ISSN (0): Applied, ISSN (P): Applied 2025, Volume 1, Issue 1, Page: 6-16.
WORLD JOURNAL OF ADVANCE MEDICINE
www.wjam.net

Research Article

DEVELOPMENT AND VALIDATION OF A UV SPECTROPHOTOMETRIC METHOD USING AREA UNDER THE CURVE FOR THE SIMULTANEOUS ESTIMATION OF LOBEGLITAZONE SULPHATE AND DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE IN A SYNTHETIC MIXTURE

Khan Sheherbanu[1]* and Mahida Rajvi[2]

Research Student[1]*, Assistant Professor[2]
Department of Pharmaceutical Quality Assurance ROFEL Shri G.M. Bilakhia College of Pharmacy, Vapi, Gujarat, 396191.

Article Info

Article Received: 19 May 2025,
Article Revised: 10 June 2025,
Published on: 01 July 2025.

***Corresponding author:**
Khan Sheherbanu
Research Student, Department of Pharmaceutical Quality Assurance ROFEL Shri G.M. Bilakhia College of Pharmacy, Vapi, Gujarat, 396191.
shehersk2000@gmail.com

ABSTRACT

A simple, rapid, and cost-effective UV spectroscopic method has been developed and validated for the simultaneous estimation of Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate in a synthetic mixture using the Area Under the Curve (AUC) method. The method was optimized with Lobeglitazone Sulphate measured in the wavelength range 233-243 nm (0.5-2.5 µg/ml) and Dapagliflozin measured in the range 220-230 nm (10-50 µg/ml). Methanol was selected as the solvent after solubility studies. The method was validated for linearity, precision, accuracy, LOD (Limit of Detection), and LOQ (Limit of Quantitation). The linearity of the method was confirmed with a correlation coefficient for both drugs, while precision was assessed through repeatability, intraday, and interday studies. The LOD and LOQ were calculated to determine the sensitivity of the method. Accuracy was evaluated by recovery studies, demonstrating the reliability of the method. The developed method provides a reliable tool for the routine analysis of these drugs in combination dosage forms.

INTRODUCTION

Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate are two important drugs used in the management of type 2 diabetes mellitus.[1]

Lobeglitazone Sulphate(LOBE), a thiazolidinedione derivative, improves insulin sensitivity and helps control blood sugar levels. It has a molecular formula of $C_{24}H_{26}N_4O_9S_2$ and a molecular weight of 578.6 g/mol. The IUPAC name of Lobeglitazone is 5-[[4-[2-[[6-(4-methoxyphenoxy) pyrimidin-4-yl]-methylamino]ethoxy] phenyl]methyl]-1,3-thiazolidine-2,4-dione; sulfuric acid. It is freely soluble in methanol and slightly soluble in water, with a mechanism of action that involves activating peroxisome proliferator-activated receptor gamma (PPAR-γ), which regulates insulin action.[2,3,4,7,8]

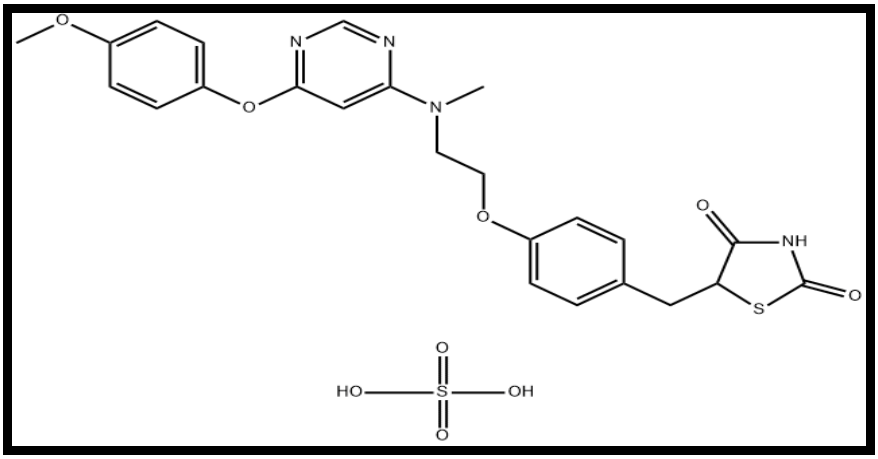

Figure 1: Chemical Structure of Lobeglitazone Sulphate.

Dapagliflozin Propanediol Monohydrate(DAPA), an SGLT2 inhibitor, aids in the reduction of blood sugar levels by promoting the excretion of glucose through urine. Its molecular formula is $C_{24}H_{35}CLO_9$ with a molecular weight of 502.98 g/mol. The IUPAC name is(2S,3R,4R,5S,6R)-2-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol;(2S)-propane-1,2-diol; hydrate. It is freely soluble in methanol and water. It works by inhibiting the sodium-glucose co-transporter 2 (SGLT2), which prevents glucose reabsorption in the kidneys.[2,5-8]

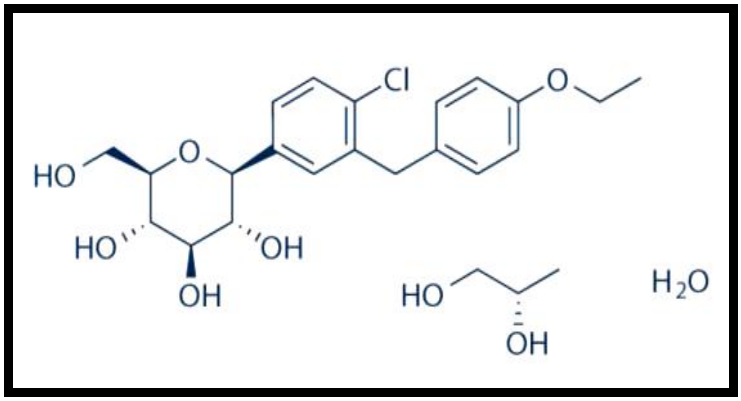

Figure 2: Chemical Structure of Dapagliflozin Propanediol Monohydrate.

The combination of these two drugs in a single dosage form has been shown to provide an effective treatment strategy for diabetes, helping in better glycemic control. However, the simultaneous estimation of these drugs in their combination dosage form presents a challenge due to their overlapping absorbance spectra. Therefore, a reliable, simple, and cost-effective method for their simultaneous determination is essential.

UV spectrophotometry, particularly the Area Under the Curve (AUC) method, offers a suitable solution for such analytical challenges. This method provides an accurate, precise, and rapid means of determining both drugs in a synthetic mixture. The AUC method avoids interference between the drugs, ensuring precise quantification in the presence of excipients and other formulation components.[9-12]

MATERIAL AND METHOD

The Drug's used in this study include Lobeglitazone Sulphate, a gift sample from Akums Pharmaceutical, Haridwar, India, and Dapagliflozin Propanediol Monohydrate, a gift sample from Exemed Pharmaceuticals, Vapi, Gujarat, India. The solvents used in the study were methanol, which was chosen based on solubility studies, as both drugs were found to exhibit linear spectra in methanol. All chemicals used were of analytical grade.

The instrumentation used included a Shimadzu UV-Visible Spectrophotometer (Model: 1900i, Software: UV Probe, Version 2.42) equipped with matched quartz cells of 1 cm light path. An electronic analytical balance (Shimadzu, 0.1 mg sensitivity), ultrasonicator cleaner (Labman Scientific Instruments), volumetric flasks (10 ml, 25 ml, Borosil), and pipettes (1 ml, 5 ml, and 10 ml, Borosil) were also used in this study.

For the spectrophotometric analysis, the method involved scanning the samples in the range of 200-400 nm. The scan speed was set to medium, with the absorbance scale ranging from 0.00 to 2.00 Aº. The baseline correction was performed using methanol as the blank. The selected wavelengths for measurement were 233-243 nm for Lobeglitazone Sulphate and 220-230 nm for Dapagliflozin Propanediol Monohydrate based on their absorption spectra.

PREPARATION OF STANDARD SOLUTION

1. Preparation of LOBE standard stock solution (1000 µg/ml)

10 mg of LOBE was weighed and transferred to 10 ml volumetric flask. Lobe was dissolved in methanol and volume was made up to the mark with methanol to give a solution 1000 µg/ml.

2. Preparation of LOBE standard stock solution (100 µg/ml)

Aliquot of 1 ml from above standard stock solution was pipetted out into 10 ml of volumetric flask and volume was made up to the mark with methanol to give a solution conttaining 100 µg/ml.

3. Preparation of LOBE standard stock solution (10 µg/ml)

Aliquot of 2.5 ml from above standard stock solution was pipetted out into 25 ml of volumetric flask and volume was made up to the mark with methanol to give a solution containing 10 µg/ml.

4. Preparation of DAPA standard stock solution (1000 µg/ml)

10 mg of DAPA was weighed and transferred to 10 ml volumetric flask. It was dissolved into methanol and volume was made up to the mark with methanol to give a solution containing 1000 µg/ml.

5. **Preparation of DAPA standard stock solution (100 µg/ml)**
Aliquot of 2.5 ml from above standard stock solution was pipetted out into 25 ml of volumetric flask and volume was made up to the mark with methanol to give a solution conttaining 100 µg/ml.

SELECTION OF WAVELENGTHS
Appropriate dilutions were prepared for drugs from the working stock solution were scanned in the wavelength range of 200-400nm. The absorption spectra of Area Under Curve (AUC) in absorption spectra of DAPA were measured between the wavelength range 220-230 nm and for LOBE were measured between the wavelength range 233-243 nm.

PREPARATIONS OF CALIBRATION CURVE
1. Calibration curve for LOBE
Calibration curve for LOBE consisted of five different concentrations of standard solution of LOBE ranging from 0.5- 2.5 µg/ml. The solution was prepared by pipetting out 0.5, 1, 1.5, 2 and 2.5ml of working stock solution of LOBE (10 µg/ml) into series of 10 ml volumetric flasks and the volume was made up to mark with methanol to produce 0.5, 1, 1.5, 2 and 2.5 µg/ml respectively. The AUC of the solution was measured under wavelength 233- 243 nm against methanol as blank. Calibration Curve was plotted at both wavelength and equation were formed using specific absorbance.

2. Calibration curve for DAPA
Calibration curve for DAPA consisted of five different concentrations of standard solution of DAPA ranging from 10- 50 µg/ml. The solution was prepared by pipetting out 1, 2, 3, 4 and 5 ml of working stock solution of DAPA (100 µg/ml) into series of 10 ml volumetric flasks and the volume was made up to mark with methanol to produce 10, 20, 30, 40 and 50 µg/ml respectively. The AUC of the solution was measured under wavelength 220- 230 nm against methanol as blank. Calibration Curve was plotted at both wavelength and equation were formed using specific absorbance.

VALIDATION OF PROPOSED METHOD
Parameters to be considered for the validation of method are:
1. Linearity (n=5)
The linearity response was determined by analyzing 5 independent levels of calibration curve in the range of 0.5-2.5 µg/ml for LOBE and 10-50 µg/ml for DAPA. The Calibration curve of dA/dλ absorbance vs. concentration was plotted and correlation coefficient and regression line equations for LOBE and DAPA were calculated.

2. Precision
A. Repeatability (n=6)
Aliquot of 1.5 ml of working stock solution of LOBE (10 µg/ml) were taken into series of 10 ml volumetric flask. Aliquot of 3 ml of working stock solution of DAPA (100 µg/ml) were taken into series of 10 ml volumetric flask. Using methanol, volume was made up to mark to give a solution containing 1.5 µg/ml of LOBE and 30 µg/ml 1of DAPA. Solution was analyzed six times (n=6) and % R.S.D. was calculated.

B. Intraday (n=3)
Aliquots of 1, 1.5 and 2 ml of working stock solution of LOBE (10 µg/ml) were taken into series of 10 ml volumetric flask. Aliquot of 2, 3 and 4 ml of working stock solution of DAPA (100 µg/ml) were taken into series of 10 ml volumetric flask. Using methanol, volume was made up to mark to give a solution containing 1, 1.5 and 2 µg/ml of LOBE and 20, 30 and 40 µg/ml of DAPA. Solution was analyzed for three times (n=3) on the same day within short interval of time and % R.S.D. was calculated.

C. Interday (n=3)
Aliquots of 1, 1.5 and 2 ml of working stock solution of LOBE (10 µg/ml) were taken into series of 10 ml volumetric flask. Aliquot of 2, 3 and 4 ml of working stock solution of DAPA (100 µg/ml) were taken into series of 10 ml volumetric flask. Using methanol, volume was made up to mark to give a solution containing 1, 1.5 and 2 µg/ml of LOBE and 20, 30 and 40 µg/ml of DAPA. Solution was analyzed for three times (n=3) on the different days and % R.S.D. was calculated.

3. Accuracy (n=3)
Preparation of Sample Solution for LOBE
Mixture Solution X: LOBE (5 µg/ml) + DAPA (100 µg/ml)
Solution Y: LOBE (10 µg/ml).

Table No. 1: Steps for Accuracy Measurement for LOBE.

Sr. No.	Step 1	Step 2	Step 3	Total Conc. (µg/ml)
1.	Take 1 ml of solution X	-	Make up the volume to 10 ml with methanol	0.5
2.	Take 1 ml of solution X	Add 0.4 ml of solution Y	Make up the volume to 10 ml with methanol	0.9
3.	Take 1 ml of solution X	Add 0.5 ml of solution Y	Make up the volume to 10 ml with methanol	1
4.	Take 1 ml of solution X	Add 0.6 ml of solution Y	Make up the volume to 10 ml with methanol	1.1

Preparation of Sample Solution for DAPA
Mixture Solution X: LOBE (5 µg/ml) + DAPA (100 µg/ml)
Solution Y: DAPA (100 µg/ml)

Table No. 2: Steps for Accuracy Measurement for DAPA.

Sr. No.	Step 1	Step 2	Step 3	Total Conc. (µg/ml)
1.	Take 1 ml of solution X	-	Make up the volume to10 ml with methanol	10
2.	Take 1 ml of solution X	Add 0.8 ml of solution Y	Make up the volume to10 ml with methanol	18
3.	Take 1 ml of solution X	Add 1 ml of solution Y	Make up the volume to10 ml with methanol	20
4.	Take 1 ml of solution X	Add 1.2 ml of solution Y	Make up the volume to10 ml with methanol	22

Each solution was scanned from 200-400 nm against methanol as blank. Absorbance of solution was measured at selected wavelengths for LOBE and DAPA. The amount of LOBE and DAPA was calculated at each level (80%, 100% and 120%) and % recoveries were computed.

4. LOD and LOQ
The LOD (Limited of Detection) was estimated from the set of 5 calibration curves that were used to determine linearity of the method. The LOD was calculated by using the formula:
LOD: 3.3 x S.D. / Slope

Where, S.D. = Standard deviation of the Y – intercepts of 5 calibration curves.Slope
= Mean slope of 5 calibration curves

The LOQ (Limit of Quantitation) was estimated from the set of 5 calibration curves that were used to determine linearity of the method. The LOQ was calculated by using the formula:
LOQ: 10 x S.D. / Slope

Where, S.D. = Standard deviation of the Y – intercepts of 5 calibration curves .Slope
= Mean slope of 5 calibration curves

SIMULTANEOUS ESTIMATION OF LOBEGLITAZONE SULPHATE AND DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE IN SYNTHETIC MIXTURE (TABLET) BY AREA UNDER CURVE METHOD
Applicabilty of the method (Assay n=5)
A synthetic mixture (tablet) equivalent to 10 mg of DAPA and 0.5 mg of LOBE was taken into 10 ml of volumetric flask and added 3 ml of methanol, the solution was warmed for 5-10 mins, ultrasonicated for 20 mins to completely disperse the tablet, followed by addition of 3 ml methanol and ultrasonicated for 15 min and was make up to the mark with methanol. The solution was filtered through Whatman filter paper no. 41. Thus, resulting solution gave 1000 µg/ml of DAPA and 50 µg/ml of LOBE respectively. From the above solution, 1 ml was pipette out and transferred to 10 ml volumetric flask and volume was made up to mark with methanol in order to give a solution containing DAPA (100 µg/ml) + LOBE (5 µg/ml). From the above solution, 2 ml was pipette out and transferred to 10 ml volumetric flask and volume was made up to mark with methanol in order to give a solution containing DAPA (20 µg/ml) + LOBE (1 µg/ml).

Estimation of Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate
A set of equation were established using mean absorptivity of coefficient of Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate at selected wavelength range interval.

A1= $ax_1C_1 + ay_1C_1$..Eq (1) at 220-233 nm,
A2= $ax_2C_2 + ay_2C_2$…Eq (2) at 233-243nm
By applying Cramer's rule to Eq 1 and 2
Where, A1 is area of sample solution at AUC 220-230 nm A2 is the area of sample solution at AUC 233-243 nm.

ax1 and ax2 are mean absorptivity of coefficient of Dapagliflozin Propanediol Monohydrate and ay1 and ay2 are mean absorptivity of coefficient of Lobeglitzone Sulphate .

C_1 and C_2 are concentration (gm/l) of Dapagliflozin Propanediol Monohydrate and Lobeglitazone Sulphate which is obtained using Cramer's Rule.

RESULT AND DISCUSSION

AREA UNDER CURVE METHOD

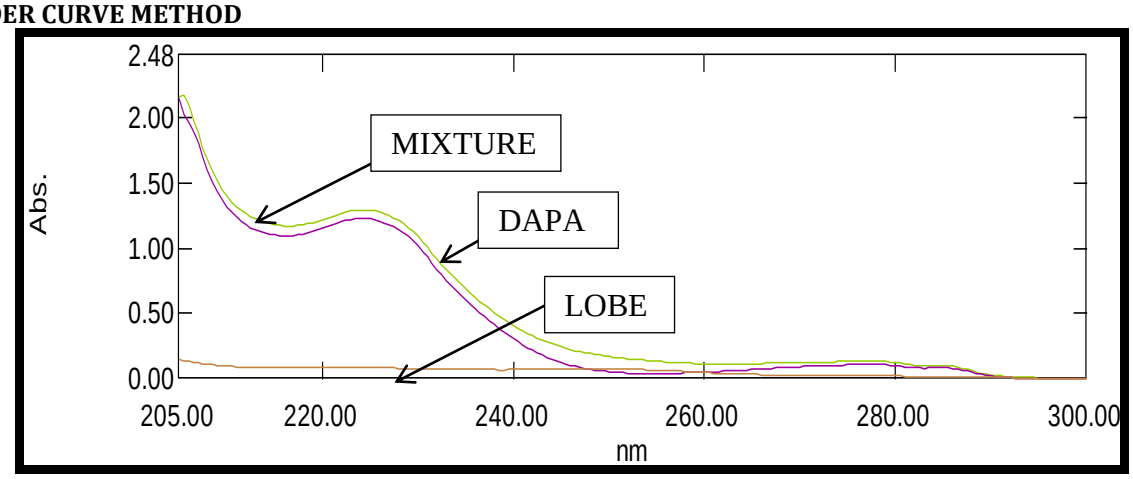

Figure 3: Overlain Spectra of LOBE (1.5 µg/ml), DAPA(30 µg/ml) and Mixture (1.5 + 30 µg/ml)

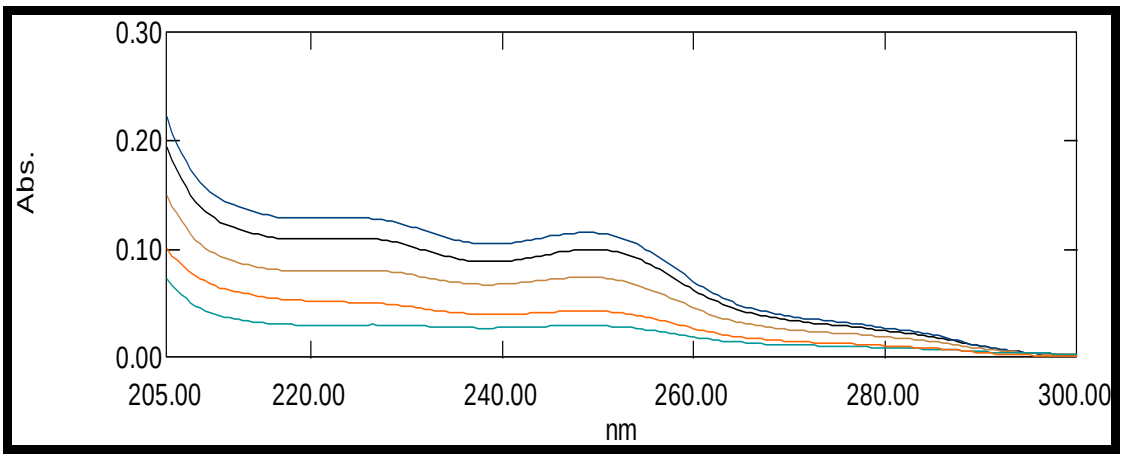

Figure 4: Zero Order Spectra of LOBE (0.5 -2.5 µg/ml)

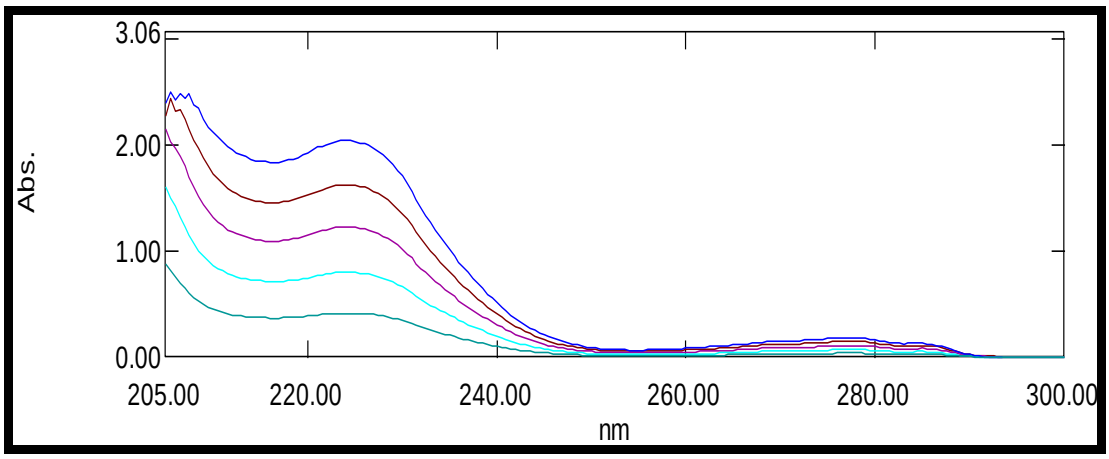

Figure 5: Zero Order Spectra of DAPA (10-50 µg/ml)

Selection of Wavelength for estimation of Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate

The standard solution of Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate were diluted with methanol individually to get the concentration of 1.5 µg/ ml and 30 µg/ ml respectively of Lobeglitazone Sulphate and Dapagliflozin Propanediol Monohydrate. The drugs were scanned in the UV range 200-400 nm. The areas were selected for Lobeglitazone Sulphate 233-243 nm and Dapagliflozin Propanediol Monohydrate 220-230 nm. As linearity of drugs are good in this selected wavelength.

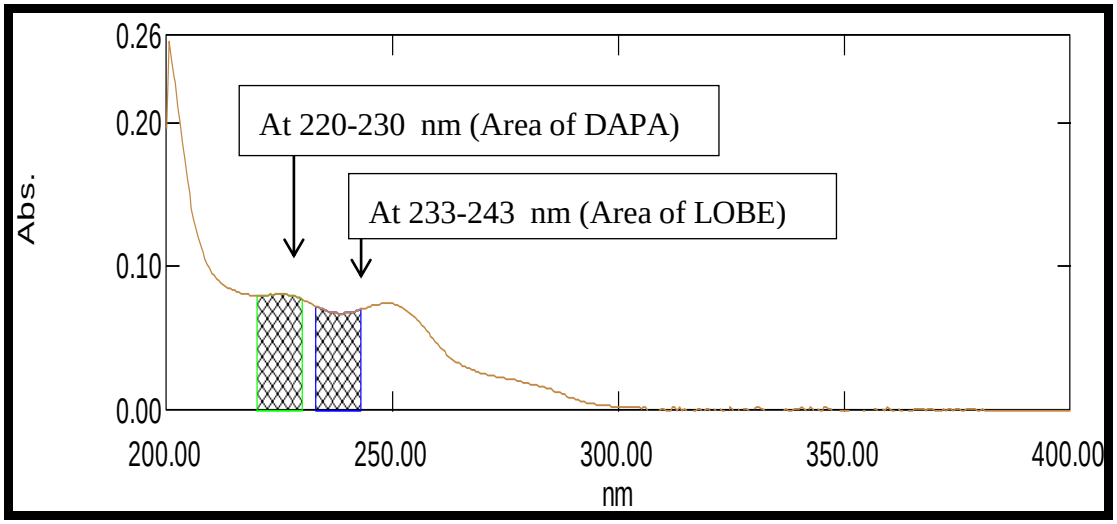

Figure 6: AUC Spectra of Lobeglitazone Sulphate 1.5 µg/ml in wavelength range 220-230 nm and 233-243 nm.

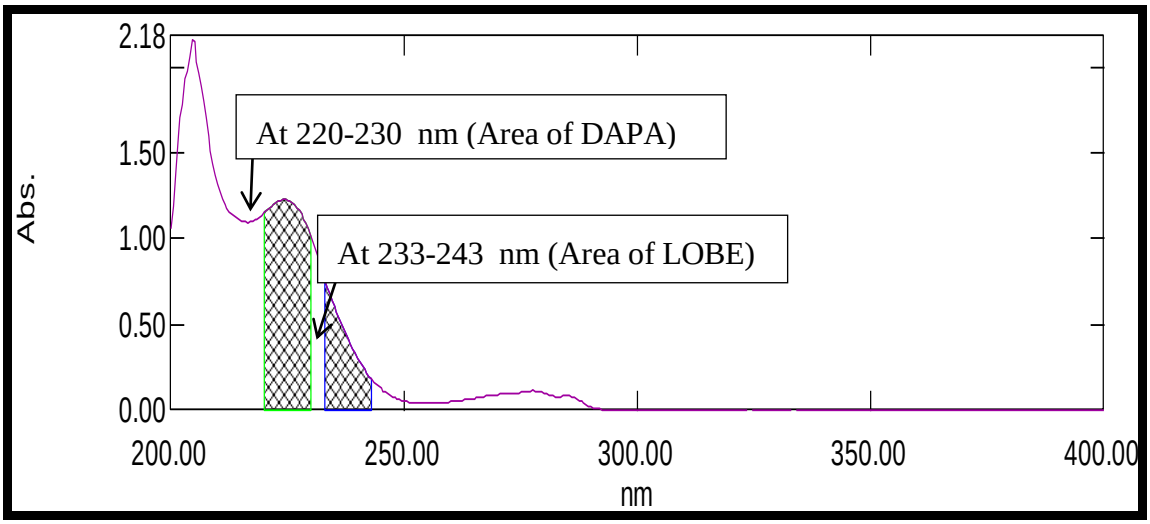

Figure 7: AUC Spectra of Dapagliflozin Propanediol Monohydrate 30 µg/ml in wavelength range 220-230 nm and 233-243 nm.

Validation of Proposed UV Method

1. LINEARITY

The linearity range for LOBE and DAPA was found to be in the range of 0.5-2.5 µg/ml and 10-50 µg/ml respectively. Linearity data for LOBE at 233-243 nm and DAPA at 220-230 nm.

Table No. 3: Linearity data for LOBE at 220-230 nm (Area of DAPA).

Sr.No.	Concentration (µg/ml)	Mean AUC ± S.D. (n=5)	%R.S.D.
1.	0.5	0.302 ± 0.0026	0.8820
2.	1	0.567 ± 0.0043	0.7767
3.	1.5	0.801 ± 0.0053	0.6645
4.	2	1.053 ± 0.0058	0.5501
5.	2.5	1.278 ± 0.0056	0.4452

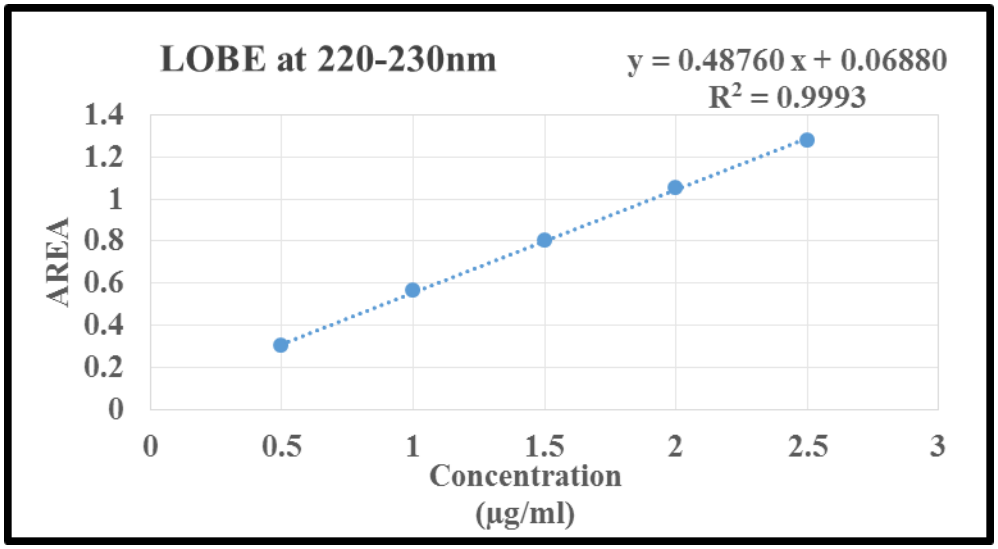

Figure 8: Calibration curve of LOBE at 220-230 nm (Area of DAPA)

Table No. 4: Linearity data for LOBE at 233-243 nm (Area of LOBE)

Sr.No.	Concentration (µg/ml)	Mean AUC ± S.D. (n=5)	%R.S.D.
1.	0.5	0.276 ± 0.0023	0.8323
2.	1	0.484 ± 0.0037	0.7729
3.	1.5	0.684 ± 0.0045	0.6574
4.	2	0.904 ± 0.0052	0.5788
5.	2.5	1.079 ± 0.0049	0.4597

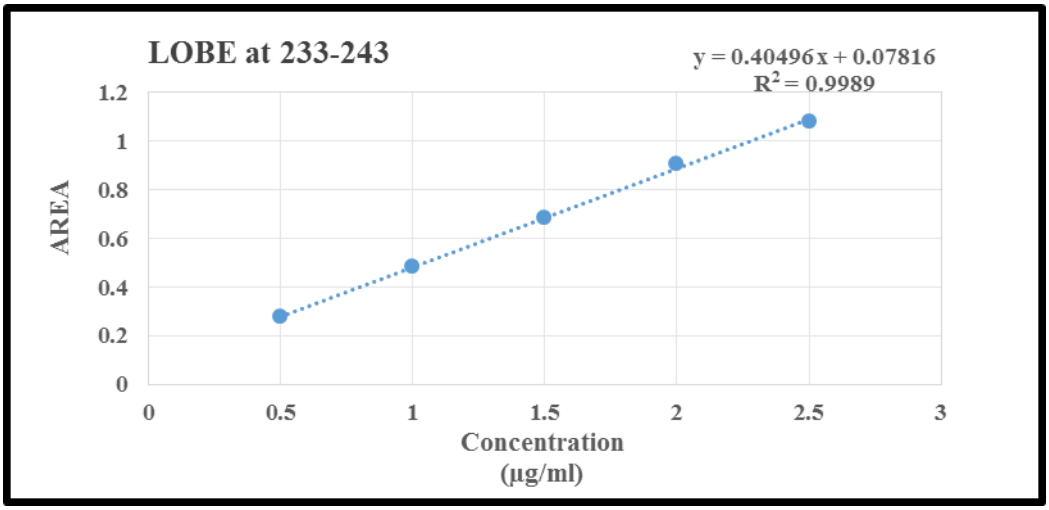

Figure 9: Calibration curve of LOBE at 233-243 nm (Area of LOBE)

Table No. 5: Linearity data for DAPA at 220-230 nm (Area of DAPA)

Sr.No.	Concentration (µg/ml)	Mean AUC ± S.D. (n=5)	%R.S.D.
1.	10	3.739 ± 0.0309	0.8266
2.	20	7.694 ± 0.0547	0.7137
3.	30	11.995 ± 0.0789	0.6585
4.	40	17.010 ± 0.0984	0.5743
5.	50	21.354 ± 0.0969	0.4558

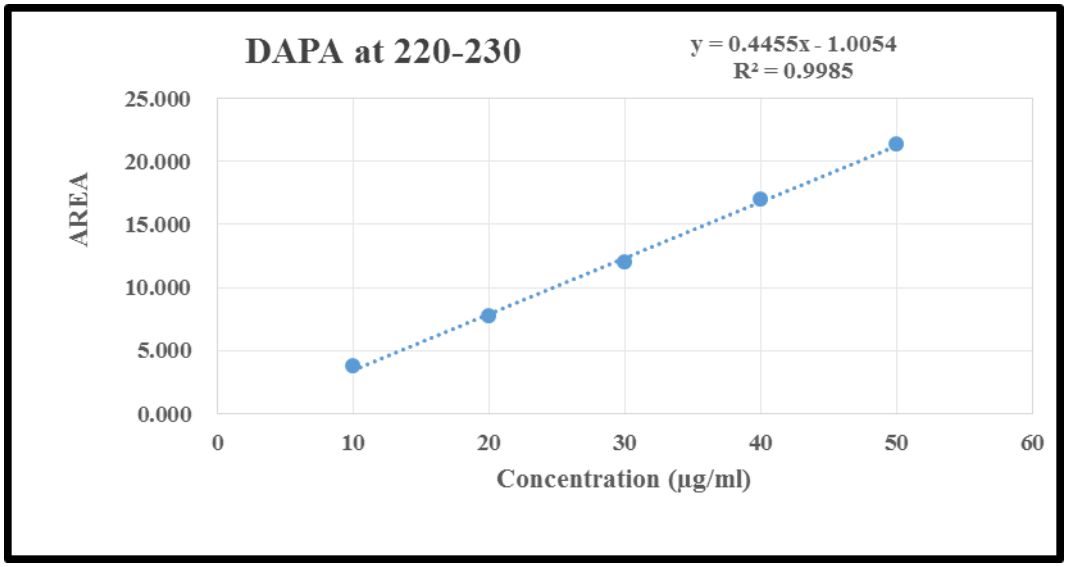

Figure 10: Calibration curve of DAPA at 220-230 nm (Area of DAPA)

Table No. 6: Linearity data for DAPA at 233-243 nm (Area of LOBE)

Sr.No.	Concentration (µg/ml)	Mean AUC ± S.D. (n=5)	%R.S.D.
1.	10	1.401 ± 0.0116	0.8316
2.	20	2.898 ± 0.0202	0.7024
3.	30	4.499 ± 0.0272	0.6063
4.	40	6.301 ± 0.0317	0.5029
5.	50	8.091 ± 0.0333	0.4108

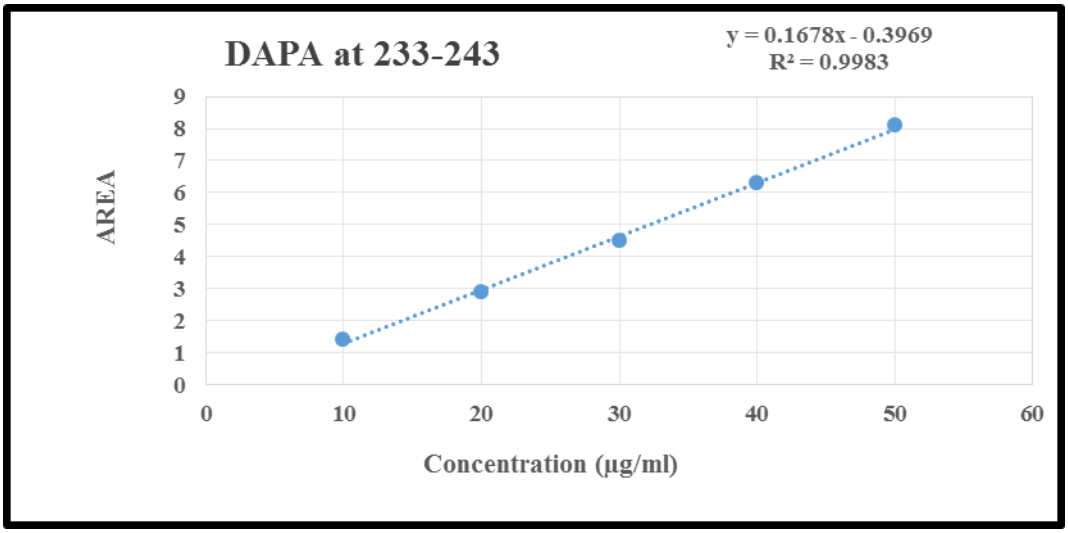

Figure 11: Calibration curve of DAPA at 233-243 nm (Area of LOBE)

2. PRECISION

a. Repeatability (n=6)

The data of Repeatability for DAPA at 220-230 nm (Area of DAPA) and LOBE at 233-243 nm (Area of LOBE) is shown in table.

Table No. 7: Repeatability of LOBE and DAPA.

Sr.No.	Drugs	Concentration(µg/ml)	Mean AUC ± S.D. (n=6)	% R.S.D.
1.	LOBE	1.5	0.6859 ± 0.0052	0.7645
2.	DAPA	30	12.01183 ± 0.0880	0.7326

b. Intraday Precision (n=3)

The data of Intraday Precision for DAPA at 220-230 nm (Area of DAPA) and LOBE at 233-243 nm (Area of LOBE) is shown in table.

Table No. 8: Intraday Precision LOBE at 233-243 nm.

Sr.No.	Concentration(µg/ml)	Mean AUC ± S.D. (n=6)	% R.S.D.
1.	1	0.4820 ± 0.0045	0.9507
2.	1.5	0.6931± 0.0055	0.8003
3.	2	0.9076 ± 0.0068	0.7499

Table No. 9: Intraday Precision DAPA at 220-230 nm.

Sr.No.	Concentration(µg/ml)	Mean AUC ± S.D. (n=6)	% R.S.D.
1.	20	7.723 ±0.0672	0.8712
2.	30	11.974 ±0.0955	0.7975
3.	40	17.139 ± 0.1210	0.7063

c. Interday Precision (n=3)

The data of Interday Precision for DAPA at 220-230 nm (Area of DAPA) and LOBE at 233-243 nm (Area of LOBE) is shown in table.

Table No. 10: Interday Precision LOBE at 233-243 nm.

Sr.No.	Concentration(µg/ml)	Mean AUC ± S.D. (n=6)	% R.S.D.
1.	1	0.4860 ± 0.0051	1.0691
2.	1.5	0.6956 ± 0.0066	0.9571
3.	2	0.9090 ± 0.0075	0.8305

Table No. 11: Interday Precision DAPA at 220-230 nm.

Sr.No.	Concentration(µg/ml)	Mean AUC ± S.D. (n=6)	% R.S.D.
1.	20	7.788 ± 0.0768	0.9866
2.	30	12.049 ± 0.1032	0.8565
3.	40	17.140 ± 0.1412	0.8239

3. ACCURACY

Accuracy of the proposed method was assured by performing recovery study from synthetic mixture at three levels by standard addition method. Percentage recovery for LOBE and DAPA at 233-243 nm and 220-230 nm were obtained respectively. The result is depicted in table. Recovery was found to be in the limit of 98-102%.

Table No. 12: Determination of Accuracy of LOBE and DAPA.

Drugs	Level	Amount of sample (µg/ml)	Amount of Std. spiked (µg/ml)	Total amount (µg/ml)	Amount of sample found (µg/ml)± S.D.	% Recovery ± S.D.
LOBE	0%	0.5	0	0.5	0.498 ± 0.0090	99.77 ± 1.8004
	80%	0.5	0.4	0.9	0.903 ± 0.0115	100.37 ± 1.2830
	100%	0.5	0.5	1	0.997 ± 0.0100	99.76 ± 1.0016
	120%	0.5	0.6	1.1	1.107 ± 0.1000	100.66 ± 9.0947
DAPA	0%	10	0	10	10.001 ± 0.0072	100.01 ± 0.0721
	80%	10	8	18	17.998 ± 0.0020	99.99 ± 0.0116
	100%	10	10	20	19.995 ± 0.0241	99.97 ± 0.1208
	120%	10	12	22	22.000±0.0112	100.00±0.0511

6.2.1.3 Analysis of Synthetic Mixture

Suitability of the method was tested by analyzing the synthetic mixture. The data of assay for tablet using Cramer's Rule at wavelength 220-230 nm and 233-243 nm. The outcomes are show in table.

Table No. 13: Determination of Assay of LOBE and DAPA.

Synthetic Mixture (Tablet)	Actual conc. %w/w)		Amt. obtained Mean ± S.D. (n=5) (%w/w)		LOBE% Purity ± S.D. (n=5)	DAPA % Purity ± S.D. (n=5)
	LOBE	DAPA	LOBE	DAPA	99.86 ± 0.7300	100.02 ± 0.0816
	1	20	0.99 ± 0.0073	20.00 ± 0.0163		

6.2.1.4 SUMMARY OF VALIDATION PARAMETER FOR PROPOSED METHOD.

Table No. 14: Summary of Area Under Curve Method.

Parameters	LOBE	DAPA
Wavelength (nm)	233-243 nm	220-230 nm
Linearity (µg/ml) (n=5)	0.5- 2.5 µg/ml	10-50 µg/ml
Regression Equation (y= mx+c)	y = 0.40496x + 0.07816	y = 0.4455x + 1.0054
Slope (m)	0.40496	0.4455
Intercept (c)	0.07816	1.0054
Regression Coefficient (R^2)	0.9989	0.9985
Correlation coefficient(r)	0.9994	0.9992
Repeatability (n=6) (%RSD)	0.7645	0.7326
Intraday precision (n=3)(%RSD)	0.9507-0.7499	0.8712- 0.7063
Interday precision (n=3) (%RSD)	1.0691-0.8305	0.9866-0.8239
LOD (µg/ml)	0.0129	0.4334
LOQ (µg/ml)	0.0393	1.3133
% Recovery (n=3)	99.76 - 100.66%	99.97 - 100.01%
% Assay ± S.D. (n=5)	99.86% ± 0.7300	100.02% ± 0.0816

CONCLUSION

Based on the results, obtained from the analysis of LOBE and DAPA in their synthetic mixture using Area Under Curve Method, it can be concluded that the method has linearity in the range of 0.5-2.5 µg/ml for LOBE and 10-50 µg/ml for DAPA. The regression coefficient (R^2) was found to be 0.9989 and 0.9985 for LOBE and DAPA correlation (r) was found to be 0.9994 and 0.9992 for LOBE and DAPA at 233-243 nm and 220-230 nm respectively. Limit of detection for LOBE and DAPA were found to be 0.0129 and 0.4334 µg/ml and Limit of Quantification for LOBE and DAPA were found to be 0.0393 and 1.3133 µg/ml respectively. Further % R.S.D. was found to be less than 2% for repeatability, intraday and interday study. Overall, the proposed AUC method is simple, accurate, precise, and suitable for routine quality control analysis of both drugs in combination formulations.

AKNOWLEDGEMENT

The authors are thankful to Akums Pharmaceutical Pvt. Ltd., Haridwar. And Exemed Pharmaceutical for providing the Lobeglitazone Sulfate and Dapagliflozin Propanediol Monohydrate API as a gift sample also thankful to the principal of ROFEL Shri G.M. Bilakhia College of Pharmacy, Vapi for providing necessary facilities, equipment and chemicals for doing research work.

REFERENCES

1. Drug Information, "Central Drugs Standard Control Organisation Directorate General Of Health Services Ministry of Health & Family Welfare, Government of lndia"
2. "Introduction to diabetes", October 2024, https://www.ncbi.nlm.nih.gov/books/NBK1671/
3. Drug Profile, ''LOBEGLITAZONE SULFATE'', October 2024, lobeglitazone sulfate | DrugBank Online
4. Drug Profile, "LOBEGLITAZONE SULFATE'', October 2024, Lobeglitazone sulfate | C24H26N4O9S2 | CID 15951505 - PubChem
5. Drug Profile, "DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE'', October 2024, www.ncbi.nlm.nih.gov/pmc/articles/PMC4267514/
6. Drug Profile, "DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE'', October 2024, https://go.drugbank.com/salts/DBSALT001101
7. Tripathi KD. Essentials of Medical Pharmacology: 7th Ed. Jaypee Brothers Medical Publishers: LTD, 2010; 270.
8. Sharma HL, and Sharma KK Principal of Pharmacology. 2nd Edn; New Delhi: Paras Medical Publisher: New Delhi, 2012; 637-639.
9. Beckett AH and Stenlake JB. Practical Pharmaceutical Chemistry, 4th Edn; Part II, CBS publisher and distributors: New Delhi, 2002; 279-300.
10. Chatwal GR, Anand SK. Instrumental Methods of Chemical Analysis; 5th Edn; Himalaya Publishing House: New Delhi, 2002; 2.167-2.172.
11. Shethi PD. HPLC-Quantitative Analysis of Pharmaceutical Formulations, vol.2, CBS publisher & distributors: New Delhi, 2007; 507-508.
12. Settele F. Handbook of Instrumental Techniques for Analytical Chemistry; Prentice hall book, 147-154.
13. ICH Harmonized Tripartite Guideline. Validation of Analytical Procedures: Textand Methodology Q2 (R1); International Conference on Harmonization, Geneva: Switzerland, 2005; 4-13.
14. Mante, Gajanan Vithoba, Krishna Radheshyam Gupta, and Atul Tryambakrao Hemke. "Estimation of dapagliflozin from its tablet formulation by UV-spectrophotometry." Pharm Methods, 2022; 8(2): 102-7.
15. Bhavyasri K, Navya SV, Sumakanth M and Swethasri R "Method Development and Validation for the estimation of Dapagliflozin in bulk and tablet dosage form by UV Visible Spectroscopy." Int. J. Recent Sct. Res., 2019; 10(8): 34419-34422.
16. Pathak S, "Development and Validation of UV-Spectroscopy Method for the determination of

Dapagliflozin." Bull. Env. Pharmacol. Life Sci., 2020; 9(12): 128- 133.
17. Harde M, Lakade S, et.al. "Ultraviolet-Spectrophotometric Method for Simultaneous Estimation of Dapagliflozin Propanediol and Metformin Hydrochloride." Int. Res. J. Pharm., 2019; 10(4): 90-94.
18. Minal Harde, Sameer Lakade, Valmik Gite, Vitthal Chopade, Anuja Khomne. 'Ultraviolet-spectrophotometric method for simultaneous estimation of dapagliflozin propanediol and metformin hydrochloride". Int. Res. J. Pharm, 2019; 10(4): 90-94.
19. Indian Pharmacopoeia, Government of India, Ministry of Health and Family Welfare, 9th Edn; Indian Pharmacopoeia Commission, Ghaziabad, 2022; II: 2476-2479.
20. The United States Pharmacopoeia: The National Formulary, 47th Edn; United State Pharmacopoeia Convention inc. Rockville, U.S.A, 2024.