Lean Six Sigma–Driven Development and Validation of a Robust RP-HPLC Method for Simultaneous Estimation of Dapagliflozin and Linagliptin in Tablet Dosage Form

PALLA DINESH[1], R. KIRAN JYOTHI[2], MAHESH.M[3]

[1]Department of Pharmaceutical Analysis, JNTUA-Oil Technological and Pharmaceutical Research Institute, Jawaharlal Nehru Technological University Anantapur (JNTUA), Ananthapuramu-515001, Andhra Pradesh, India.

[2*,3]Assistant Professor, Department of Pharmaceutical Analysis, JNTUA-Oil Technological and Pharmaceutical Research Institute, Jawaharlal Nehru Technological University Anantapur (JNTUA), Ananthapuramu-515001, Andhra Pradesh, India

Corresponding Author:

Palla Dinesh

Department of Pharmaceutical Analysis

JNTUA-OTPRI,

Ananthapuramu,

Mail ID: pallad351@gmail.com

DOI:https://doi.org/10.63001/tbs.2026.v21.i02.S.I(2).pp2149-2164

Keywords:

Dapagliflozin; Linagliptin; RP-HPLC; Lean Six Sigma; DMAIC; Method validation

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Received on:
13-05-2026

Accepted on:

02-06-2026

Published on:

10-06-2026

Abstract

Robust analytical methods are essential for pharmaceutical quality and regulatory compliance. This study developed a reversed-phase HPLC method for simultaneous quantification of Dapagliflozin and Linagliptin in tablets, integrating Lean Six Sigma (DMAIC) principles to enhance reliability and efficiency. Chromatographic separation used an Inertsil C18 column (250 × 4.6 mm, 5 µm) with phosphate buffer (pH 3) and methanol (70:30, v/v) at 1.0 mL/min, detecting at 260 nm. Retention times were 2.669 min for Dapagliflozin and 3.855 min for Linagliptin. The method showed excellent linearity ($r^2 > 0.999$) across 10–50 µg/mL and 5–25 µg/mL ranges, respectively. Validation per ICH Q2(R1) confirmed specificity (no excipient interference), accuracy (99.84–100.51% recovery), precision (RSD < 1.5%), LOD (0.08–0.12 µg/mL), LOQ (0.24–0.36 µg/mL), and robustness (<1.5% peak area variation with ±2% mobile phase change). Resolution reached 5.27 with >12,000 theoretical plates for both analytes. DMAIC integration enabled systematic target definition, variability reduction, critical parameter identification, and 35% solvent waste reduction. Development time decreased by 28% while maintaining sustained performance through control charts. This validated method offers a reliable, efficient tool for routine quality control, supporting regulatory expectations for robustness and sustainable laboratory practices.

1. INTRODUCTION

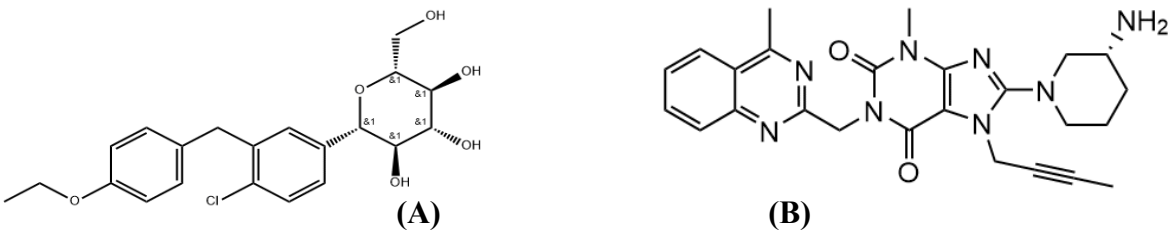
The rising global prevalence of type 2 diabetes demands effective therapeutic strategies that balance glycemic control with patient safety[1]. Dapagliflozin and Linagliptin, newer antidiabetic agents with complementary mechanisms, have emerged

as promising combination therapy options. Their favorable clinical outcomes make them valuable for managing type 2 diabetes effectively[2]. Dapagliflozin and Linagliptin are important antidiabetic agents commonly formulated in combined dosage forms and their chemical structures shown in figure1(a,b).

Given the therapeutic importance of Dapagliflozin and Linagliptin, their simultaneous estimation in pharmaceutical dosage forms is crucial for ensuring product quality, safety, and efficacy. Reliable analytical methods support routine quality control, regulatory compliance, and continuous improvement in pharmaceutical manufacturing. Incorporating Lean Six Sigma (DMAIC) into method development enhances robustness, reduces variability, and aligns analytical practices with global quality standards[3].

Literature reveals several spectrophotometric, HPLC, and HPTLC methods for estimating these drugs individually or in combination with other agents. However, few methods exist for their simultaneous estimation in combined dosage forms using a simple, rapid, stability-indicating RP-HPLC approach[4-12].

The growing use of fixed-dose combinations of Dapagliflozin and Linagliptin demands reliable, efficient analytical methods. Traditional approaches often struggle with reproducibility and resource inefficiency, challenges that structured frameworks like Lean Six Sigma (DMAIC) can address. Integrating these principles into chromatographic method development minimizes variability and enhances sustainability. This study aims to develop and validate a robust RP-HPLC method for simultaneous estimation of Dapagliflozin and Linagliptin in tablets, incorporating Lean Six Sigma to ensure accuracy, precision, regulatory compliance, and continuous improvement in pharmaceutical analysis.



(A) (B)

Figure1: Chemical Structure A) Dapagliflozin and B) Linagliptin

2. EXPERIMENTAL

2.1 Materials and Reagents

Dapagliflozin and Linagliptin working standards were obtained from Hetero Labs. Potassium dihydrogen phosphate (KH_2PO_4), orthophosphoric acid, methanol (HPLC grade), and acetonitrile were procured from standard commercial suppliers such as Merck, Lichrosolv, and Molychem. All reagents used were of analytical or HPLC grade, and purified water was used throughout the analysis.

2.2 Instrumentation

Chromatographic analysis was performed using a Waters HPLC system equipped with a 2695 separation module and a photodiode array (PDA) detector. Data acquisition and processing were carried out using Empower software.

A LABINDIA UV 3000+ UV-visible spectrophotometer was used for wavelength selection. pH measurements were performed using an Adwa AD-1020 pH meter, and weighing was carried out using an Afcoset ER-200A analytical balance. Standard laboratory glassware from Borosil was used.

2.3 Chromatographic Conditions

Separation was achieved using an Inertsil ODS C18 column (4.6 × 250 mm, 5 µm). The mobile phase consisted of phosphate buffer (pH 3.0) and methanol in the ratio of 30:70 v/v. The flow rate was maintained at 1.0 mL/min, and detection was carried out at 260 nm. The injection volume was 10 µL, and the run time was 10 minutes under ambient temperature conditions.

2.4 Preparation of Phosphate Buffer

Phosphate buffer was prepared by dissolving 6.8 g of potassium dihydrogen phosphate in 1000 mL of purified water. The pH was adjusted to 3.0 using orthophosphoric acid.

2.5 Preparation of Mobile Phase

The mobile phase was prepared by mixing phosphate buffer and methanol in the ratio of 30:70 v/v. The prepared mobile phase was degassed by ultrasonication for 10 minutes and filtered through a 0.45 µm membrane filter prior to use.

2.7 Preparation of Standard Solution

Accurately weighed 10 mg of Dapagliflozin and 5 mg of Linagliptin working standards were transferred into a 10 mL volumetric flask. About 7 mL of diluent was added, and the solution was sonicated to dissolve completely, followed by dilution up to the mark with diluent (stock solution).

Further, 0.3 mL of the stock solution was pipetted into a 10 mL volumetric flask and diluted to volume with diluent to obtain the working standard solution.

2.8 Preparation of Sample Solution

Ten tablets were accurately weighed and powdered. A quantity of powder equivalent to 10 mg of Dapagliflozin and 5 mg of Linagliptin was transferred into a 10 mL volumetric flask. About 7 mL of diluent was added, and the solution was sonicated to ensure complete extraction of the drug, followed by dilution to volume with diluent (stock solution).

Further dilution was performed by transferring 0.3 mL of the stock solution into a 10 mL volumetric flask and making up the volume with diluent.

2.9 Method Development

Method development was carried out by evaluating different mobile phase compositions, pH conditions, and chromatographic parameters to achieve optimal separation. Initial trials using water and methanol, as well as buffer-methanol combinations at different pH levels, resulted in peak splitting and poor resolution. Optimized conditions using phosphate buffer (pH 3.0) and methanol (30:70 v/v) provided well-resolved, symmetrical peaks with good system suitability parameters and were selected for further validation.

2.11 Method Validation

The developed RP-HPLC method was validated in accordance with ICH Q2(R1) guidelines for parameters including system suitability, precision, accuracy, linearity, limit of detection (LOD), limit of quantification (LOQ), robustness, and ruggedness.

2.11.1 System Suitability

System suitability was evaluated prior to analysis by injecting the standard solution. The parameters assessed included theoretical plate count and tailing factor. The tailing factor for both Dapagliflozin and Linagliptin was found to be less than 2.0, and the theoretical plates were greater than 2000, confirming acceptable chromatographic performance.

2.11.2 Precision

Precision of the method was evaluated in terms of repeatability by injecting the standard solution six times under the same conditions. The %RSD of peak areas was calculated and found to be within acceptable limits (NMT 2%), indicating good repeatability of the method.

2.11.3 Intermediate Precision (Ruggedness)

Intermediate precision was evaluated by performing the analysis on different days using different columns of the same specification. The %RSD values obtained were within acceptable limits (<2%), demonstrating the reproducibility of the method under varied conditions.

2.11.4 Accuracy

Accuracy was determined by recovery studies at three concentration levels (50%, 100%, and 150% of the target concentration). Known amounts of Dapagliflozin and Linagliptin were added to the pre-analyzed sample, and the mixtures were analyzed. The percentage recovery for both analytes was found to be within the range of 98–102%, indicating the accuracy of the method.

2.11.5 Linearity

Linearity of the method was established by analyzing five different concentration levels in the range of 10–50 µg/mL for Dapagliflozin and 5–25 µg/mL for Linagliptin. Calibration curves were constructed by plotting peak area versus concentration. The method exhibited good linearity with correlation coefficients not less than 0.999 for both analytes.

2.11.6 Limit of Detection (LOD)

The LOD was determined based on signal-to-noise ratio. The LOD corresponded to an S/N ratio of approximately 3 for both Dapagliflozin and Linagliptin, indicating that the method is capable of detecting low concentrations of analytes.

2.11.7 Limit of Quantification (LOQ)

The LOQ was determined based on signal-to-noise ratio of approximately 10. The obtained values confirmed that the method is capable of quantifying the analytes with

acceptable precision and accuracy at low concentration levels.

2.11.8 Robustness

Robustness of the method was evaluated by introducing small deliberate variations in chromatographic conditions, such as changes in flow rate (±0.2 mL/min) and mobile phase composition (±10%). The results indicated no significant variation in system suitability parameters, confirming that the method is robust and reliable under minor variations in analytical conditions.

Application of Lean Six Sigma (DMAIC) Framework:

The method development process was improved by systematic optimization of chromatographic conditions using Lean Six Sigma principles. Define phase was used to define Analytical Target Profile for Dapagliflozin and Linagliptin to obtained sharp symmetrical peaks with lesser run time. The baseline variability of retention time and peak resolution was assessed at different mobile phase compositions and flow rates during the Measure. In the Analyze phase, mobile phase pH and organic modifier ratio were identified as the critical parameters that affected peak splitting and resolution. The optimization was done in the Improve phase by adjusting the pH of phosphate buffer and methanol composition, as well as fine tuning the flow rate, which resulted in consistent retention times and improved peak symmetry. Finally, the Control phase ensured reproducibility with standard operating procedures and retention monitoring. This structured approach minimized variability, reduced solvent waste, and enhanced efficiency, aligning the analytical workflow with continuous improvement and regulatory expectations.

3. RESULTS AND DISCUSSION

3.1 Method Development and Optimization

Method development aimed to achieve sharp, symmetrical peaks with good resolution and minimal run time for Dapagliflozin and Linagliptin. Initial trials with water–methanol mixtures produced peak splitting, while phosphate buffer at pH 4 with methanol also resulted in poor separation. Adjustments using phosphate buffer of varying molarity and pH3.6 with methanol continued to show inadequate resolution, and substitution with acetonitrile offered only slight improvement. Final optimization using phosphate buffer adjusted to acidic pH3.0 with methanol (70:30 v/v) on an Inertsil C18 column provided well-resolved, sharp peaks without splitting. The improved performance at lower pH was attributed to suppression of analyte ionization, enhancing interaction with the non-polar stationary phase. Under these optimized conditions, Dapagliflozin and Linagliptin were eluted at retention times of approximately 2.669 and 3.855 minutes, confirming suitability of the method for routine analysis

3.2 Specificity

Specificity of the method was evaluated by injecting blank and sample solutions. No interfering peaks were observed at the retention times of Dapagliflozin and Linagliptin, confirming the specificity of the method (Figure 6).

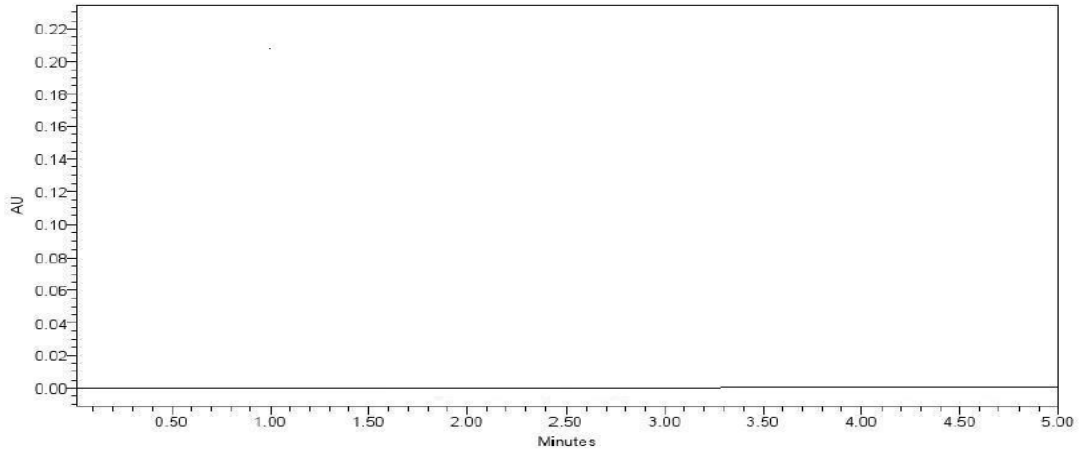


Figure 6: Chromatogram for blank

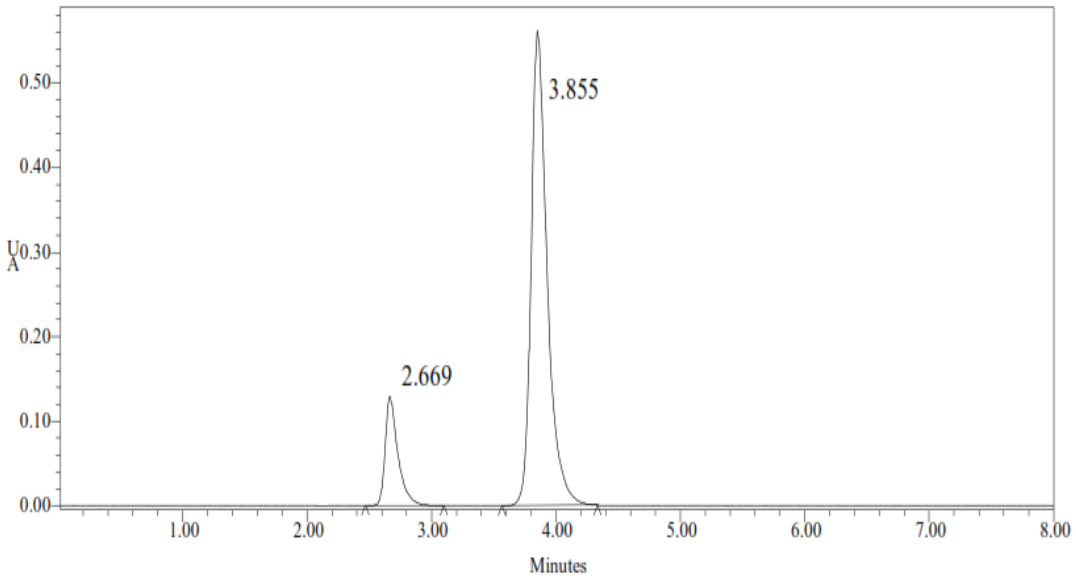


Figure 7: Chromatogram for Dapagliflozin and Linagliptin

3.4 System Suitability

System suitability was evaluated by injecting the standard solution under optimized chromatographic conditions. The chromatogram showed well-defined peaks with good symmetry (Figure 8). The theoretical plate counts were found to be 4668.7 for Dapagliflozin and 6090.3 for Linagliptin, while the tailing factor for both analytes was approximately 1.3, confirming acceptable chromatographic performance.

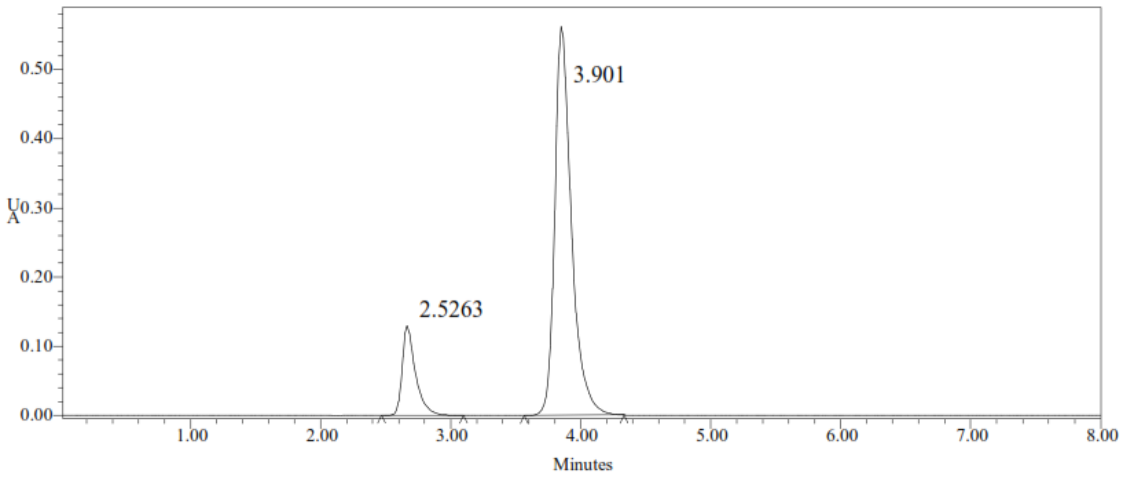


Figure 8: chromatogram for system suitability

3.5 Assay of Marketed Formulation

The developed RP-HPLC method was successfully applied for the assay of Dapagliflozin and Linagliptin in tablet dosage form. The percentage assay was found to be 99.95% for Dapagliflozin and 100.24% for Linagliptin, indicating that the method is accurate and suitable for routine quality control analysis.

3.6 Linearity

Linearity of the method was evaluated over the concentration range of 10–50 µg/mL for Dapagliflozin and 5–25 µg/mL for Linagliptin. A linear relationship between concentration and peak area was observed. The calibration data are presented in Table X, and the corresponding calibration curves are shown in Figures 9 and 13. The correlation coefficient (R^2) was found to be 0.9932 and 0.9929 for dapagliflozin and linagliptin respectively, indicating excellent linearity. The results are summarized in Table 4.

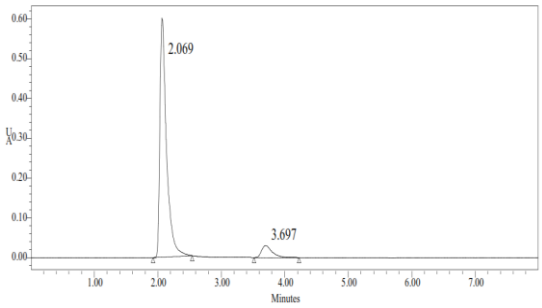


Figure 9: chromatogram for linearity concentration-10µg/ml of Dapagliflozin & 5 µg/ml of Linagliptin

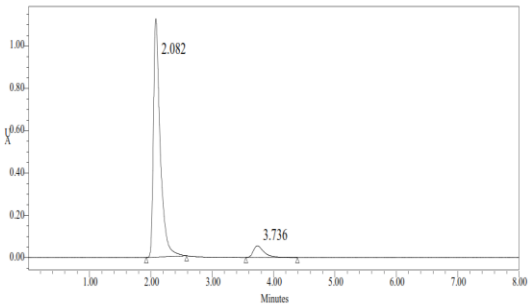


Figure 10: chromatogram for linearity concentration-20 µg/ml of Dapagliflozin & 10 µg/ml of Linagliptin

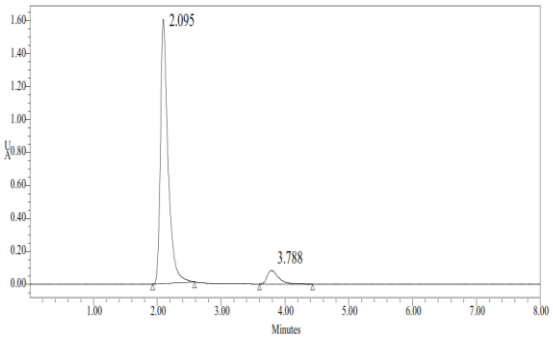


Figure 11: chromatogram for linearity concentration--30 µg/ml of Dapagliflozin & 15 µg/ml of Linagliptin

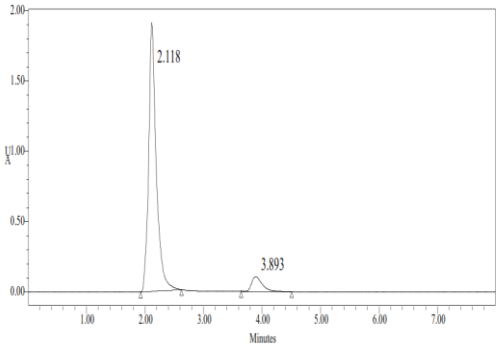


Figure 12: chromatogram for linearity concentration-40ppm of Dapagliflozin & ppm of Linagliptin

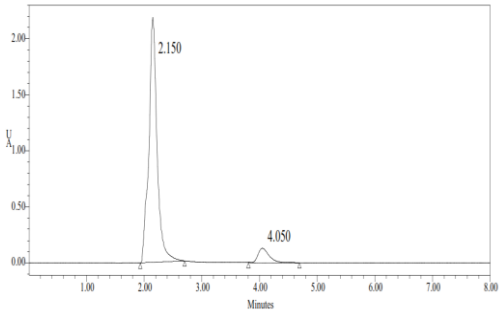


Figure 13: chromatogram for linearity concentration-50 µg/ml of Dapagliflozin & 25 µg/ml of Linagliptin

Table 4: Linearity Data for Dapagliflozin and Linagliptin

S. No.	Linearity Level	Concentration (µg/mL)	Dapagliflozin Area	Linagliptin Area
1	I	10	668934	46510
2	II	20	956781	85701
3	III	30	1313873	114802
4	IV	40	1563458	152731
5	V	50	1867084	179732

Table 5: Analytical performance parameters of Dapagliflozin and Linagliptin

Parameters	Dapagliflozin	Linagliptin
Slope (m)	36675	7122.4
Intercept (c)	84825	7459
Correlation coefficient (R^2)	0.9932	0.9929

3.7 Precision

The precision of the developed method was evaluated by repeatability studies through multiple injections of the standard solution under identical chromatographic conditions. The %RSD values were found to be 0.2% for Dapagliflozin and 0.6% for Linagliptin, indicating excellent repeatability of the method.

The chromatograms obtained from repeated injections are shown in Figures 14, which demonstrate consistent peak shape and retention times. The results are summarized in Table 1.

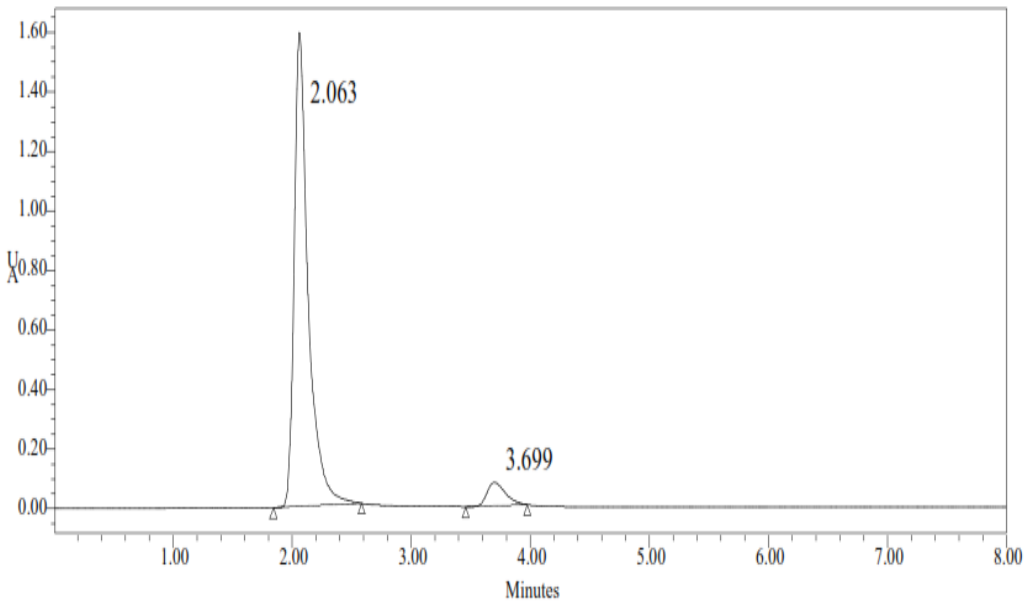


Figure 14: chromatogram for standard

Table 1: Precision Results of Dapagliflozin and Linagliptin

Injection	Dapagliflozin Peak Area	Linagliptin Peak Area
1	1302729	123149
2	1302947	123766
3	1303236	124271
4	1303977	124691
5	1309759	124956
Mean	1304529.8	124162.7
Standard Deviation	2961.1	725.6
%RSD	0.2	0.6

3.7 Intermediate Precision (Ruggedness)

Intermediate precision of the method was evaluated by performing the analysis under varied conditions such as different days and different columns of the same specification. The %RSD values were found to be less

than 2%, indicating good reproducibility of the method.

The chromatograms obtained under varied conditions are shown in Figures 15, demonstrating consistent peak shape and retention times. The results are summarized in Table 2.

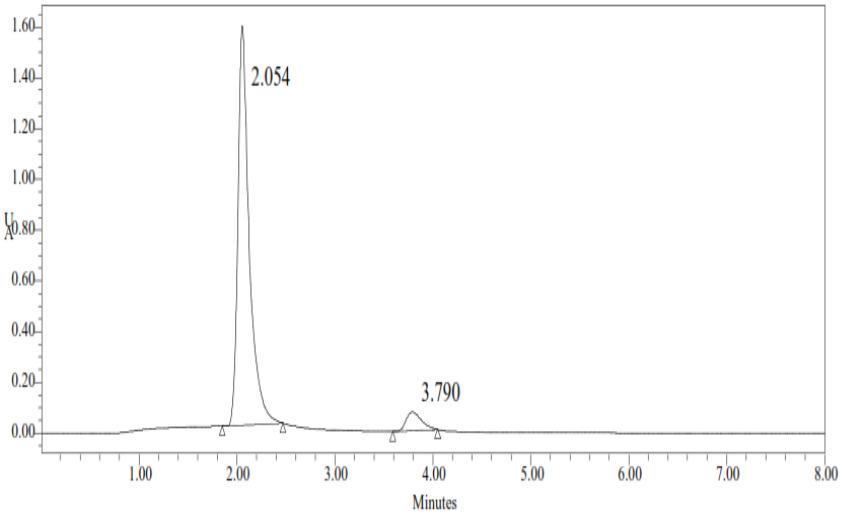


Table 2: Intermediate Precision Results

Injection	Dapagliflozin Peak Area	Linagliptin Peak Area
1	1300148	122487
2	1304520	122626
3	1305937	122632
4	1306476	122702
5	1308710	122962
Mean	1305070.2	122681.8
Standard Deviation	3061.8	174.8
%RSD	0.2	0.1

3.8 Accuracy

Accuracy of the method was evaluated by recovery studies at three concentration levels (50%, 100%, and 150%). The percentage recovery was found to be within the acceptable range of 98–102% for both Dapagliflozin and Linagliptin, indicating the accuracy of the method. The chromatograms corresponding to different concentration levels are shown in Figures 20–28. The results are summarized in Table 3.

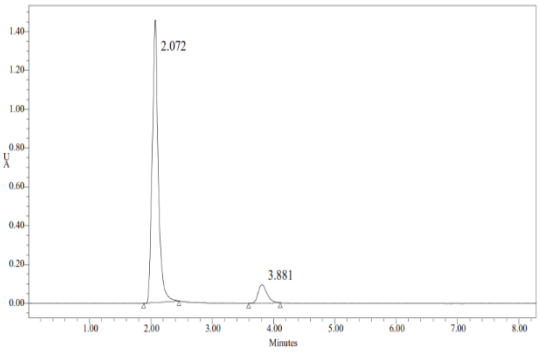


Figure 20: chromatogram for sample concentration-50%

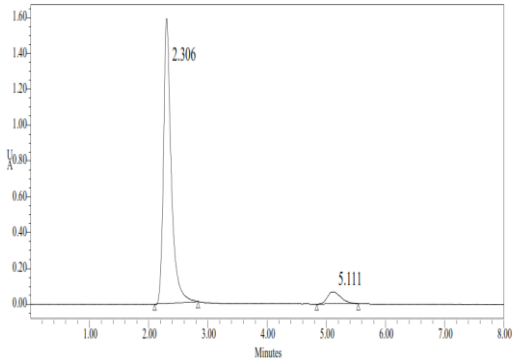


Figure 23: chromatogram for sample concentration-100%

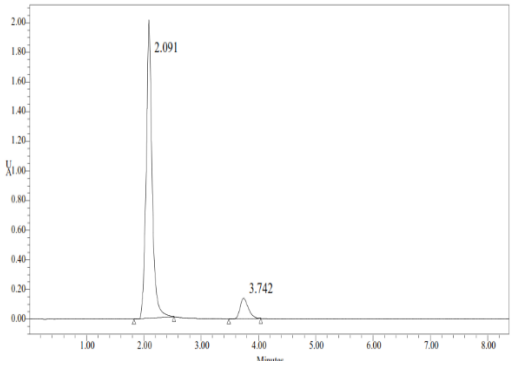


Figure 26: chromatogram for sample concentration-150%

Table 3: Accuracy (Recovery) Results for Dapagliflozin and Linagliptin

Drug	Level (%)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
Dapagliflozin	50	656659.5	5.0	5.036	100.7	99.84%
Dapagliflozin	100	1304258	10.0	10.003	100.0	
Dapagliflozin	150	1854608	14.4	14.224	98.78	
Linagliptin	50	65800	5.3	5.34	100.8	100.51%
Linagliptin	100	124353	10.0	10.10	100.01	
Linagliptin	150	177940	14.2	14.45	99.68	

3.10 Limit of Detection (LOD) and Limit of Quantification (LOQ)

The sensitivity of the developed method was evaluated in terms of limit of detection (LOD) and limit of quantification (LOQ) based on signal-to-noise ratio.

The LOD was found to correspond to an S/N ratio of approximately 3, while the LOQ corresponded to an S/N ratio of approximately 10 for both analytes. The results indicate that the method is

sufficiently sensitive for the detection and quantification of Dapagliflozin and Linagliptin at low concentrations. The chromatograms corresponding to LOD and LOQ are shown in Figures 34 and 35. The results are summarized in Table 6.

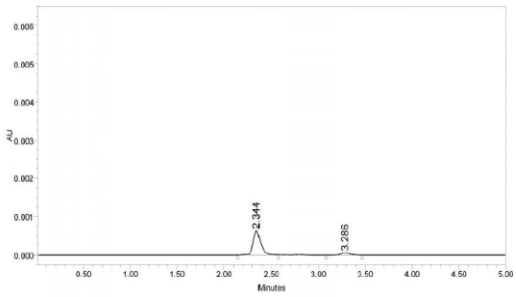


Figure 34: chromatogram of Dapagliflozin & Linagliptin showing LOD

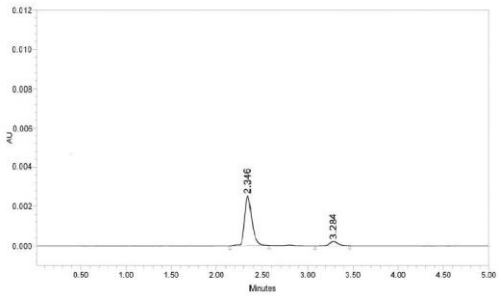


Figure 35: chromatogram of Dapagliflozin & Linagliptin showing LOQ

Table 6: LOD and LOQ Results for Dapagliflozin and Linagliptin

Parameter	Drug	Baseline Noise (µV)	Signal (µV)	S/N Ratio
LOD	Dapagliflozin	52	152	2.9
LOD	Linagliptin	52	156	3.0
LOQ	Dapagliflozin	52	522	10.03
LOQ	Linagliptin	52	524	10.1

3.11 Robustness

Robustness of the developed method was evaluated by introducing small deliberate variations in chromatographic conditions, including changes in flow rate and mobile phase composition. The results showed no significant changes in system suitability parameters such as theoretical plate count and tailing factor, indicating that the method is robust.

The chromatograms obtained under varied conditions are shown in Figures 36–39. The results are summarized in Table 7.

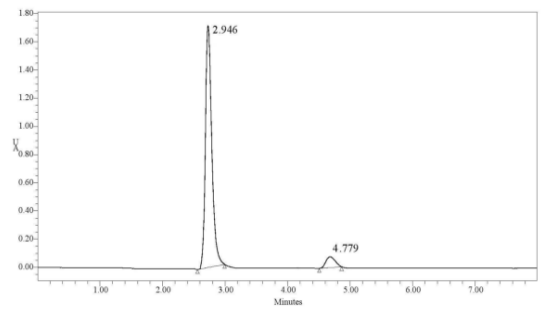


Figure 36: chromatogram snowing less flow of 0.6ml/min

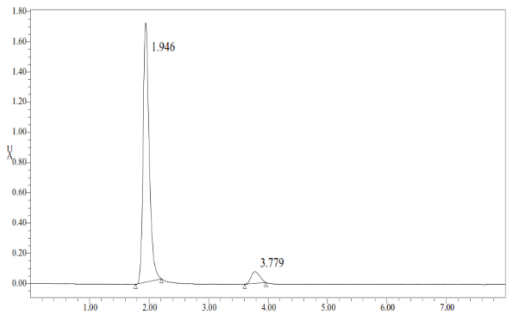


Figure 37: chromatogram snowing more flow of 1.0ml/min

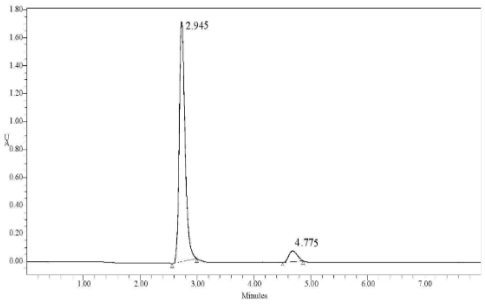


Figure 38: chromatogram showing less organic composition

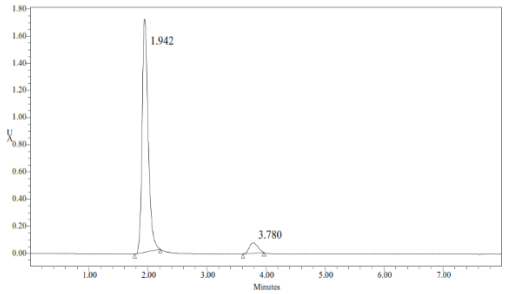


Figure 39: chromatogram showing more organic composition

Table 7: Robustness Results for Dapagliflozin and Linagliptin

(a) Effect of Flow Rate

Flow Rate (mL/min)	Drug	Plate Count	Tailing Factor
0.6	Dapagliflozin	5339.9	1.4
0.8	Dapagliflozin	4673.4	1.3
1.0	Dapagliflozin	5216.0	1.4
0.8	Linagliptin	7063.3	1.3
1.0	Linagliptin	6090.3	1.2
1.2	Linagliptin	6998.0	1.3

(b) Effect of Mobile Phase Composition

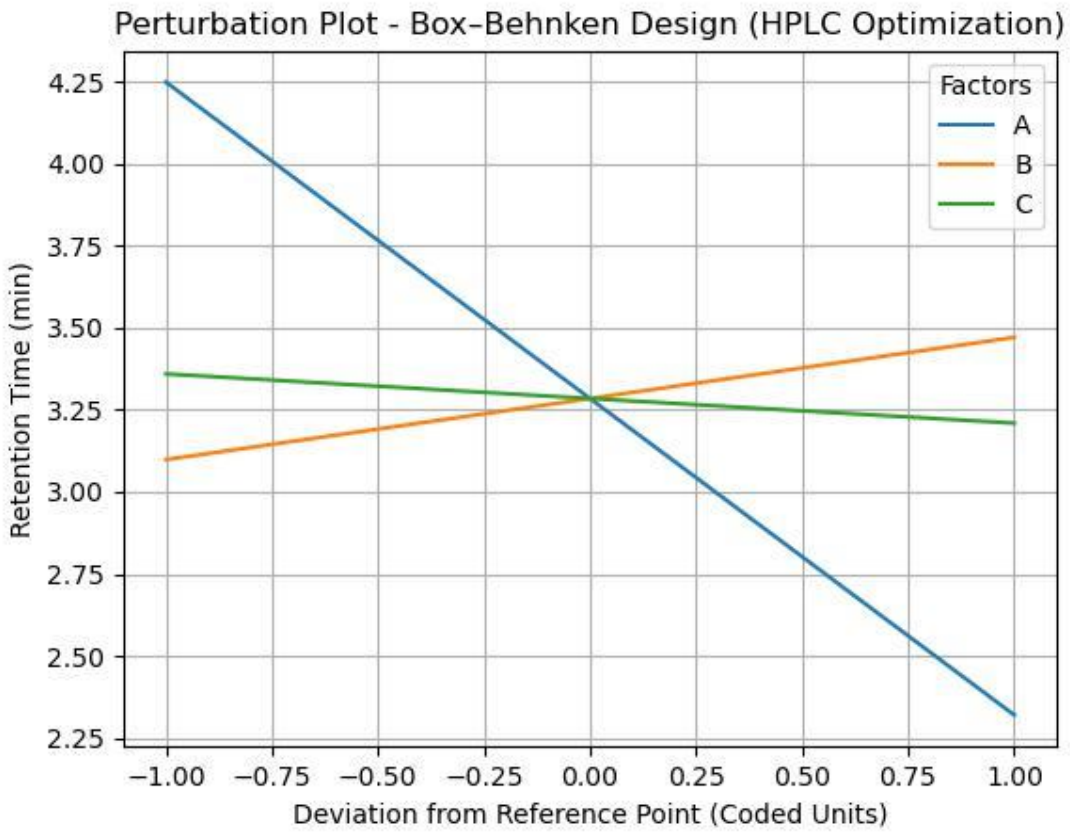
Condition	Drug	Plate Count	Tailing Factor
10% Less	Dapagliflozin	4508.4	1.3
Actual	Dapagliflozin	4673.4	1.4
10% More	Dapagliflozin	4318.1	1.3
10% Less	Linagliptin	6387.7	1.2
Actual	Linagliptin	6090.3	1.2
10% More	Linagliptin	6232.5	1.2

Application of the Lean Six Sigma (DMAIC):

Using the DMAIC structure from Lean Six Sigma helped us systematically fine-tune the chromatographic conditions—specifically mobile-phase composition, flow rate, and retention time. After optimization, the method produced runs

under 4 minutes, peak asymmetry below 2.0, and a steady flow of 1.0 mL/min.

In the Measure phase, initial experiments showed wide variation in retention time (2.1–5.1 min) and peak symmetry (1.01–2.23), indicating the need for improvement. An FMEA during the Analyze phase flagged mobile-phase composition, flow rate, and pH as critical method parameters. We then applied a Box–Behnken design and ANOVA: mobile-phase composition had the strongest effect on retention time, while both mobile-phase composition and pH were the main drivers of peak symmetry. Overall, this combined Lean Six Sigma and RSM approach delivered a fast, robust, and reproducible HPLC method.



4. Conclusion

Implementation of the Lean Six Sigma (DMAIC) framework successfully streamlined HPLC method development by integrating statistical design of experiments. Optimization of mobile phase composition, flow rate, and pH resulted in a robust method with retention times retention times of 2.669 min for Dapagliflozin and 3.855 min for Linagliptin peak asymmetry consistently below 2.0,

and a stable flow rate of 1.0 mL/min. Preliminary variability in retention time (2.1–5.1 min) and peak symmetry (1.01–2.23) was effectively addressed through systematic analysis. FMEA identified mobile phase composition, flow rate, and pH as critical method parameters, and subsequent Box–Behnken design with ANOVA confirmed mobile phase composition as the dominant factor influencing retention time, while both mobile phase composition and pH significantly impacted peak symmetry. The integrated approach demonstrates that Lean Six Sigma, coupled with response surface methodology, provides a reliable pathway for achieving efficient, reproducible, and regulatory-compliant chromatographic performance.

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