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Development and Validation of Stability Indicating Method of UV- Spectrophotometry for the Estimation of Linagliptin and Dapagliflozin in Bulk and Tablet Dosage Form

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Abstract: *A simple, rapid, accurate, precise, and economic stability-indicating first-order derivative UV spectrophotometric method was developed and validated for the simultaneous estimation of Linagliptin and Dapagliflozin in bulk drugs and tablet dosage forms. The method was based on the zero-crossing technique, with analytical wavelengths selected at 243.6 nm for Linagliptin and 266.6 nm for Dapagliflozin. Standard and sample solutions were prepared using distilled water as the solvent, making the method environmentally friendly and cost-effective. The developed method was validated according to ICH Q2(R2) guidelines for specificity, linearity, precision, accuracy, repeatability, robustness, limit of detection (LOD), and limit of quantitation (LOQ). The method exhibited excellent linearity over concentration ranges of 5–30 µg/mL for Linagliptin (r^2 = 0.999) and 0.5–3.0 µg/mL for Dapagliflozin (r^2 = 0.997). Accuracy studies showed percentage recoveries between 98% and 102%, while precision studies demonstrated %RSD values below 2%, confirming the reliability of the method. Assay of the marketed tablet formulation showed satisfactory results within acceptable pharmacopeial limits. Forced degradation studies under acidic, alkaline, neutral, oxidative, photolytic, and thermal stress conditions confirmed the stability-indicating nature of the proposed method by effectively detecting degradation without interference from degradation products. The proposed first-order derivative UV spectrophotometric method is simple, sensitive, robust, and suitable for routine quality control analysis and stability testing of Linagliptin and Dapagliflozin in bulk materials and pharmaceutical dosage forms.*

Keywords: Linagliptin; Dapagliflozin; First-order derivative UV spectrophotometry; Stability-indicating method; Method validation; ICH Q2(R2); Forced degradation; Pharmaceutical analysis

I. INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin resistance, or both.[1] The global prevalence of diabetes continues to rise, creating a significant healthcare burden and increasing the risk of serious complications such as cardiovascular disease, nephropathy, neuropathy, and retinopathy.[2] Combination therapy has become an effective strategy for achieving optimal glycemic control by targeting multiple pathogenic mechanisms involved in T2DM. Linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, enhances endogenous incretin activity by preventing the degradation of glucagon-like peptide-1 (GLP-1), thereby improving glucose-dependent insulin secretion and suppressing glucagon release. Dapagliflozin, a sodium-glucose co-transporter-2 (SGLT2) inhibitor, lowers blood glucose levels by reducing renal glucose reabsorption and promoting urinary glucose excretion. The complementary mechanisms of these two drugs provide superior glycemic control while minimizing the risk of hypoglycemia. [3,4]

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Reliable analytical methods are essential for ensuring the quality, safety, efficacy, and stability of pharmaceutical products throughout their shelf life. Stability-indicating analytical methods are particularly important because they can accurately quantify the active pharmaceutical ingredients in the presence of degradation products generated under various stress conditions. Although chromatographic techniques such as HPLC are widely employed for the simultaneous estimation of Linagliptin and Dapagliflozin, these methods are often expensive, time-consuming, and require sophisticated instrumentation and large volumes of organic solvents. In contrast, UV spectrophotometric methods are simple, rapid, economical, and environmentally friendly, making them highly suitable for routine quality control laboratories. First-order derivative spectrophotometry further enhances selectivity by resolving overlapping spectra through the zero-crossing technique, allowing simultaneous estimation without prior separation. [6,7]

Therefore, the present study aimed to develop and validate a simple, accurate, precise, robust, and stability-indicating first-order derivative UV spectrophotometric method for the simultaneous estimation of Linagliptin and Dapagliflozin in bulk drugs and tablet dosage forms. The developed method was validated according to ICH Q2(R2) guidelines and evaluated through forced degradation studies under acidic, alkaline, oxidative, neutral, photolytic, and thermal stress conditions to establish its suitability for routine pharmaceutical quality control and stability assessment. [8,9]

Materials and Methods

Linagliptin and Dapagliflozin reference standards were obtained as gift samples from a reputed pharmaceutical company, while the marketed tablet formulation containing both drugs was procured from the local market. All chemicals and reagents used, including hydrochloric acid, sodium hydroxide, hydrogen peroxide, methanol, acetonitrile, and distilled water, were of analytical reagent (AR) grade. UV spectrophotometric analysis was performed using a double-beam UV–Visible spectrophotometer equipped with 1 cm matched quartz cells. Standard stock solutions of Linagliptin (1000 µg/mL) and Dapagliflozin (1000 µg/mL) were prepared in distilled water and diluted to obtain appropriate working concentrations. The absorption spectra of both drugs were recorded over the wavelength range of 200–400 nm, and the first-order derivative spectrophotometric method was developed using the zero-crossing technique. The selected analytical wavelengths were 243.6 nm for Linagliptin and 266.6 nm for Dapagliflozin. The developed method was applied for the simultaneous estimation of both drugs in marketed tablets and validated according to ICH Q2(R2) guidelines for linearity, accuracy, precision, repeatability, limit of detection (LOD), limit of quantitation (LOQ), robustness, and assay. The stability-indicating capability of the proposed method was evaluated by subjecting the drugs to forced degradation under acidic, alkaline, oxidative, photolytic, thermal, and neutral hydrolytic conditions, followed by analysis at the selected wavelengths to determine the percentage degradation and assay.[10-14]

RESULT AND DISCUSSION

Preparation of standard stock solution (1000 µg/ml)

Standard stock solutions of Linagliptin and Dapagliflozin (1000 µg/mL) were prepared by accurately weighing 100 mg of each drug separately, transferring them into 100 mL volumetric flasks, dissolving in a sufficient quantity of distilled water with sonication for 5 min, and making the volume up to the mark with distilled water. Subsequently, 100 µg/mL standard solutions were prepared by diluting 10 mL of each stock solution to 100 mL with distilled water. A 10 µg/mL standard solution of Dapagliflozin was obtained by further diluting 10 mL of the 100 µg/mL solution to 100 mL with distilled water. Working standard solutions were prepared by diluting 2.5 mL of the 100 µg/mL Linagliptin solution to 10 mL to obtain a final concentration of 25 µg/mL and by diluting 1 mL of the 10 µg/mL Dapagliflozin solution to 10 mL to obtain a final concentration of 1 µg/mL. For wavelength selection, 5 µg/mL working standard solutions of both drugs were scanned in the UV region (200–400 nm) using a UV–Visible spectrophotometer. The obtained spectra were converted into first-order derivative spectra and overlaid. Using the zero-crossing method, the analytical wavelengths were selected at 243.6 nm for Linagliptin and 266.6 nm for Dapagliflozin, providing suitable conditions for their simultaneous estimation.

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Development and validation of stability indicating method of UV- spectrophotometry

The developed first-order derivative UV spectrophotometric method was successfully applied for the analysis of the marketed tablet formulation containing Linagliptin and Dapagliflozin. Twenty tablets were accurately weighed, and the average tablet weight was found to be 948 mg. The tablets were finely powdered, and an amount of powder equivalent to 100 mg of Linagliptin (189.6 mg) was transferred into a 100 mL volumetric flask, dissolved in distilled water with sonication for 15 min, filtered through Whatman No. 41 filter paper, and appropriately diluted to obtain a final concentration of 25 µg/mL of Linagliptin and 1 µg/mL of Dapagliflozin. The prepared solution was scanned over the UV range of 200–400 nm, and the analysis was performed six times to ensure repeatability. The developed method was validated according to ICH guidelines by evaluating linearity, precision, accuracy, limit of detection (LOD), limit of quantitation (LOQ), and robustness. Linearity was established over concentration ranges of 5–30 µg/mL for Linagliptin and 0.5–3.0 µg/mL for Dapagliflozin by constructing calibration curves. Precision was assessed through intraday, interday, and repeatability studies, with results expressed as percentage relative standard deviation (%RSD). Accuracy was determined using recovery studies at 80%, 100%, and 120% concentration levels by the standard addition method. The sensitivity of the method was evaluated by calculating LOD and LOQ using the equations LOD = 3.3σ/S and LOQ = 10σ/S, where σ represents the standard deviation of the response and S is the slope of the calibration curve. Robustness was examined by introducing small deliberate variations in analytical conditions to confirm the reliability of the method. Furthermore, forced degradation studies were performed to establish the stability-indicating nature of the method by exposing the drugs to acid hydrolysis, base hydrolysis, oxidative degradation, thermal degradation (60°C), UV photolysis, and sunlight stress conditions. Under each stress condition, solutions containing 25 µg/mL of Linagliptin and 1 µg/mL of Dapagliflozin were prepared and analyzed. In the acid hydrolysis study, standard solutions were treated with 0.1 M hydrochloric acid, kept at room temperature for 24 h, neutralized with 0.1 M sodium hydroxide, diluted to the required concentrations, and analyzed at the selected analytical wavelengths of 243.6 nm for Linagliptin and 266.6 nm for Dapagliflozin to evaluate the extent of degradation and confirm the stability-indicating capability of the proposed method.

Forced Degradation Studies: Forced degradation studies were performed to evaluate the stability of Linagliptin and Dapagliflozin under different stress conditions, including alkaline hydrolysis, oxidative, photolytic, and thermal degradation. For alkaline hydrolysis, accurately weighed 100 mg each of Linagliptin and Dapagliflozin were transferred separately into 100 mL volumetric flasks, and stock solutions of 100 µg/mL and 10 µg/mL, respectively, were prepared by serial dilution. An aliquot of 10 mL from each stock solution was mixed with 10 mL of 0.1 M NaOH and kept at room temperature for 24 h. After the stress period, the solutions were neutralized with 0.1 M HCl and further diluted to obtain final concentrations of 25 µg/mL for Linagliptin and 1 µg/mL for Dapagliflozin. For oxidative degradation, the same procedure was followed except that 10 mL of 3% hydrogen peroxide was used instead of NaOH, and the solutions were kept at room temperature for 24 h before dilution to the required concentrations. Photolytic degradation was carried out by exposing the pure drugs to UV radiation for 6 h, while thermal degradation was performed by exposing the pure drugs to dry heat at 60°C for 2 h. After exposure, the samples were diluted with distilled water to obtain final concentrations of 25 µg/mL of Linagliptin and 1 µg/mL of Dapagliflozin. The absorbance of all stressed samples was measured at 243.6 nm for Linagliptin and 266.6 nm for Dapagliflozin using a UV-visible spectrophotometer. The absorbance values were compared with those of the corresponding unstressed standard solutions, and the percentage degradation under each stress condition was calculated.

Table 1: Solvent system used for solubility testing of Linagliptin and Dapagliflozin

Sr. No.	Solvent system	Linagliptin	Dapagliflozin
1)	Distilled water	Slightly soluble	Slightly soluble
2)	Methanol	Slightly soluble	Slightly soluble
3)	Acetonitrile	Insoluble	Slightly soluble

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4)	0.1 N HCl	Soluble	Soluble
5)	0.1 N NaOH	Slightly soluble	Freely soluble
6)	Methylene chloride	Insoluble	Insoluble
7)	Ethylacetate	Insoluble	Insoluble

The absorption spectra obtained for Linagliptin

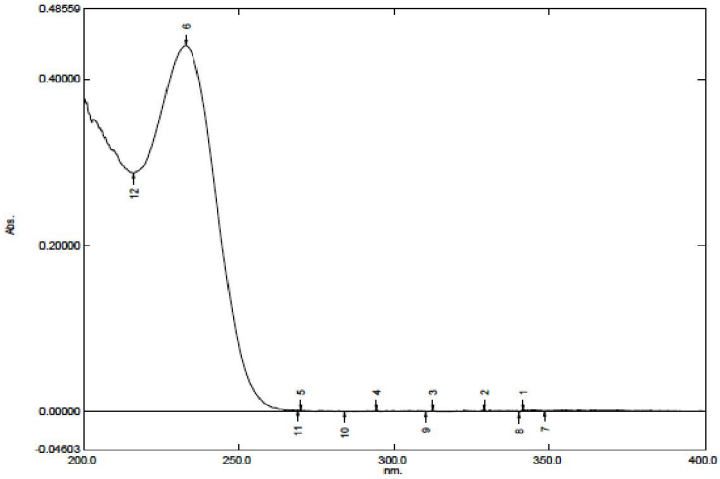

Fig. 1: UV- spectrum of Linagliptin

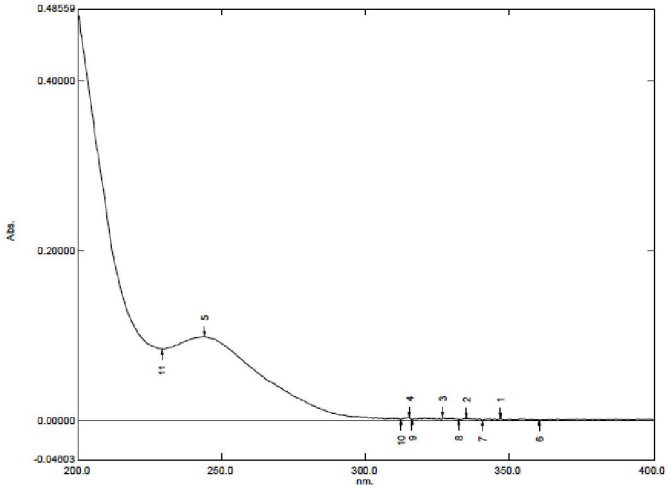

Fig. 2: UV- spectrum of Dapagliflozin

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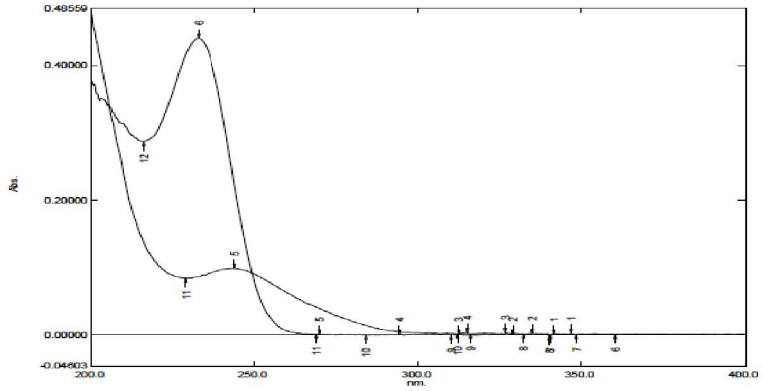

Fig. 3: Overlain Spectrum of Linagliptin and Dapagliflozin

First order derivative spectrum of Linagliptin

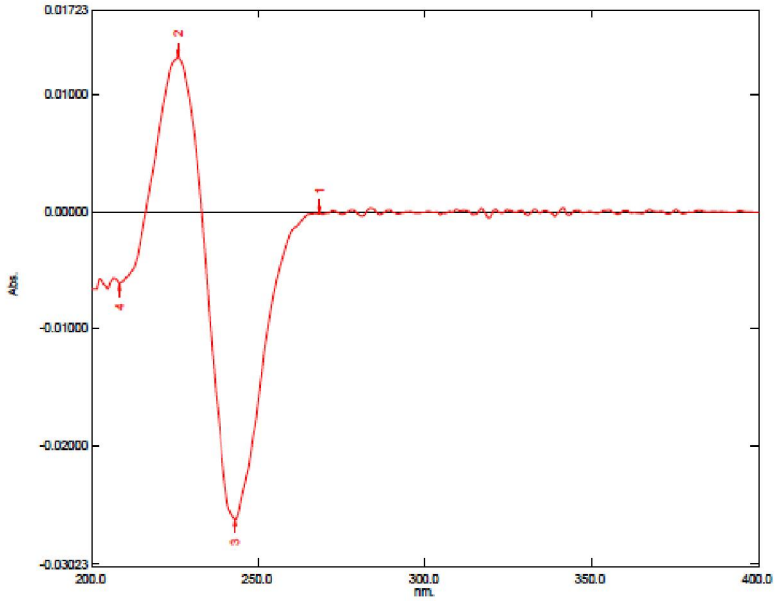

Fig. 4: First order derivative spectrum of Linagliptin

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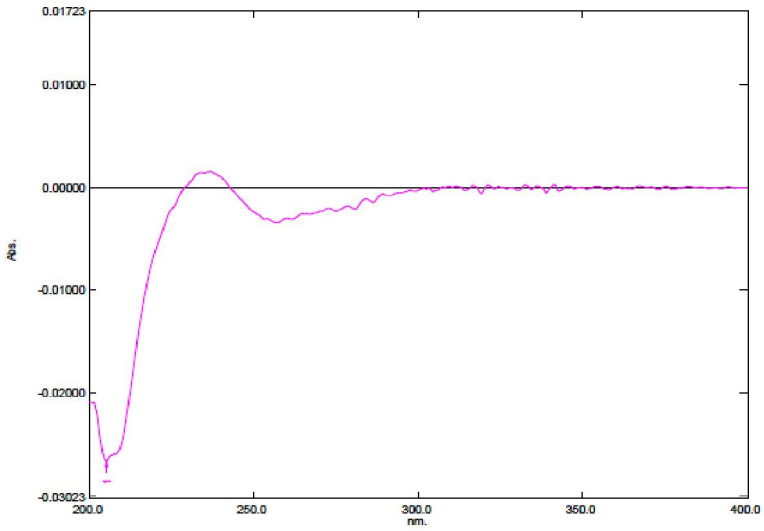

Fig. 5: First order derivative spectrum of Dapagliflozin

First derivative overlain Spectrum of Linagliptin and Dapagliflozin

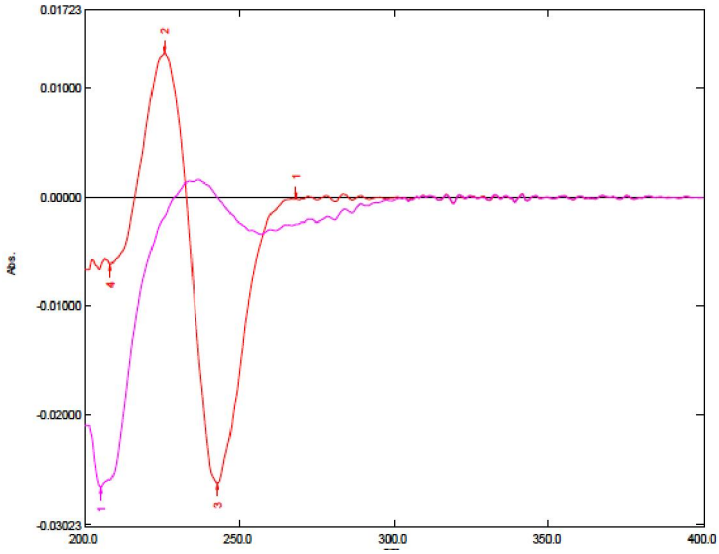

Fig. 6: First derivative overlain Specrum of Linagliptin and Dapagliflozin

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Linearity Specrum of Linagliptin

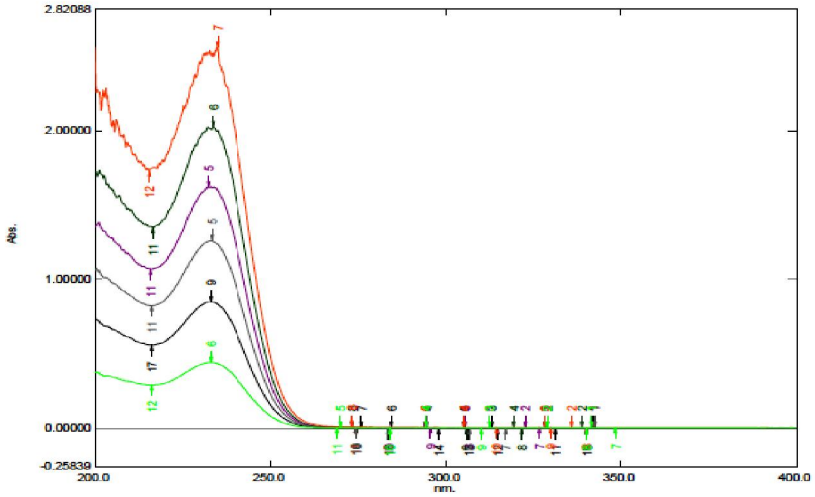

Fig. 7: Linearity Spectrum of Linagliptin

Table 2: Linearity study data of Linagliptin

Sr. No.	Conc. (µg/ml)	Absorbance at (243.6)
1	5	0.2
2	10	0.443
3	15	0.666
4	20	0.901
5	25	1.115
6	30	1.378

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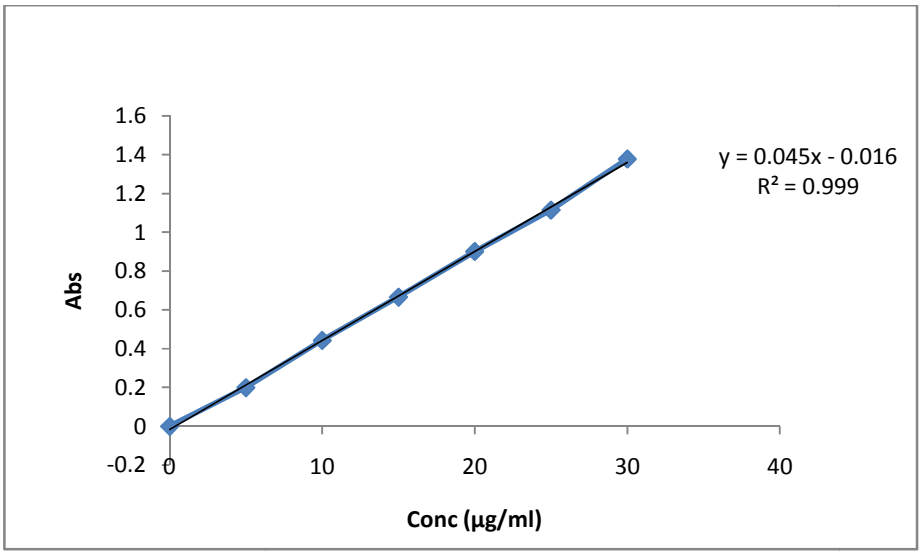

Fig. 8: Linearity Graph of Linagliptin

Linearity Specrum of Dapagliflozin

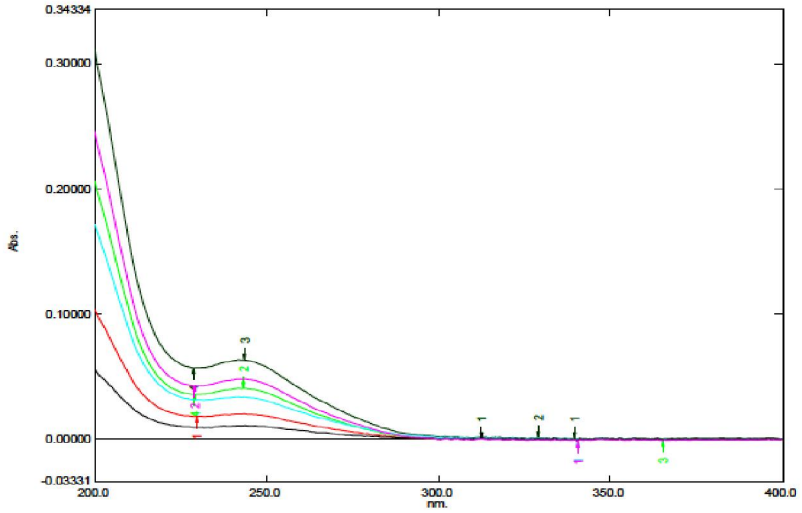

Fig. 9: Linearity Spectrum of Dapagliflozin

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Table 3: Linearity study data of Dapagliflozin

Sr. No.	Conc. (µg/ml)	Absorbance at (266.6)
1	0.5	0.005
2	1	0.009
3	1.5	0.014
4	2	0.018
5	2.5	0.023
6	3	0.029

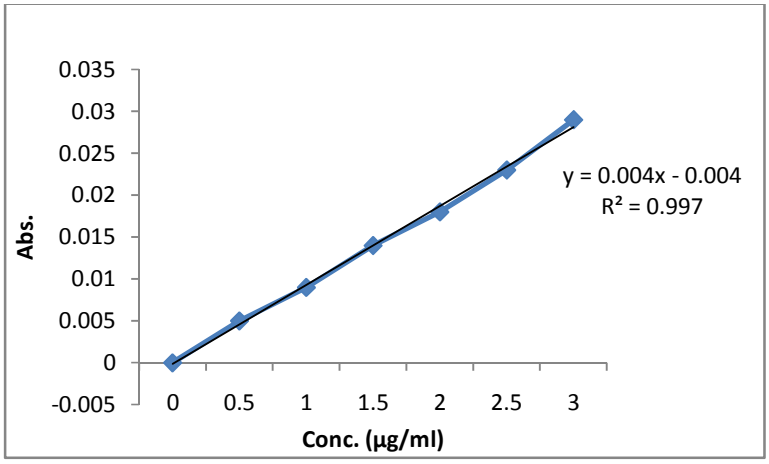

Fig. 10: Linearity Graph of Dapagliflozin

Table 07: Optical characteristics and other parameter

Parameters	Linagliptin	Dapagliflozin
λ_{max} i.e. selected wavelength (nm)	243.6 nm	266.6 nm
Linearity range (µg/ml)	5-30 µg/ml	0.5-3 µg/ml
Regression Equation (Y)	Y= 0.045x - 0.016	Y = 0.004x - 0.004
Regression coefficient (r^2)	0.999	0.997
Slope (m)	0.045	0.004
Intercept (c)	0.016	0.004
Limit of detection (µg/ml)	0.858	0.528
Limit of quantitation (µg/ml)	2.60	1.60
SE of Intercept	0.0117	0.00064

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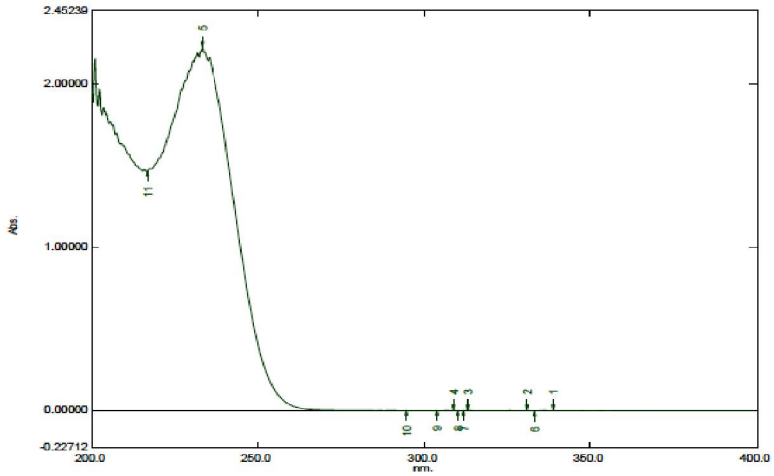

Fig. 11: Acid degradation of Linagliptin

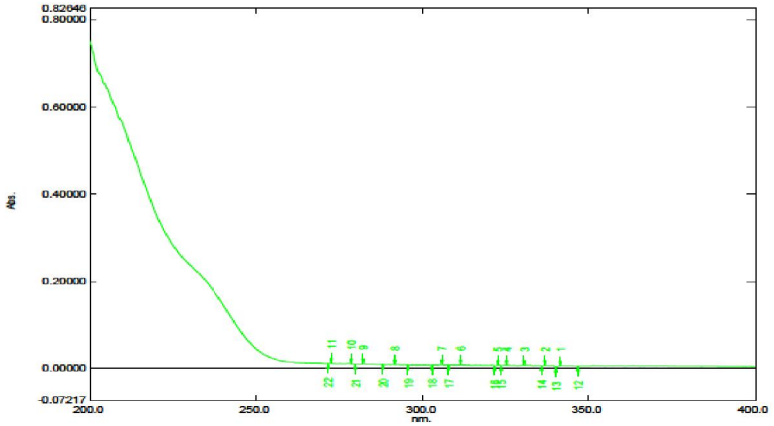

Fig. 12: Acid degradation of Dapagliflozin

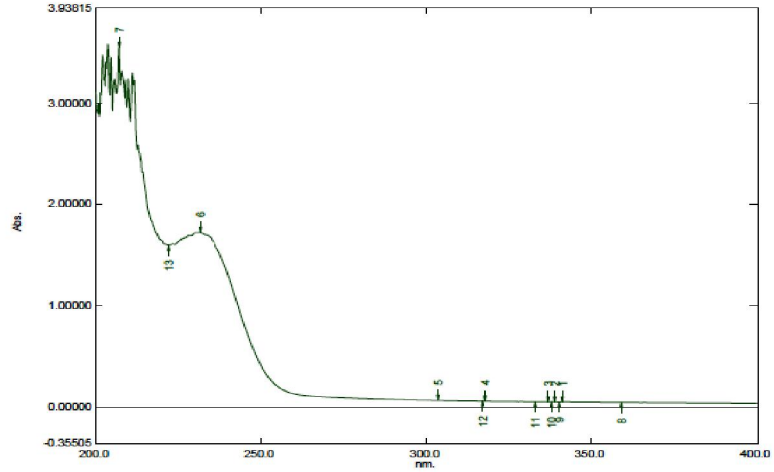

Fig. 13: Base degradation of Linagliptin

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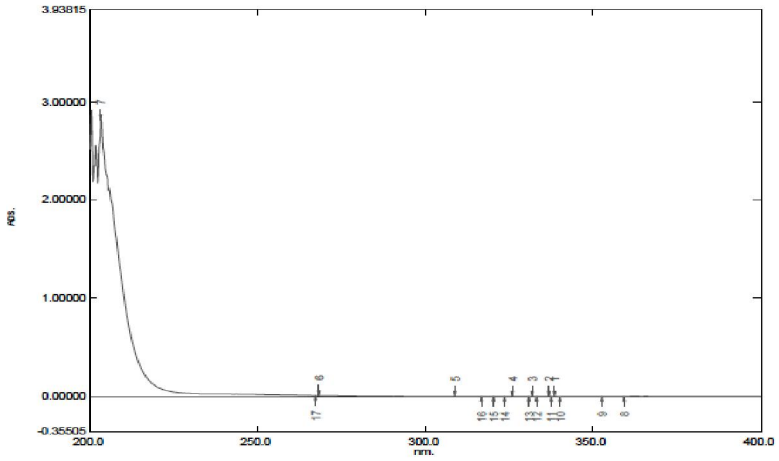

Fig. 14: Base degradation of Dapagliflozin

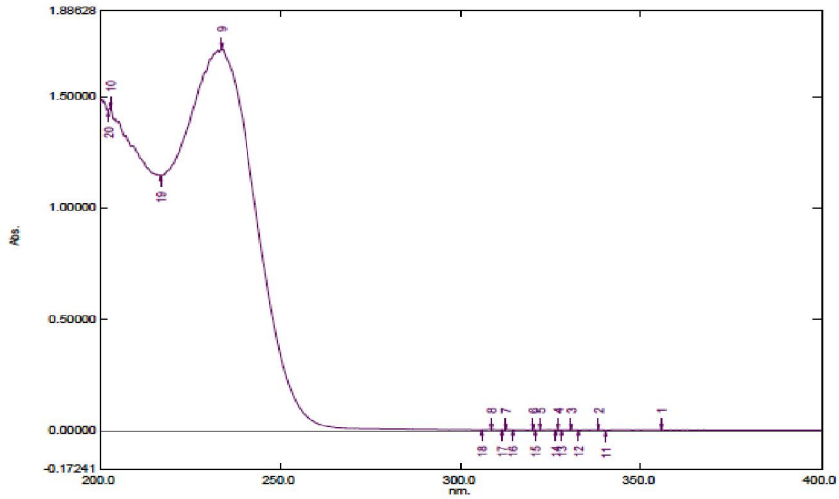

Fig. 15: Oxidative degradation of Linagliptin

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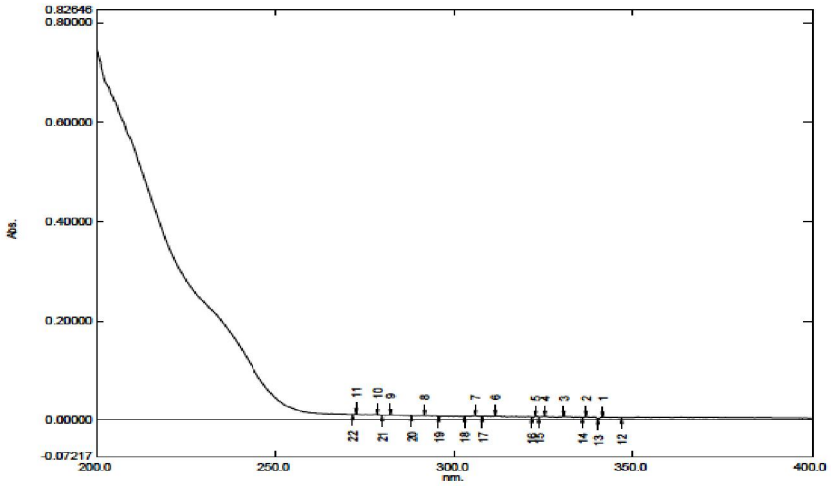

Fig. 16: Oxidative degradation of Dapagliflozin

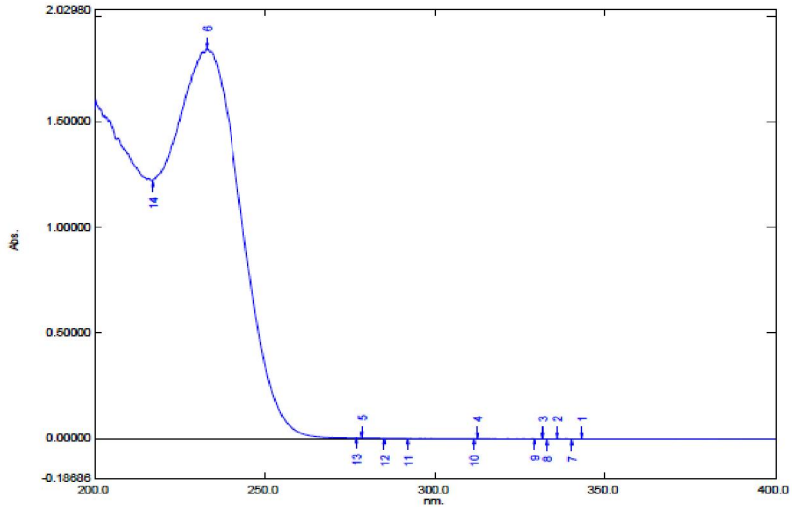

Fig. 17: Photolytic degradation of Linagliptin

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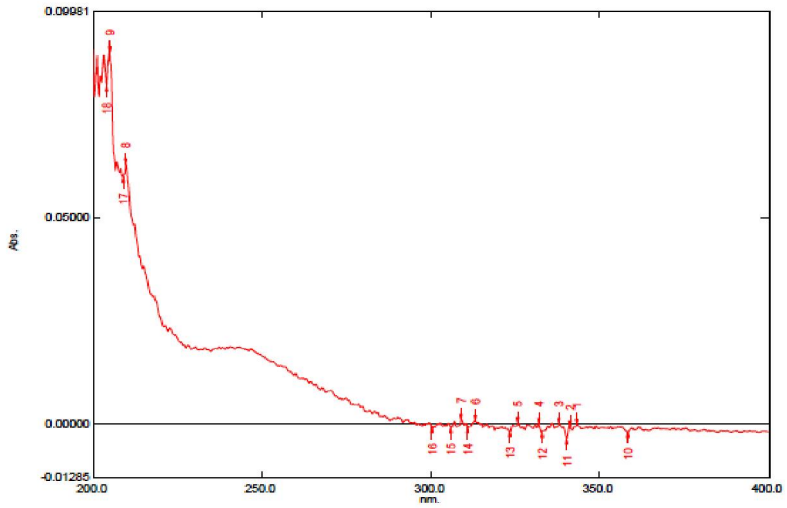

Fig. 18: Photolytic degradation of Dapagliflozin

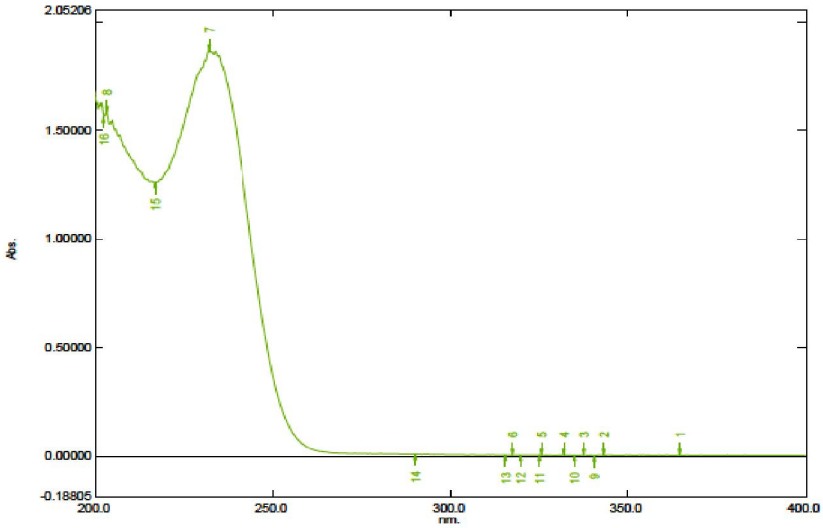

Fig. 20: Thermal degradation of Linagliptin

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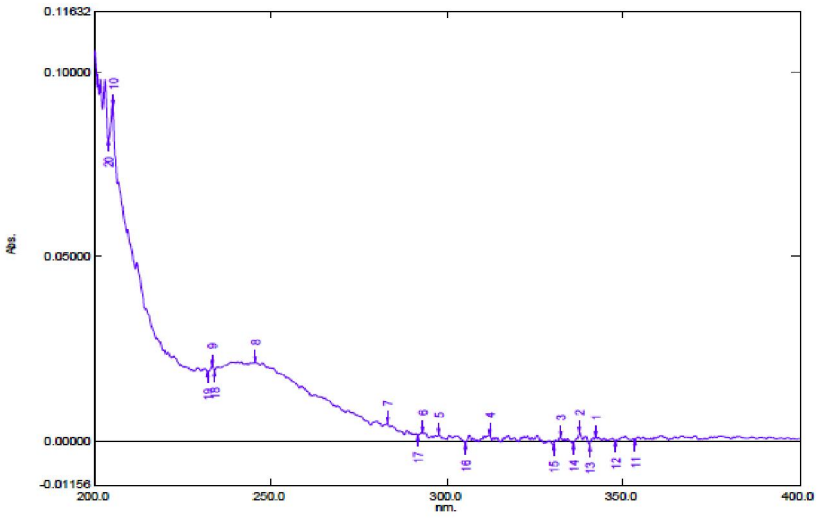

Fig. 21: Thermal degradation of Dapagliflozin

Table 4: Analysis of Marketed formulation

Sr. No.	label claim (mg/tab)		Amount found (mg/tab)		% Label claim	
	Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin
1	5	10	4.83	10.674	96.62	103.37
2	5	10	4.93	10.232	98.72	101.16
3	5	10	4.93	10.230	98.73	101.15
4	5	10	4.93	10.220	98.67	101.10
5	5	10	4.99	10.012	99.92	100.06
6	5	10	4.99	10.038	99.82	100.19

Table 5: Statistical validation: Analysis of Marketed formulation

Name of drug	Mean*	SD*	%RSD*
Linagliptin	98.74	1.188	1.2009
Dapagliflozin	101.17	1.186	1.1726

*Indicates average of six determinants

Table 6: Linear regression data for calibration curve of Linagliptin and Dapagliflozin

Drug	Linearity (µg/ml)	r^2	Slope	Intercept
Linagliptin	5- 30 µg/ml	0.999	0.045	0.016

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Dapagliflozin	0.5- 3 µg/ml	0.997	0.004	0.004

Table 7: Precision data of Linagliptin and Dapagliflozin

Sr. No.	Time Interval	Concentration (mg/tab)		% Recovery	
		Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin
1	Intra – day	5	10	100.783	99.412
2		5	10	99.82	100.197
3		5	10	100.169	99.813
1	Inter – day	5	10	98.708	101.141
2		5	10	100.421	99.725
3		5	10	100.257	99.807

Table 8: Statistical validation of precision data

Name of drug	Mean*	SD*	%RSD*
Linagliptin	100.2573	0.487539	0.486288
Dapagliflozin	99.80733	0.392531	0.393288

***indicates average of three determinations**

Table 9: Statistical validation of inter- day precision data

Name of drug	Mean*	SD*	%RSD*
Linagliptin	99.7933	0.9573	0.9592
Dapagliflozin	100.2241	0.7733	0.7716

*indicates average of nine determinations

Table 10: Intra-day Precision data of Linagliptin and Dapagliflozin

Sr. No.	Concentration (mg/tab)		Absorbance		% Recovery	
	Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin
1	5	10	1.278	0.023	98.72	101.168
2	5	10	1.284	0.021	98.73	101.151
3	5	10	1.231	0.022	98.67	101.104
4	5	10	1.318	0.020	101.42	99.05
5	5	10	1.299	0.020	99.94	100.064
6	5	10	1.295	0.025	99.92	100.062

Table 11: Statistical validation of Intra-day precision data

Name of drug	Mean*	SD*	%RSD*
Linagliptin	99.56667	1.088112	1.092847
Dapagliflozin	100.4332	0.859358	0.855652

*indicates average of six determinations

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Table 12: Repeatability data of Linagliptin and Dapagliflozin

Sr. No.	Concentration (mg/tab)		Absorbance		% Recovery	
	Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin	Linagliptin	Dapagliflozin
1	5	10	1.278	0.023	98.72	101.168
2	5	10	1.284	0.021	98.73	101.151
3	5	10	1.231	0.022	98.67	101.104
4	5	10	1.318	0.020	101.42	99.05
5	5	10	1.299	0.020	99.94	100.064
6	5	10	1.295	0.025	99.92	100.062

Table 13: Statistical validation of repeatability data

Name of drug	Mean*	SD*	%RSD*
Linagliptin	99.56667	1.088112	1.092847
Dapagliflozin	100.4332	0.859358	0.855652

*Average of six determinants

Table 14: Recovery study data of MET and TEN

Level of Recovery %	Label claim (mg/tab)		Amount of pure drug added (mg)		Total Amount recovered (mg)		% Recovery	
	LIN	DAP	LIN	DAP	LIN	DAP	LIN	DAP
80	5	10	4	1.6	886.182	36.212	98.46	100.58
	5	10	4	1.6	891.672	36.166	99.07	100.46
	5	10	4	1.6	887.038	36.302	98.55	100.83
100	5	10	5	2	978.20	40.405	97.82	101.01
	5	10	5	2	985.80	40.242	98.58	100.60
	5	10	5	2	995.722	40.06	99.57	100.15
120	5	10	6	2	1098.01	44.025	99.81	100.05
	5	10	6	2	1104.48	43.914	100.40	99.80
	5	10	6	2	1085	44.148	98.64	100.33

Table 15: Statistical validation of recovery study data of Linagliptin and Dapagliflozin

Level of Recovery %	% Mean Recovery		SD*		%RSD*	
	LIN	DAP	LIN	DAP	LIN	DAP
80	98.69	100.6233	0.329292	0.188768	0.3337	0.1876
100	98.65667	100.5867	0.877515	0.430155	0.8895	0.4276
120	99.61667	100.060	0.895786	0.265141	0.8992	0.2650

*average of three determinants

Table 16: Force degradation study data of Linagliptin and Dapagliflozin

Sr. No.	Conditions	% Degradation		% Assay	
		LIN	DAP	LIN	DAP
01.	Acid hydrolysis (0.1M HCl, room temp, 24 hrs)	13.23	20	86.77	80

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2.	Base hydrolysis (0.1M NaOH, room temp, 24 hrs)	19.98	20	80.02	80
3.	Neutral hydrolysis (H_2O, room temp, 24 hr)	19.90	13.33	80.10	86.67
4.	Photolytic degradation (UV-radiation, room temp, 2hrs)	15.40	20	84.60	80
5.	Oxidative degradation (3% H_2O_2, room temp, 24 hr)	19.90	20	80.1	80
6	Thermal degradation (60ºC,room temp, 2 hrs)	20	13.65	80	86.35

Table 17: Summary of validation data of proposed UV method

Parameters			LIN	DAP
Wavelength(λ_{max})			243.6 nm	266.6 nm
Linearity range			5-30 µg/ml	0.5-3 µg/ml
Regression equation $y = mx + c$			Y= 0.045x - 0.016	Y = 0.004x - 0.004
Regression coefficient (r^2)			0.999	0.997
Precision	Mean ± %RSD	Repeatability	99.5666 ± 1.0928	100.4332 ± 0.8556
		Intra-day	99.5666 ± 1.0928	100.4332 ± 0.8556
		Inter-day	99.7953 ± 0.9471	100.2243 ± 0.7931
Accuracy (% recovery)		Mean 80% ± %RSD	98.69 ± 0.3337	100.6233 ± 0.1876
		Mean 100% ± %RSD	98.6566 ± 0.8895	100.5867 ± 0.4276
		Mean 120% ± %RSD	99.6166 ± 0.8992	100.060 ± 0.2650
Limit of Detection (µg/ml)			0.858	0.528
Limit of Quantitation (µg/ml)			2.60	1.60

II. CONCLUSION

A simple, rapid, precise, accurate, economical, and stability-indicating first-order derivative UV spectrophotometric method was successfully developed and validated for the simultaneous estimation of Linagliptin and Dapagliflozin in bulk drugs and tablet dosage forms. The proposed method demonstrated excellent linearity, precision, accuracy, repeatability, robustness, and sensitivity in accordance with ICH Q2(R2) validation guidelines. Forced degradation studies confirmed that the method was capable of effectively distinguishing the analytes from their degradation products under acidic, alkaline, oxidative, neutral, thermal, and photolytic stress conditions, thereby establishing its stability-indicating capability. The assay results of the marketed formulation were within acceptable limits, confirming the applicability of the method for routine pharmaceutical quality control. Owing to its simplicity, low cost, minimal solvent requirement, and reliable analytical performance, the developed first-order derivative UV spectrophotometric method represents an effective alternative to more sophisticated chromatographic techniques for the routine analysis and stability evaluation of Linagliptin and Dapagliflozin in pharmaceutical formulations.

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