 8 µg/ml of DAPA and 4 µg/ml of BISO were determined by using simultaneous equation method. The absorbances of the tablet sample solution, i.e. A1 and A2 were recorded at 224 nm and 265 nm and ratios of absorbance were calculated, i.e. A2/A1. Relative concentration of two drugs in the sample solution was calculated using respective simultaneous equations generated by using absorptivity coefficients and absorbance values of BISO and DAPA at these wavelengths.

4. RESULTS AND DISCUSSION

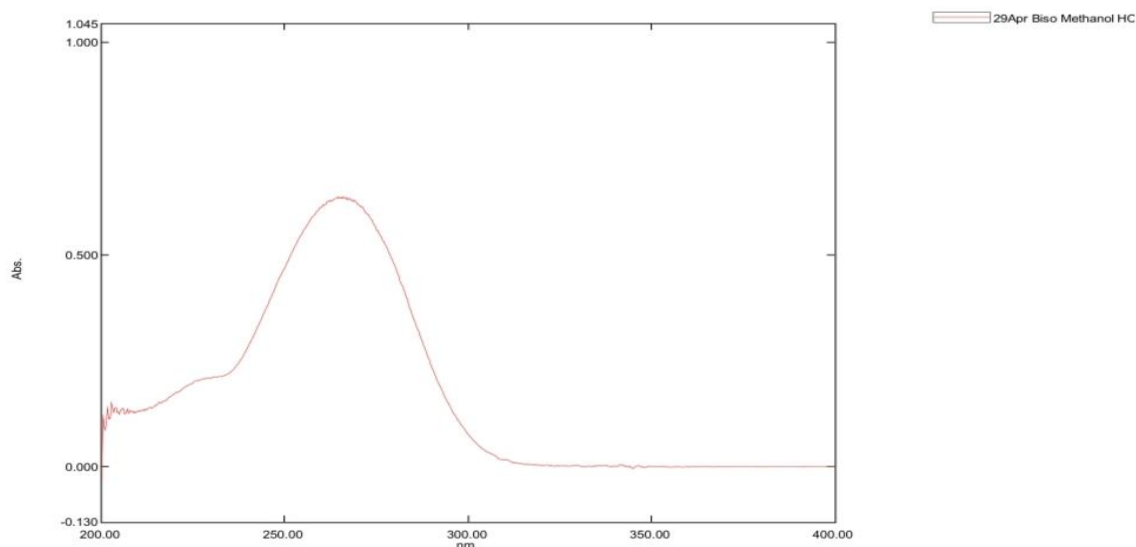
In this method, two wavelengths were used for the analysis of the drugs. Further, 224 nm (λ max of DAPA) and 265 nm (λ max of BISO) are the wavelengths at which calibration curves were prepared for both the drugs. The criteria for obtaining maximum precision by this method were calculated and found to be inside the range 0.1–2. Once the absorptivity values are determined, very little time is required for analysis, as would require determination of absorbances of the sample solution at two selected wavelengths and few simple calculations. The standard solutions of BISO and DAPA were scanned separately in the UV range, and zero-order spectra for BISO and DAPA were recorded [Figure 1 & 1.1]. Maximum absorbance was obtained at 224 nm and 265 nm for DAPA and BISO, respectively. Linear correlation was obtained between absorbances and concentrations of DAPA and BISO in the concentration ranges of 4–20 µg/ml and 2–10 µg/ml for both drugs, respectively. The linearity of the calibration curve was validated by the high values of correlation coefficient of regression. LOD and LOQ values for DAPA were found to be 0.420 µg/ml and 0.363 µg/ml and 1.274 and 1.100 µg/ml at 224 and 265 nm, respectively. LOD and LOQ values for BISO were found to be 0.252 and 0.117 µg/ml and 0.764 and 0.354 µg/ml at 224 and 265 nm, respectively. These data show that the method is sensitive for the determination of DAPA and BISO. All the regression analysis data and the summary of validation parameters for the proposed

method are reported in Table 1. The recovery experiment was performed by the standard addition method. The mean recoveries were 99.653 ± 1.780 for DAPA and 99.85 ± 0.721 for BISO, respectively, which indicates the accuracy of the proposed method [Table 3]. The proposed validated method was successfully applied to determine DAPA and BISO in their combined dosage

form. The results obtained for DAPA and BISO were comparable with the corresponding labelled amounts [Table 2]. The relative standard deviation (RSD) values for assay of DAPA and BISO were found to be 1.7 and 1.81, respectively. The RSD was less than 2%, which indicates that the proposed method is repeatable.

Overlay Spectrum Graph Report

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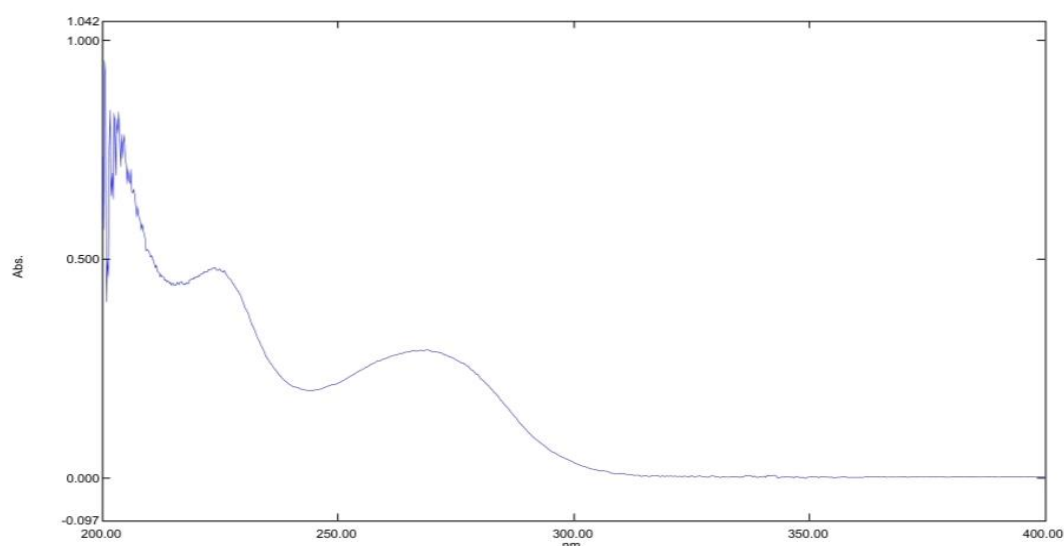
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Figure 1: Bisoprolol fumarate.

Active Spectrum Graph Report

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Data Set: 29Apr Dapa Methanol HCl - RawData

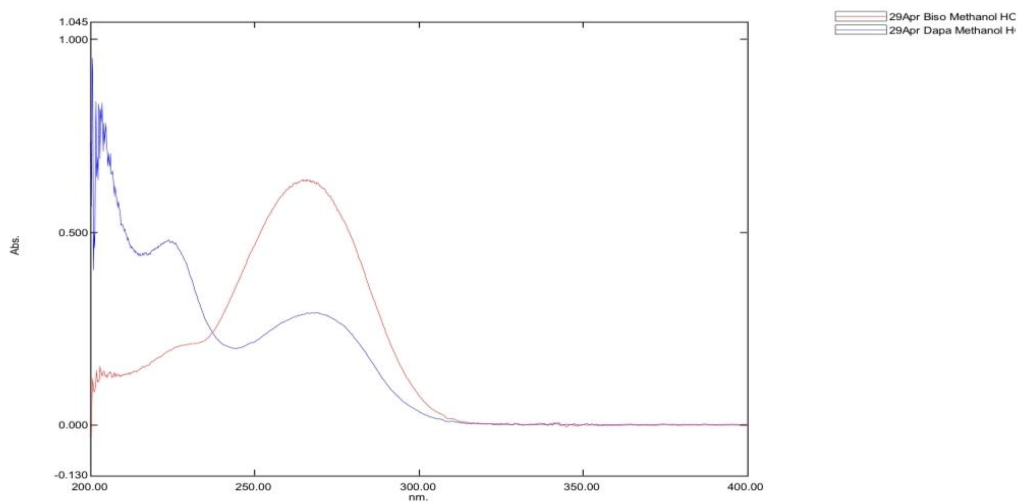


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Figure 2: Dapagliflozin Propanediol Monohydrate.

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Figure 3: Overlay UV SPRCTRUM OF Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate.

Table 1: Optical Characterization.

Dapagliflozin Propanediol Monohydrate		
PARAMETER	AT 224nm	At 265nm
Regression equation (y=mx + c)	0.9998	0.9998
Slope (m)	0.0254	0.0472
Intercept (c)	0.0007	0.0019
S.D	0.6017	0.1901
LOD (µg/ml)	0.420	0.363
LOQ (µg/ml)	1.274	1.100

Table 1.1: Optical Characterization.

Bisoprolol Fumarate		
PARAMETER	AT 224nm	At 265nm
Regression equation (y=mx + c)	0.9997	0.9999
Slope (m)	0.022	0.0628
Intercept (c)	0.0005	0.0013
S.D	0.1677	0.22201
LOD (µg/ml)	0.252	0.117
LOQ (µg/ml)	0.764	0.354

Table 2: Quantification of Dapagliflozin Propanediol Monohydrate And Bisoprolol Fumarate Formulation.

Drug	Sample No	Labelled Amount (mg/tab)	Amount Found (mg/tab)	Percentage Obtained (%)	Average	±S. D	% RSD
Dapagliflozin Propanediol Monohydrate	1	10	9.98	99.8	99.70	1.7116	1.722
	2	10	9.70	97.02			
	4	10	9.96	99.69			
	5	10	10.20	102.06			
	6	10	10.54	98.26			
Bisoprolol fumarate	1	5	4.98	99.7	100.61	1.8988	1.8877
	2	5	4.98	99.7			
	4	5	4.94	98.86			
	5	5	5.01	100.43			
	6	5	5.03	100.70			

FORMULATION

Table 3: Recovery Study Of Dapagliflozin Propanediol Monohydrate And Bisoprolol Fumarate.

Sample	%	Amount present (µg/ml)	Amount ADDED (µg/ml)	Estimated amount (µg/ml) *	Recovered amount (µg/ml) *	Average % Recovery *	SD	% RSD
BISO	50	4	2	5.96	1.96	98	0.2573	0.2574
	100	4	4	8.021	4.021	100.525	0.2877	0.2978
	150	4	6	9.98	5.98	99.66	0.2796	0.2899
DAPA	50	8	4	12.03	4.03	100.75	0.6851	0.6856
	100	8	8	15.99	7.99	99.8	0.6982	0.6875
	150	8	12	20.06	12.06	100.5	0.6859	0.6885

Table 4: Intraday And Interday Of Dapagliflozin Propanediol Monohydrate And Bisoprolol Fumarate.

Drug	Sample No.	Labelled Amount (mg/tab)	Percentage obtained		±SD		%RSD	
			Intra day (%)	Inter day (%)	Intra day (%)	Inter day (%)	Intra day (%)	Inter day (%)
DAPA	1	10	99.87	99.87	0.3407	0.2021	0.3901	0.2031
	2	10	100.53	100.24				
	3	10	99.84	100.09				
BISO	1	5	99.86	100.00	0.11788	0.13785	0.11788	0.13785
	2	5	100.125	100.03				
	3	5	99.95	100.28				

CONCLUSION

No interference of the excipients with the absorbance of interest appeared; hence the proposed method is applicable for the routine simultaneous estimation of DAPA and BISO in pharmaceutical tablet dosage forms. The proposed spectrophotometric method was found to be simple, sensitive, accurate, and precise for simultaneous determination of DAPA and BISO in the tablet dosage form. The method utilizes easily available and low cost solvent like distilled water for analysis of DAPA and BISO. Hence, the method was also found to be economical for the estimation of DAPA and BISO from tablets.

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