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DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF SAXAGLIPTIN AND DAPAGLIFLOZIN IN BULK AND DOSAGE FORM

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Keywords:

Saxagliptin, Dapagliflozin, Method Development, Validation, UV spectrophotometric, Dosage forms

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ABSTRACT: Objective: In the present work, A Simple, rapid, sensitive, precise, and reproducible, specific UV spectrophotometric method for the determination of Saxagliptin (SAXA) and Dapagliflozin (DAPI) in bulk drug and pharmaceutical dosage form were developed and validated. **Methods:** A simple double beam UV spectrophotometric method has been developed and validated with different parameters such as linearity, precision, repeatability, the limit of detection (LOD), Limit of Quantification (LOQ), accuracy as per ICH guidelines. **Results:** UV-visible spectrophotometric method, measurement of absorption at a maximum wavelength in 10 ml methanol and volume make with water solvent system as reference SAXA and DAPI were found to be at 224 nm and 274 nm respectively. The drug obeyed the Beer's law and showed a good correlation. Beer's law was obeyed in the concentration range 2-10 µg/ml for Saxagliptin and 4-20 µg/ml for Dapagliflozin, respectively with a correlation coefficient was 0.999. The LOD and LOQ of Saxagliptin were found to be 0.040 µg/ml and 0.01230 µg/ml, Dapagliflozin was found to be 0.1230 µg/ml and 0.5460 µg/ml, respectively. Percentage assay of SAXA and DAPI in tablets. **Conclusion:** The proposed method is simple, precise, accurate, and reproducible can be used for routine analysis of Saxagliptin and Dapagliflozin in bulk and tablet dosage form.

INTRODUCTION: Type 2 diabetes mellitus (T2DM) is a chronic progressive metabolic disorder characterized by absolute or relative insulin deficiency [1]. The expected rise in the prevalence of diabetes is mainly due to increased life span because of better healthcare facilities and an increase in risk factors, especially physical inactivity and obesity due to a sedentary lifestyle.

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Pancreatic β-cell function gradually deteriorates in patients with T2DM, which is reflected in inadequate glycemic control in the long run [2]. Dapagliflozin **Fig. 1** is chemically known as (1s)-1, 5- anhydro- 1- C- [4- chloro- 3- [(4-ethoxyphenyl) methyl] phenyl]-D-glucitol.

It has a molecular formula of $C_{24}H_{33}ClO_8$ with a molecular weight of 408.98 g/mol [3]. Dapagliflozin is selective Sodium-Glucose Co Transporter 2 inhibitor (SGLT 2). It acts by reducing the reabsorption of glucose by the kidney, leading to excretion of excess glucose in the urine, thereby improving glycemic control in patients with type 2 diabetes mellitus [4]. Saxagliptin **Fig. 2** is chemically known as (1S, 3 S, 5S) - 2 [(2S) - 2 - amino - 2- (3 -

hydroxy- 1- adamantyl) acetyl] - 2 azabicyclo hexane-3-carbonitrile) with molecular formula of $C_{18}H_{25}N_3O_2$ and molecular weight of 315.41 g/mol [5]. Saxagliptin is a selective and potent dipeptidyl peptidase (DPP)-4 inhibitor, approved as an adjunct to diet and exercise to improve glycemic control in type 2 diabetes mellitus (T2DM). In patients with T2DM, once-daily administration of Saxagliptin before breakfast achieves sustained inhibition of plasma DPP-4 activity and reduction of postprandial hyperglycaemia, including after dinner, associated with an increase in plasma glucagon-like peptide-1 levels [6, 8]. A combination of Dapagliflozin and Saxagliptin is marketed as a Tablet (Qtern) containing 10 mg of Dapagliflozin, 5 mg of Saxagliptin. A combination of these two drugs is indicated for the treatment of type-2 Diabetes. Using Dapagliflozin leads to heavy glycosuria (glucose excretion in the urine), which can lead to weight loss and tiredness.

Literature survey revealed a variety of analytical methods *viz.* HPLC, LC-MS, and GC has been reported for estimation of Dapagliflozin and Saxagliptin individually or in combination with other drugs. The reported methods are Spectrohotometric [9-15], HPLC 16-37, LC-MS [38, 39,] and GC [40] methods are reported for the simultaneous estimation of DAPI and SAXA in combined pharmaceutical formulation.

UV Spectro-photometric methods have been reported for determination of SAXA and DAPI in single or in combination with other drugs [41, 42]. There is no evidence of the determination of the drug combination by UV Spectrophotometry. Thus, the present study is to develop simple, precise, and accurate UV Spectrophotometric methods for the quantification of Dapagliflozin and Saxagliptin in the combined dosage form.

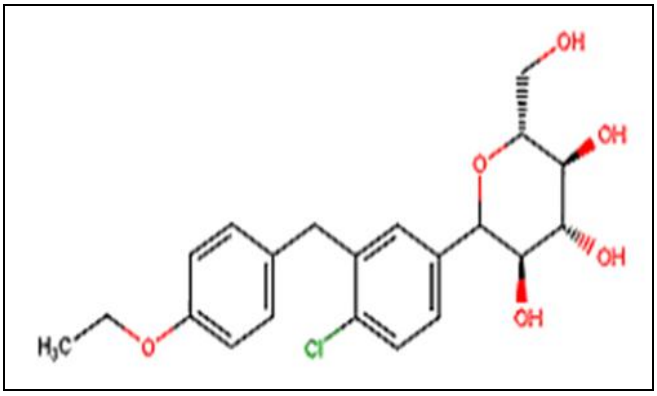

FIG. 1: STRUCTURE OF DAPAGLIFLOZIN

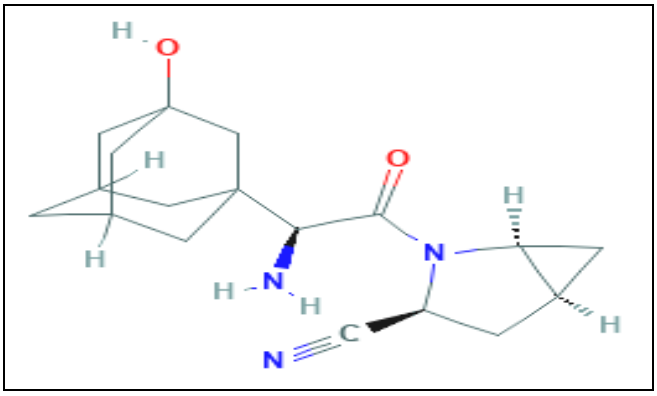

FIG. 2: STRUCTURE OF SAXAGLIPTIN

MATERIALS AND METHODS:

Instrument: A Shimadzu UV/Visible double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells was used in the present study for multi-component analysis.

Materials and Reagents: Dapagliflozin and Saxagliptin were obtained as gift samples from R. S. I. T. C Jalgaon. O-phosphoric acid was procured from Avantor Performance material India Ltd. Thane, Maharashtra, and Methanol were HPLC grade procured from Merck specialties Pvt. Ltd. Shiv Sager Estate 'A' Worli, Mumbai. The pharmaceutical preparations of a binary combination of Dapagliflozin and Saxagliptin that is (AstraZeneca AB) QTERN. The commercial formulation of Dapagliflozin and Saxagliptin is available in a ratio of (10:5 mg) in the tablet.

Preparation of Standard Stock Solution:

Saxagliptin Standard Stock Solution: (Stock I) An accurately weighed quantity, 10 mg of Saxagliptin was dissolved in methanol in a 10ml volumetric flask and volume made up to 10.0 ml to produce a solution of 1000 µg/ml **Fig. 3.**

Dapagliflozin Standard Stock Solution: (Stock II) An accurately weighed quantity, 20 mg of Dapagliflozin was dissolved in methanol in 10 ml volumetric flask and volume made up to 10.0 ml to produce a solution of 2000 µg/ml. **Fig. 4.**

Preparation of Stock Standard Combination Solution: (Stock III) [SAXA + DAPI] Accurately weight and transfer 10 mg Saxagliptin and Dapagliflozin 20 mg working standard into 10 ml volumetric flask as about diluent methanol

completely and make volume up to the mark with the same solvent to get 1000 & 2000 µg/ml standard (stock solution) and 15 min sonicates to dissolve it and remove the unwanted gas, further an aliquots portion of Saxagliptin and Dapagliflozin stock solution in ratio of 1:2 were mixed in a volumetric flask in 10 ml and volume was adjusted up to mark with mobile phase from the resulting solution 0.1 ml was transferred to 10 ml volumetric flask and the volume was made up to the mark with MeOH: Water (0.1% OPA), prepared in (40 ml MeOH: 60 ml Water (0.1% OPA) solvent. Result as shown as respectively**; Fig. 5.**

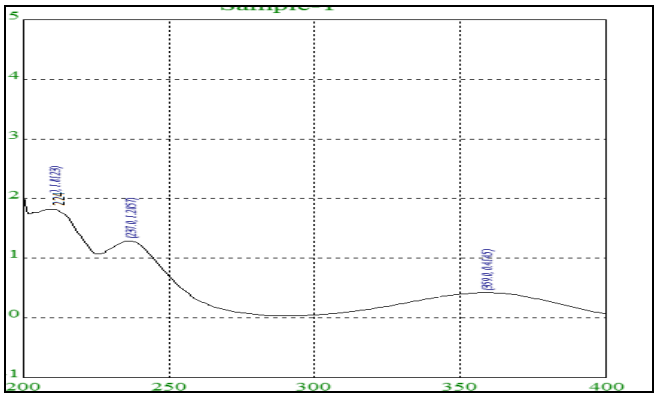

FIG. 3: UV SPECTRUM OF SAXAGLIPTIN

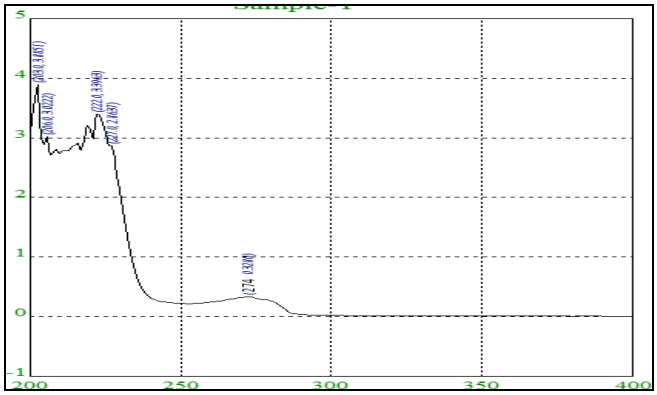

FIG. 4: UV SPECTRUM OF DAPAGLIFLOZIN

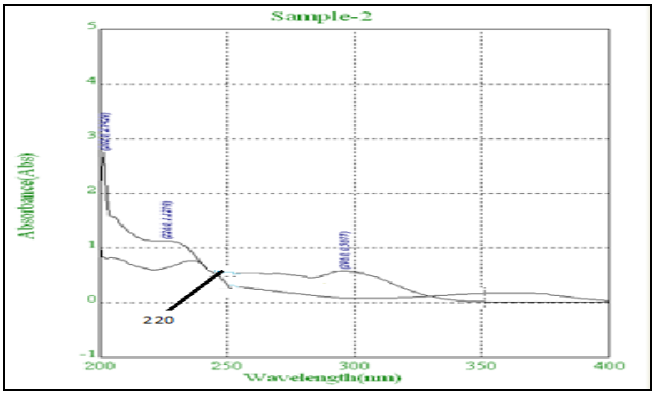

FIG. 5: ISO-ABSORPTIVE POINT OF SAXAGLIPTIN AND DAPAGLIFLOZIN

Assay Preparation for Marketed Formulation: For analysis of the tablet dosage form, 20 tablets were weighed individually, and their average weight was determined. After that, they were crushed to fine powders and powder equivalent to 0.70 mg Saxagliptin and Dapagliflozin into 10 ml volumetric flask and diluted with 10 ml methanol and sonicate to dissolve it completely and make volume up to the mark with diluent. The solutions were shaken vigorously for 10 min and filtered through 0.45 µm filters. Further, pipette 0.1ml of the above stock solution into a 10 ml volumetric flask and dilute up to the mark with diluents (10 µg/ml). The simple chromatogram of test Saxagliptin and Dapagliflozin showed in **Fig. 6**. The amounts of SAXA and DAPI per tablet were calculated by extrapolating the value of area from the calibration curve. The analysis procedure was repeated five times with tablet formulation Analysis of marketed formulation was also % label claim was found to be 99-101% satisfactory were concluded **Table 1.**

TABLE 2: ANALYSIS OF MARKETED FORMULATION

Assay	Drug	Amt. Found	% Label Claim	SD	% RSD
UV Method	SAXA	9.92	99.20	0.03	0.11
	DAPI	39.78	99.45	0.16	0.75
	SAXA	9.68	99.00	0.001	0.37
	DAPI	39.56	98.90	0.64	0.61

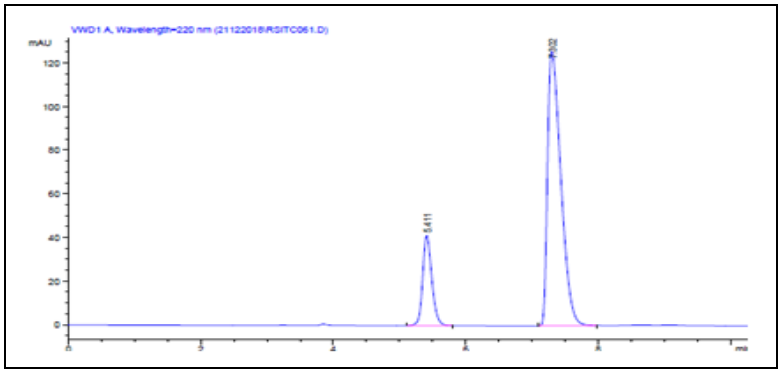

FIG. 6: CHROMATOGRAM FOR MARKETED FORMULATION

Method Validation: [43-47] The proposed methods were validated in accordance to ICHQ2 (R1) guidelines for linearity, precision, accuracy, the limit of detection, limit of quantification.

RESULTS:

Linearity and Range: The mobile phase was allowed to equilibrate with the stationary phase until OPA by baseline was obtained. From the freshly prepared standard stock solution, pipette out 10 mg Saxagliptin and 20 mg Dapagliflozin in 10 ml of volumetric flask and diluted with the mobile phase. From it 0.1, 0.2, 0.3, 0.4, and 0.5 of solution were pipette out in 10 ml volumetric flask and volume were made up to 10 ml with mobile phase to get final concentration 10, 20, 30, 40, and 50 µg/ml of Saxagliptin and 20, 40, 60, 80, and 100 µg/ml of Dapagliflozin **Table 3 and 4.**

The respective linear equation for Saxagliptin was y = 0.098 x + 0.006 and Dapagliflozin equation y = 0.038 x + 0.104 where x is the concentration and y is area of peak. The correlation coefficient was 0.9975 and 0.9984. The calibration curve of SAXA and DAPI is depicted in **Fig. 7 and 8.**

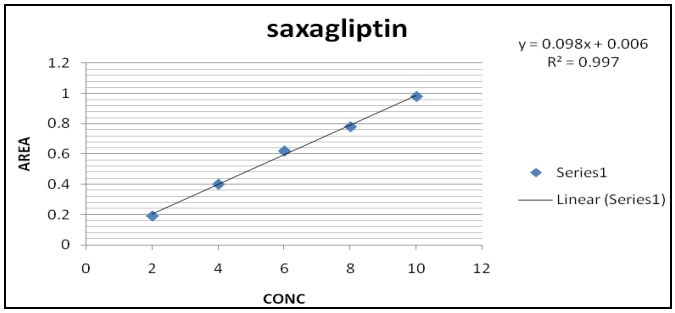

FIG. 7: CALIBRATION CURVE OF SAXAGLIPTIN

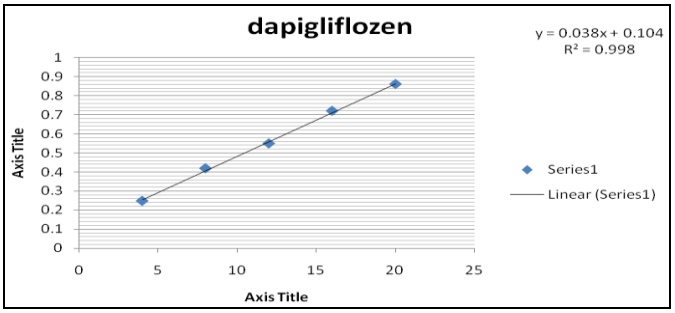

FIG. 8: CALIBRATION CURVE OF DAPAGLIFLOZIN

TABLE 3: LINEARITY DATA FOR SAXAGLIPTIN

Conc. µg/ml	Peak Area(µv. sec)		Average peaka (µv.sec)	S. D. of Peak Area	% RSD of Peak Area
	1	2			
2	0.1938	0.1944	0.19	0.0004	0.22
4	0.4026	0.4035	0.40	0.0006	0.16
6	0.6259	0.6265	0.63	0.0004	0.07
8	0.7801	0.79	0.79	0.0070	0.89
10	0.98	0.9809	0.98	0.0006	0.06
Equation			y = 0.098 x + 0.006		
R^2			0.997		

TABLE 4: LINEARITY DATA FOR DAPAGLIFLOZIN

Conc. µg/ml	Peak area (µv.sec)		Average Peak Area (µv.sec)	S.D. of Peak Area	% RSD of Peak Area
	1	2			
8	0.2569	0.2511	0.25	0.004	1.61
16	0.425	0.4257	0.43	0.0005	0.12
24	0.5512	0.5499	0.55	0.001	0.17
32	0.7268	0.719	0.72	0.01	0.76
40	0.8612	0.8587	0.86	0.002	0.21
Equation			y = 0.038 x + 0.104		
R^2			0.998		

Accuracy: Recovery studies were performed to validate the accuracy of the developed method. To pre-analyzed tablet solution, a definite concentration of the standard drug (80%, 100% and 120%) was added, and then its recovery was analyzed **Table 5**. The accuracy of UV spectroscopic method was ascertained by recovery studies performed at different levels of concentrations (80%, 100%, and 120%). The % recovery was found to be within 98-102%. Statistical validation of recovery studies shown in **Table 6.**

TABLE 5: RESULT OF RECOVERY DATA FOR SAXA AND DAPI

Drug	Level (%)	Amt. Taken (ug/ml	Amt. Added (ug/ml	Absorbance Mean*± S.D.	Amt. Recovered Mean *±S.D.	%Recovery Mean*± S. D.
	80%	2	1.6	3.62± 0.01	2.02± 0.01	101.17± 0.65
SAXA	100**%**	2	6.4	4.06± 0.02	2.06± 0.02	102.45 ±1.94
	120**%**	2	2.4	4.36± 0.04	1.96 ±0.04	97.84± 1.90
	80**%**	8	6.4	14.39± 0.11	6.39 ±0.11	99.89± 1..70
DAPI	100**%**	8	8	15.96± 0.06	7.96 ±0.06	99.44± 0.79
	120**%**	8	9.6	17.53± 0.14	9.53 ±0.14	99.30± 1.44

Mean of each 3 reading for UV method

TABLE 6: STATISTICAL VALIDATION OF RECOVERY STUDIES SAXA AND DAPI

Level of Recovery (%)	Drug	% RSD	Standard Deviation*	Mean % Recovery
80%	SAXA	0.64	0.65	101.17
	DAPI	1.71	1.70	99.89
100%	SAXA	1.90	1.94	102.45
	DAPI	0.80	0.79	99.44
120%	SAXA	1.45	1.44	99.30
	DAPI	1.94	1.90	97.84

*Denotes average of three determinations for UV method

System Suitability Parameters: Repeatability studies on UV method for Saxagliptin and Dapagliflozin was found to be, the % RSD was less than 2%, which shows a high percentage amount found in between 98% to 101% indicates the analytical method that concluded **Table 7.**

TABLE 7: REPEATABILITY STUDIES FOR SAXA AND DAPI

Method	Conc. of SAXA & DAPI (mg/ml)	Peak Area	Amount Found (mg)	% Amount Found
UV method for SAXA	4	0.411	4.13	103.94
	4	0.4097	4.11	101.25
	4	0.4082	4.10	102.60
	4	0.4026	4.04	101.17
	4	0.4011	4.03	100.79
		Mean	4.08	101.95
		SD	0.04	1.31
		%RSD	1.09	1.28
UV method for DAPI	16	0.4012	15.64	97.76
	16	0.4036	15.76	98.50
	16	0.4089	16.04	101.63
	16	0.4025	15.71	98.19
	16	0.4011	15.63	97.73
		Mean	15.76	98.76
		SD	0.17	1.63
		%RSD	1.06	1.66

Precision: Precision was studied to find out intra and inter-day variations in the test method of Saxagliptin and Dapagliflozin. Intra-day precision was determined by analyzing three concentrations in three replicate measurements of within the linearity range of drugs on three different times in the same day. Inter-day precision was conducted during routine operation of the system over a period of 3 consecutive days. Intraday and Inter day Precision studies on UV method for Saxagliptin and Dapagliflozin, which shows the high precision % amount in between 98% to 101% indicates to analytical method that concluded **Table 8.**

TABLE 8: INTRADAY AND INTER DAY PRECISION FOR SAXA AND DAPI

Drug	Conc (µg/ml)	Intraday Precision		Interday Precision	
		Mean ± SD	%Amt Found	Mean ± SD	% Amt Found
SAXA	4	0.414 ±0.0025	0.60	0.412 ± 0.002	0.60
	6	0.622 ±0.0049	0.80	0.619 ±0.004	1.01
	8	0.772± 0.0047	0.61	0.762 ± 0.004	0.37
DAPA	16	0.4139± 0.002	0.60	0.4099 ± 0.001	0.07
	24	0.5550± 0.006	1.01	0.540 ± 0.0045	0.23
	32	0.7177± 0.003	0.37	0.7067 ± 0.0012	0.56

*Mean of each 3 reading for UV method

Limit of Detection (LOD) and Limit of Quantification (LOQ): LOD is the lowest amount of analyte in a sample that can be detected but not necessarily quantify under the stated experimental conditions. LOQ is the lowest concentration of an analyte in a sample that can be determined with acceptable precision and accuracy under stated experimental conditions. The LOD and LOQ of Saxagliptin were found to be 0.040 µg/ml and 0.01230 µg/ml, Dapagliflozin were found to be 0.1230 µg/ml and 0.5460 µg/ml, respectively.

DISCUSSION: The proposed methods for simultaneous estimation of SAXA and DAPI in tablet dosage forms were found to be simple, accurate, economical, and rapid. The method was validated as per the ICH Q2 (R1) guidelines. Standard calibration yielded a correlation coefficient (r2) of 0.999 for both Saxagliptin and Dapagliflozin at all the selected wavelengths. The values of % RSD are within the prescribed limit of 2%, showing high precision of methods, and recovery was close to 100% for both drugs. Results of the analysis of pharmaceutical formulations reveal that the proposed method is suitable for their simultaneous determination with virtual interference of any additive present in pharmaceutical formulations. Hence, the above methods can be applied successfully for simultaneous estimation of Saxagliptin and Dapagliflozin in formulations.

CONCLUSION: The developed UV spectrophotometric method in that linearity, precision, range, and robustness were found to be more accurate, precise, and reproducible. The methods were found to be simple and time-saving. All proposed methods could be applied for routine analysis in quality control laboratories.

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CONFLICTS OF INTEREST: Authors have no conflicts of interest to declare.

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