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Method Development, Validation and Forced Degradation Studies for the Determination of Teneligliptin and Dapagliflozin in Pure and combined Dosage Form Using Simultaneous Estimation Method by UV-Spectroscopy.

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ABSTRACT:
Stability indicating UV -spectrophotometric method is simple, an accurate and economic, precise and reproducible method has been used for the estimation of Teneligliptin (TENE) and dapagliflozin (DAPA) in bulk and tablets dosage form in present work. Mobile Phase ratio used for working standard is Methanol: Water (70:30). The wavelength selected for the absorption correction method was (TENE) 246 nm and (DAPA) 222 nm. The linearity range of (TENE)4-20µg/ml and (DAPA) 2-10µg/ml proved that it obeyed Beer's Law and the correlation coefficient (r2) was found to be TENE0.999 at 246 nm and DAPA 0.9972 at 222nm. The drug was subjected to acid, alkali, peroxide, UV and Heat degradation. The force degradation studies of Teneligliptin and Dapagliflozin was done on Stress degradation by hydrolysis under alkaline condition by using 0.1N NAOH was found to be TENE 11.60% and DAPA 9.94%. Stress degradation by hydrolysis under acidic condition by using 0.1N HCl and product degradation was found to be TENE 10.38% and DAPA 5.78%. Oxidative degradation was done by using hydrogen peroxide using 6% and product degradation was found to be TENE 16.27% and DAPA 11.21%. Stress Degradation study under by Photolytic UV-light by using long wavelength 294nm was found to be TENE 18.91% and DAPA 9.40%and Stress Degradation study under thermal by using 40^0C was found to be at TENE 19.52% and DAPA 14.82% Forced degradation studies of drug reveal good stability under the chosen experimental conditions.

KEYWORDS: Antidiabetic, Forced Degradation, UV Spectroscopy, Teneligliptin, Dapagliflozin, Simultaneous method.

I. INTRODUCTION:

Analytical chemistry is a field of chemistry concerned with the identification of substances and mixtures (qualitative analysis) or the determination of constituent quantities (quantitative analysis). UV-Spectroscopy is a technology used in the pharmaceutical sector nowadays. [3-15]

Teneligliptin hydrobromide hydrate (TENE) is (2S,4S)- 4-[4-(3-Methyl-1-phenyl-1H-pyrazol-5-yl) piperazin-1-yl]-[4-(3-Methyl-1-phenyl-1H-pyrazol-5-yl) piperazin-1-yl]- [4 An oral dipeptidyl peptidase inhibitor (DPP-4) is pyrrolidin-2-yl (1,3-thiazolidin-3-yl) methanone hemipenta hydrobromide hydrate. DPP-4 inhibits the incretin hormones (glucagon-like peptide-1; GLP-1 and glucose-dependent insulinotropic polypeptide; GIP) that increase insulin production. It is prescribed to treat type 2 diabetic mellitus (T2DM). (Figure.1) Teneligliptina peptidomimetic and a biguanide, is an effective treatment for type 2 diabetes mellitus. [2-16]

A review of the literature indicates that numerous approaches for estimating teneligliptin in pharmaceutical dosage form alone dose form utilising chromatographic methods have been documented. Furthermore, only one spectrophotometric approach for simultaneous measurement of teneligliptin in solid dose form has been published. As a result, the current study proposes a straightforward, accurate, and cost-effective UV-Spectrophotometric approach for determining Teneligliptin hydrobromide hydrate in bulk and tablet dosage form. The suggested procedures were optimised and validated in accordance with ICH recommendations.[15-22]

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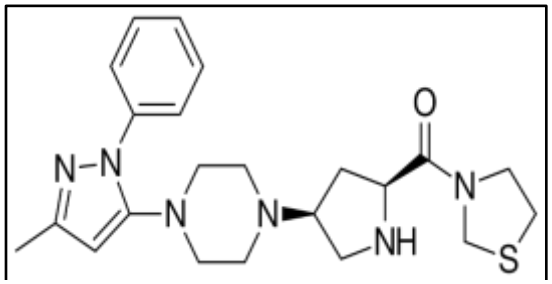

Figure.1 Chemical Structure of Teneligliptin (TEN)

Dapagliflozin is a highly selective, orally active, and reversible inhibitor of the human Sodium-Glucose Co-Transporter 2 (SGLT2), which is responsible for renal glucose reabsorption. It improves glycaemic control in Type 2 Diabetes Mellitus patients by blocking the Sodium-Glucose Co-Transporter 2 and decreasing glucose reabsorption. The mechanism of action of dapagliflozin is both complementary and distinct from that of currently available antidiabetic medicines, since it involves the direct and insulin-independent clearance of glucose by the kidney. Dapagliflozin primarily inhibits SGLT2 rather than SGLT. [1-3]

It is chemically known as (1s)-1, 5-anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl) methyl] phenyl]-D-glucitol. It has a molecular formula C24H33ClO8 with molecular weight 408.98.(Figure.2)Dapagliflozin is a white to half white crystalline powder which is soluble in water, ethanol, methanol and dimethyl formamide. [22-21]

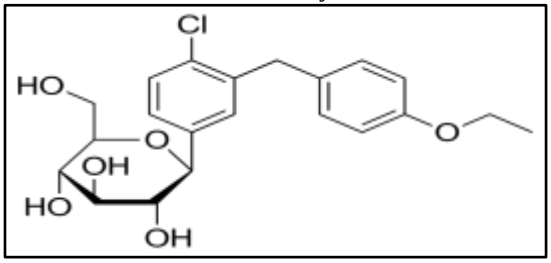

Figure.2 Chemical Structure of Dapagliflozin (DAPA)

II. MATERIALS AND METHODS:

2.1 Materials:

Teneligliptin gift sample procured from Precise laboratories limited, Navi Mumbai and Dapagliflozin gift sample procured from Morepen laboratories limited Dist. Solan Himachal Pradesh.

2.2 Chemicals and reagents:

Methanol (UV-Spectroscopy grade) obtained from research-lab fine chemical Islampur, Mumbai. Sodium Hydroxide (NaOH) obtained from Research-lab fine chemicals Islampur, Mumbai. Hydrochloric acid (HCL) obtained from Research-lab fine chemicals Islampur, Mumbai. Hydrogen Peroxide (H_2O_2) obtained from Research-lab fine chemicals Islampur, Mumbai.

2.3 Instruments:

A shimadzu 1800 UV/VIS double beam spectrophotometer with 1cm matched quartz cells was used for all spectral measurements. Single Pan Electronic balance (CONTECH, CA 223, India) was used for weighing purpose. Sonication of the solutions was carried out using an Ultrasonic Cleaning Bath (Spectra lab UCB 40, India). Calibrated volumetric glassware (Borosil®) was used for the validation study. UV cabinate was used Ececoptolimited, Mumbai.

2.4 Method Development:

Selection of Solvent (mobile Phase):

In order to select suitable solvent for determination of TEN and DAPA, various solvents were selected for the solubility studies and it was found that TEN and DAPA was freely soluble in the methanol, ethanol, acetonitrile and slightly soluble in water. In the present investigation, methanol was used as primary solvent and distilled water was used as secondary solvent. final ratio of solvent is Methanol: Water (70:30) {++ - freely Soluble And + - Slightly Soluble} (Table.1)

Table.1 Solubility of Drugs

Solvent	Teneligliptin (TEN)	Dapagliflozin (DAPA)
Methanol	++	++
Ethanol	++	++
water	+	+

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2.4.1 Preparation of stock solution:

10 mg each of Teneligliptin and Dapagliflozin were weighed separately and transferred in two different 100 ml volumetric flasks. Both the drugs were dissolved in 100 ml of Methanol: water (70:30) by vigorous shaking and then volume was made up to the mark with methanol to obtain final concentration of 100 µg/ml of each component.

2.4.2 Determination of analytical wavelength (λ_{max}):

Using appropriate dilutions of the standard stock solution is TENE (20µg/ml) and DAPA (10µg/ml), the solutions were scanned separately in the wavelength region of 400-200.It was observed that both the drugs showed considerable absorbance at 246nm for TENE and 222nm for DAPA was selected as the wavelength for detection. Mobile Phase as blank. (Figure No. 3.4)

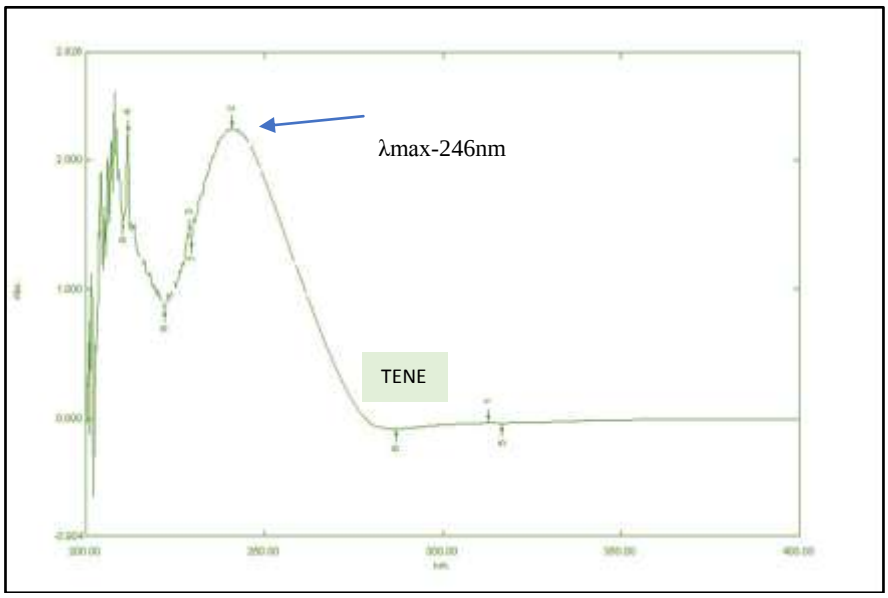

Figure.3 Teneligliptin λmax

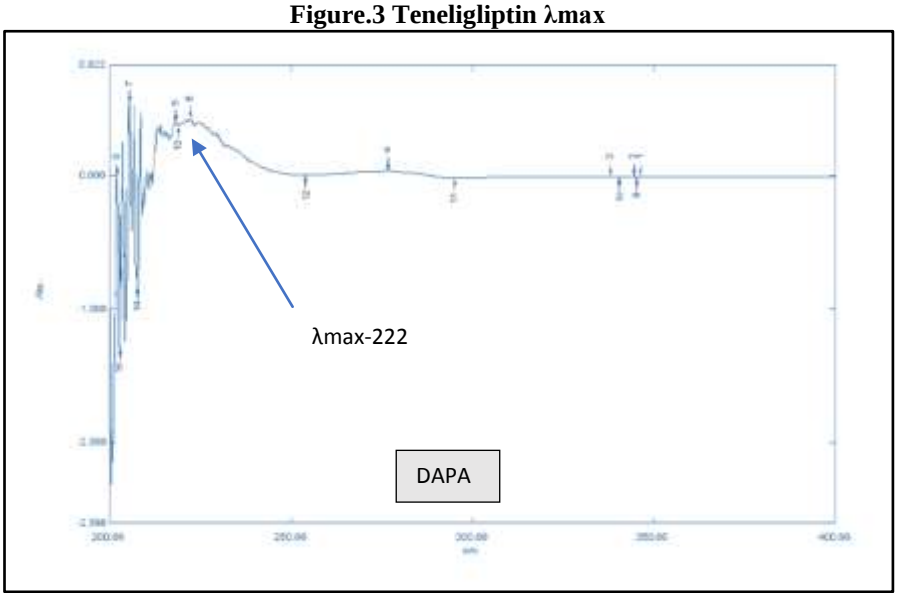

Figure.4 Dapagliflozin λmax

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2.5 Validation

2.5.1 Preparation of calibration curve:

Calibration curve for TENE consists of different concentrations of standard TENE solution ranging from 4-20 µg/ml. The solutions were prepared by pipetting out 0.4, 0.8, 1.2, 1.6 and 2 ml of the working standard solution of TENE (100µg/ml) into series of 10 ml volumetric flasks and the volume was adjusted to mark with mobile phase. As well as Calibration curve for DAPA consists of different concentrations of standard DAPA solution ranging from 2-10 µg/ml. The solutions were prepared by pipetting out 0.2, 0.4, 0.6, 0.8 and 1 ml of the working standard solution of TENE (100µg/ml) into series of 10 ml volumetric flasks and the volume was adjusted to mark with mobile phase The absorbance of the solutions was measured at 256nm for TENE and 222nm for DAPA against mobile phase as a blank. Calibration curve was plotted at both wavelengths and two equations were formed using the absorptivity**.**

2.5.2 Linearity: (Lamberts-Beers law)

This is the method ability to obtain results which are either directly, or after mathematical transformation proportional to the concentration of the analyte within a given range. The linearity of the method was demonstrated over the concentration range of DAPA 2-10 µg/ml of the target concentration. Aliquots of 2, 4, 6, 8 and 10 µg/ mL and for TENE 4-20 µg/mlAliquots 4, 8, 12, 16 and 20 in 10 ml volumetric flask prepared from Stock solution (100 µg/ml) adjust the final markup volume by mobile phase. Calibration curve was plotted and presented by Concentration against Absorbance. (n=5) (Table No. 2)

Table.2 Linearity of Teneligliptin and dapagliflozin

Sr No.	Teneligliptin		Dapagliflozin	
	Concentration	Absorbance at 246nm	Concentration	Absorbance at 222nm
1	4	0.113	2	0.095
2	8	0.229	4	0.205
3	12	0.355	6	0.273
4	16	0.468	8	0.373
5	20	0.611	10	0.455
Standard Deviation (SD)		0.19541	0.14068	
Slope		0.03088	0.0444	

2.5.3 Sandell's Sensitivity: (µg/cm2/0.001 absorbance units)

It can be calculated as,

$$\textbf{Sandel}'\textbf{ssensitivity} = \frac{\textbf{Concentration}}{\textbf{Absorbance}} \textbf{ X 0.001 ---(1)}$$

Were,

C= Concentration of drug,

A= Absorbance of drug. (Table.10)

2.6 Precision (Repeatability):

Aliquots of 2ml of working standard solution of TENE (100 µg/ml) were transferred to a 10 ml volumetric flask. Aliquots of 1ml of working standard solution of DAPA (100 µg/ml) were respectively transferred to a 10 ml volumetric flask. The volume was adjusted up to mark with mobile phase to get 20µg/ml solution of TENE and 10µg/ml solution of DAPA. The absorbance of solution was measured spectrophotometry three times and % RSD was calculated. (Table.8)

2.6.1Intraday precision:

Aliquots of 1.2, 1.6 and 2 ml of working standard solution of TENE (100 µg/ml) were transferred to a series of 10 ml volumetric flask. Aliquots of 0.6, 0.8 and 1 ml of working standard solution of METO (100 µg/ml) were respectively transferred to the same series of 10 ml volumetric flask. The volume was adjusted up to mark with mobile phase to get 12, 16, and 20µg/ml solution of TENE and 6, 8 and 10µg/ml solution of DAPA. Solutions was analysed on the same day spectrophotometry and % RSD was calculated. (Table.3)

2.6.1 Interday Precision:

Aliquots of 1.2, 1.6 and 2 ml of working standard solution of TENE (100 µg/ml) were transferred to a series of 10 ml volumetric flask. Aliquots of 0.6, 0.8 and 1 ml of working standard solution of METO (100 µg/ml) were respectively

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transferred to the same series of 10 ml volumetric flask. The volume was adjusted up to mark with mobile phase to get 12, 16, and 20µg/ml solution of TENE and 6, 8 and 10µg/ml solution of DAPA. Solutions was analysed on the after 24 hr spectrophotometry and % RSD was calculated. (Table.4)

2.7 Limit of Detection (LOD):

The LOD is estimated from the set of 5 calibration curves used to determine method linearity.
The LOD may be calculated as,

$$\textbf{Limit of Detection(LOD)} = \textbf{3.3X}\frac{\textbf{SD}}{\textbf{Slope}}$$

Were,
SD = the standard deviation of Y- intercept of 5 calibration curves.
Slope = the mean slope of the 5 calibration curves. (Table.5)

2.8 Limit of Quantification (LOQ):

The LOQ is estimated from the set of 5 calibration curves used to determine method linearity.
The LOQ may be calculated as,

$$\textbf{Limit of Quantification(LOQ)} = \textbf{10 X}\frac{\textbf{SD}}{\textbf{Slope}}$$

Were,
SD = the standard deviation of Y- intercept of 5 calibration curves.
Slope = the mean slope of the 5 calibration curves. (Table.5)

2.9 Simultaneous Estimation Method(Vierordt's method):

Simultaneous estimation of drug is very important method as the new combined formulation approved in market. The main aim behind the quantitative estimation is to ensure that whether a particular drug contains the same amount of drug as mentioned because if the dose given will be high then it will cause over dosage side effects and if it is less, then the patient will not get the required dose.When combination of drug contains two drug or more than two drugs in combined dosage form then the simultaneous equation or Vierordt's method were applied to that formulation. From the overlain spectra of TENE (10µg/ml) and DAPA (10µg/ml), two wavelengths i.e., 246nm as λmax of TENE and 222nm as λmax of TENE were selected as the working wavelength, at which both drugs showed absorbance for each other. The absorptivity of these two drugs was determined at 246nmTENE and 222nm DAPA. A set of two simultaneous equation were formed using absorptivity values as given in equation (1) and (2), at selected wavelengths. The concentrations of two drugs in formulation were calculated using following two simultaneous equations.

$$\textbf{Cy} = \frac{\textbf{A1 ax2} - \textbf{A2 ax1}}{\textbf{ax2 ay1} - \textbf{ax1 ay2}}$$

$$\textbf{Cx} = \frac{\textbf{A2 ay1} - \textbf{A1 ay2}}{\textbf{ax2 ay1} - \textbf{ax 1ay2}}$$

Cx= (A2ay1-A1ay2)/ (ax2ay1-ax1ay2) ------(1)
Cy= (A1ax2-A2ax1)/ (ax2ay1-ax1ay2) ------(2)

Were,
Cx and Cy are concentrations of TENE and DAPA (µg/ml) respectively in known sample solution. A1 and A2 areabsorbance of sample solutions at 246nm and 222nm respectively.
ax1 and ax2 are absorptivity of TENE at 246nm and 222nm.
ay1 and ay2 are absorptivity of DAPA at 246nm and 222nm.
The concentration of Cx and Cy in formulation can be obtained by solving equation (1) and (2). Validity of the equation was checked by using mixed standard of pure drug sample of two drugs, measuring their absorbance at respective wavelength and calculating concentration of two components. (Table.6)

2.10 Analysis of marketed formulation:

Five tablets of brand name Zita-D were used. A quantity of tablet powder equivalent to Teneligliptin (20mg) and Dapagliflozin (10mg) was transferred to 10ml volumetric flask and dissolved in Solvent. The aliquot portion of filtrate was further diluted to get Pregabalin (20µg/ml) and Amitriptyline Hydrochloride (10µg/ml). Measure under 246nm and 222nm respectively. (Table.11)

2.11 Accuracy:(% Recovery)

To check the accuracy of the developed method, recovery studies were carried out as per ICH guidelines. To the analysed solutions, standard solutions of all the two drugs were added equivalent to 50, 100 and 150% of its drug content. Recovery studies were carried by doing replicate studies.The accuracy of the method was determined by calculating recovery of TENE and DAPA by the standard addition method. Aliquots of 2 ml of working sample (Tablet Stock Solution) of TENE (100 µg/ml) were added at 50, 100 and 150 % level to pre-analysed sample solutions transferred to a series of 10 ml volumetric flask. The volume was

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adjusted up to mark with Mobile Phase to get20µg/ml solution of TENE.Then adding standard (Pure Drug Solution) solution by taken % of sample.

Aliquots of 1 ml of working (Tablet Stock Solution) solution of DAPA (100 µg/ml) were added at 50, 100 and 150 % level to pre-analysed transferred to a series of 10 ml volumetric flask. The volume was adjusted up to mark with mobile phase to get 10µg/ml solution of DAPA. Then adding standard (Pure Drug Solution) solution by taken % of sample. Absorbance of solution was measured at selected wavelengths for TENE and DAPA. The amount of TENE and DAPA was calculated at each level and % recoveries were calculated by measuring the absorbance and fitting the values in equation. Accuracy was assessed using three concentrations and three replicates of each.(Table.7)

$$\mathbf{Y = MX + C}$$

$$\mathbf{X = \frac{Y-C}{M} X100}$$

$$\mathbf{\%\ Recovery = \frac{Practical\ Conc.(X)}{Theorotical\ conc.(TC)}\ X\ 100}$$

X= Practical Concentration
TC= Theoretical Concentration
Y=Absorbance
%RSD= SD/MEAN X 100

2.12 Assay

Three tablets were weighed and their average weight was calculated and powdered.10mg of equivalent weight was taken into 10 ml volumetric flack volume made up to the mark by using mobile phase. from that 1 ml of solution was withdrawn and taken in to 10ml volumetric flask. The volume was adjusted with mobile phase up to 10ml to get 10µg/ml solution and its absorbance was measured at 246nm for TENE and 222nm for DAPA. (Table.7)

2.13 Forced Degradation Study:

2.13.1Acid degradation Study

From 100µg/ml of Stock solution, 1 ml of (100µg/ml) solution was taken into 10 ml volumetric flask, and then 1ml of 0.1N HCl was added and the solution was kept aside for 24 hours. After 24 hours the solution was neutralized with 1 ml of 0.1N NaOH the absorbance value was measured at Respective wavelengths 246nm for TENE and 222nm for DAPA. (Table.9)
Formula for Determine % Degradation:
%degradation=standard absorbance-observed absorbance/standard absorbance ×100

2.13.2 Alkali Degradation

From 100µg/ml of Stock solution, 1 ml of (100µg/ml) solution was taken into 10 ml volumetric flask, and then 1ml of 0.1NaOH was added and the solution was kept aside for 24 hours. After 24 hours the solution was neutralized with 1 ml of 0.1N HCL the absorbance value was measured at Respective wavelengths 246nm for TENE and 222nm for DAPA. (Table.9)
Formula for Determine % Degradation:
%degradation=standard absorbance-observed absorbance/standard absorbance ×100

2.13.3 Photolytic Degradation

5mg of drug was exposed to UV light in UV chamber (Short Wavelength 265nm) for 5hrs by placing the drug in watch glass. after 5hrs Sample was diluted to get concentration of 10µg/ml and absorbance was measured at Respective wavelengths 246nm for TENE and 222nm for DAPA. (Table.9)

2.13.4 Thermal Degradation

Drug was exposed to dry heat at 40^0C in oven for 5hrs by placing the drugs in watch glass. after 5 hours 10mg of drug weighed and diluted to get a final concentration of 10 µg/ml and absorbance was measured at Respective wavelengths 246nm for TENE and 222nm for DAPA. (Table.9)

2.13.4 Peroxide Degradation

From 100µg/ml of Stock solution, 1 ml of (100µg/ml) solution was taken into 10 ml volumetric flask, and then 1ml of 6% hydrogen peroxide solution was added and the solution was kept aside for 24 hours. After 24 hours the solution was diluted with water to get concentration of 10 µg/ml absorbance value was measured at Respective wavelengths 246nm for TENE and 222nm for DAPA. (Table.9)

III. RESULTS AND DISCUSSION

The UV scanning showed spectrum exhibiting λmax of 246nm and 222nm for TENE and DAPA respectively. The linearity of the proposed method was investigated in the range of 4-20 µg/ml and 2-10 µg/ml for TENE and DAPA respectively. Calibration curves showed a linear relationship between the absorbance and concentration. The line equation for TENE y = 0.0309x+0.0153 with r2 of 0.996 and for DAPA y = 0.0444x - 0.0138 with r2 of 0.996 was obtained. Calibration curves showed a linear relationship

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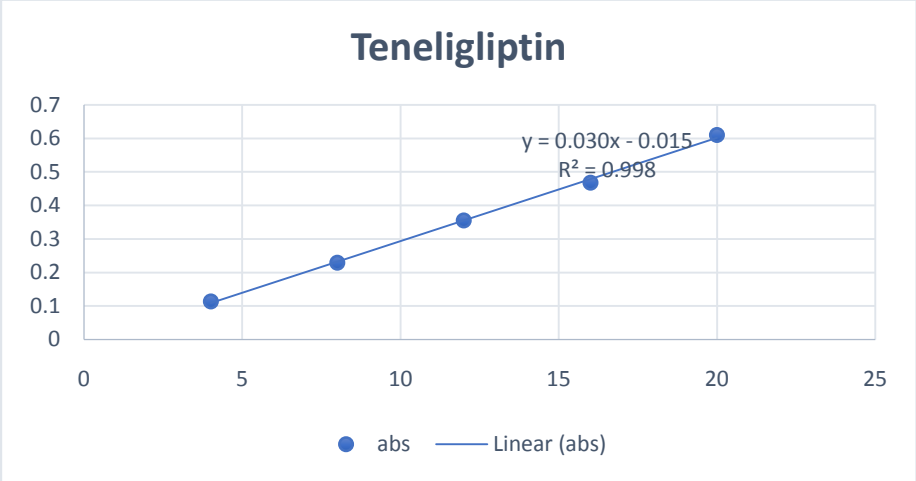
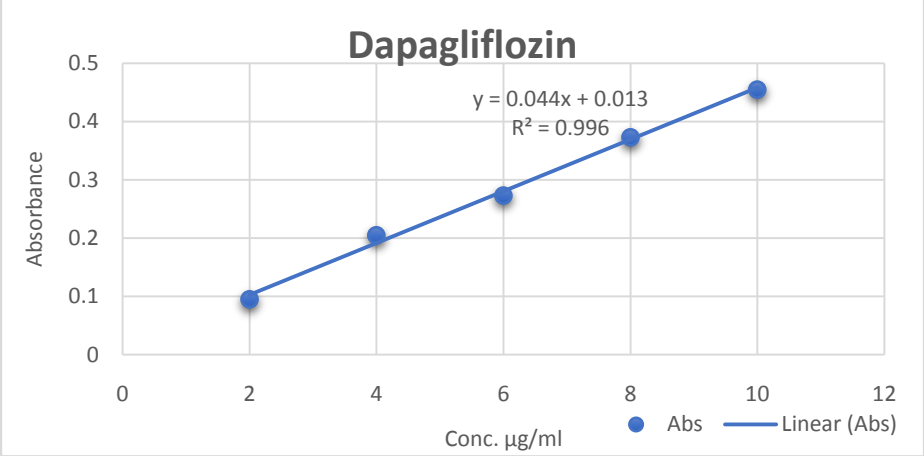
between the absorbance and concentration of TENE and DAPA.



Graph.1Linearity of TENE at 246nm



Graph.2 Linearity of DAPA at 222nm

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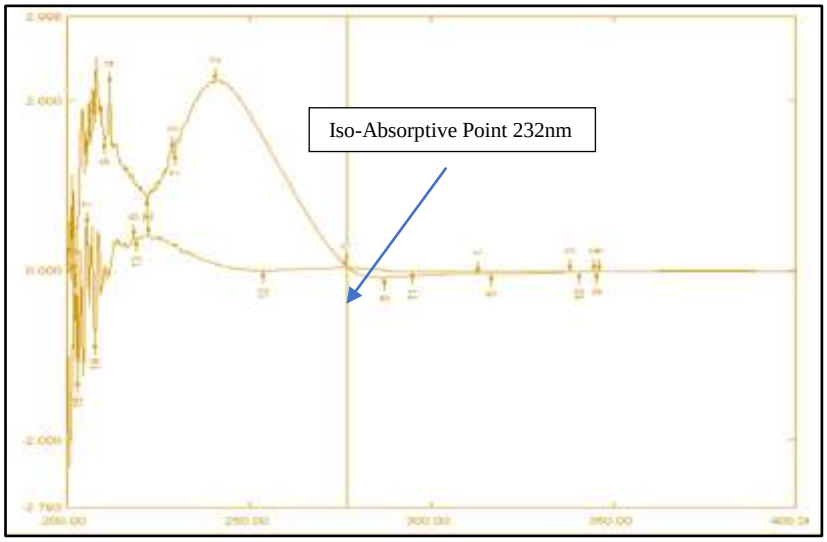

Figure.5UV Overlay Spectra of TENE and DAPA

Table.3 Intraday Precision

Intraday Precision:						
TENELIGLIPTIN						
Conc.	Trails (Absorbance)			Mean	SD	%RSD
	I	II	III			
12	0.134	0.135	0.135	0.134	0.0005	0.4287
16	0.196	0.196	0.197	0.196	0.0005	0.2940
20	0.245	0.245	0.246	0.245	0.0005	0.2353
DAPAGLIFLOZIN						
6	0.184	0.185	0.184	0.184	0.00058	0.3132
8	0.261	0.261	0.262	0.261	0.00058	0.2209
10	0.325	0.328	0.326	0.326	0.00153	0.4680

Table.4 Interday Precision

Interday Precision:						
TENELIGLIPTIN						
Conc.	Trails (Absorbance)			Mean	SD	%RSD
	I	II	III			
12	0.174	0.173	0.173	0.173	0.00057	0.3337
16	0.223	0.225	0.223	0.223	0.00115	0.5780
20	0.292	0.293	0.293	0.293	0.00057	0.1270
DAPAGLIFLOZIN						
6	0.202	0.205	0.205	0.205	0.001732	0.8449
8	0.355	0.351	0.351	0.351	0.00230	0.6579
10	0.391	0.389	0389	0.389	0.00115	0.2968

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Table.5 LOD & LOQ Limit Detection

LOD & LOQ Limit Detection:		
Condition	TENELIGLIPTIN	DAPAGLIFLOZIN
LOD	20.88	10.45
LOQ	63.29	31.68
Slope	0.0444	0.03088

Table.6 Simultaneous Estimation method

Sr. No.	**Drug Name**	**Conc. µg/ml**	**Absorbance**		**Absorptivity (Abs/Conc.)**	
			λ_1=246nm	λ_2=222nm	λ_1=246nm	λ_2=222nm
1	TENE	4	0.113	0.053	0.02825	0.01325
2		8	0.229	0.112	0.028625	0.014
3		12	0.355	0.177	0.0221875	0.0110625
4		16	0.468	0.244	0.026	0.013555556
5		20	0.611	0.399	0.03055	0.01995
		Mean=	0.3552	0.197	ax_1= 0.02712	ax_2=0.01436
1	DAPA	2	0.095	0.142	0.0475	0.071
2		4	0.205	0.102	0.05125	0.0255
3		6	0.273	0.122	0.0455	0.020333333
4		8	0.373	0.155	0.046625	0.019375
5		10	0.455	0.231	0.0455	0.0231
		Mean=	0.2802	0.1504	ay_1=0.04728	ay_2=0.03186
1	Mixture	A_1=0.565	A_2=0.701		Cx=99.97%	Cy=99.09%

Table.7 Forced degradation Study:

Forced degradation Study:

Sr. No.	Types of Degradation	TENELIGLIPTIN			DAPAGLIFLOZIN		
		Std. Abs	Obs. Abs.	%Degradation	Std. Abs	Obs. Abs.	% Degradation
1	Acid degradation (0.1N HCl)	0.491+0.10	0.440±0.10	10.38%	0.553±0.10	0.521±0.10	5.78%
2	Alkali degradation (0.1N NaOH)		0.434±0.10	11.60%		0.498±0.10	9.94%
3	Peroxide degradation		0.411±0.10	16.29%		0.49±0.10	11.21%

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	(6%H2O2)					
4	Photolytic degradation (UV light exposure	0.413±0.10	15.88%		0.501±0.10	9.40%
5	Thermal degradation (hot air oven)	0.403±0.10	17.92%		0.471±0.10	14.82%

Table.8Sandell's Sensitivity (µgcm-2/ 0.001 abs units)

Sandell's Sensitivity (µgcm-2/ 0.001 abs units)

Sr No.	Concentration	Absorbance at respected wavelengths	Sandell's Sensitivity (µgcm-2/ 0.001 abs units)
Teneligliptin			
1	4	0.113	0.0353
2	8	0.229	0.0349
3	12	0.355	0.0338
4	16	0.468	0.0341
5	20	0.611	0.0327
Dapagliflozin			
1	2	0.095	0.0210
2	4	0.205	0.0195
3	6	0.273	0.0297
4	8	0.373	0.0214
5	10	0.455	0.0219

Table.11Analysis of marketed formulation

Analysis of marketed formulation

Sr. No.	Teneligliptin			Dapagliflozin		
	Absorbance	Amount recovered (µg/ml)	% Recovery	Absorbance	Amount recovered (µg/ml)	% Recovery
1	0.611	20.52	102.6	0.456	10.23	102.3
2	0.616	20.05	100.25	0.45	9.98	99.8
3	0.608	20.51	102.55	0.451	10.11	101.1
4	0.612	20.09	100.45	0.454	10.1	101
Mean	0.61175	20.2925	101.4625	0.45275	10.105	101.05
SD	0.003304	0.257472	1.287358	0.002754	0.102144	1.021437
%RSD	0.540096	1.268802	1.268802	0.608235	1.010823	1.010823

IV. CONCLUSION:

A simple, accurate and precise UV-Visible spectrophotometric method for the estimation of Ritonavir was developed and validated. The Proposed method was found to be robust and rugged in nature and was successfully used for the estimation of Teneligliptin and dapagliflozin.(Table.12)

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Table.12 Conclusion

Sr. No.	Parameters	Teneligliptin	Dapagliflozin
1.	Absorption maxima	243nm	222nm
2.	Beer's Range	4-20	2-10
3.	Regression equation	y=0.0309x-0.0153	y=0.0444x+0.0138
4.	Slope (m)	0.03088	0.0444
5.	Intercept (c)	0.0153	0.0138
6.	Regression coefficient (r^2)	0.9985	0.996
7.	Limit of detection (LOD)	20.88	10.45
8.	Limit of quantization (LOQ)	63.29	31.65
9.	% Recovery	100.21 %	100.81 %
10.	Acid degradation (HCL)	10.38%	5.78%
11.	Alkali degradation NaOH)	11.60%	9.94%
12.	Thermal degradation (45^0C)	17.92%	14.82%
13.	Photolytic degradation (UV)	15.88%	9.40 %
14.	Peroxide degradation (H2O2)	16.29%	11.21%
15.	Intraday precision	0.4287-0.2353	0.3132-0.4680
16.	Interday precision	0.3337-0.1270	0.8449-0.2968

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