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Stability Indicating Analytical Method Development and Validation of Anti-Diabetic Drug Dapagliflozin Bulk

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ABSTRACT
An exceedingly effective, reversible, and particular inhibitor of sodium-glucose cotransporter-2, Dapagliflozin is affirmed for the treatment of type 2 diabetes (T2D) all through the world. It is given to people to improve glycaemic management. Type 2 diabetes mellitus (T2DM) is a chronic, progressive illness which has been recognised as a major health issue which is having a substantial impact on both life expectancy and medical costs. Blood glucose levels rise as a result of the disease's loss in beta cell activity. The present study is intended to develop and validate stability indicating validated RP-HPLC method for determining the oral anti-diabetic medication Dapagliflozin in bulk. A novel, simple, quick, accurate, precise and consistent RP-HPLC method was developed for the drug in study i.e. Dapagliflozin. The chromatographic separation of Dapagliflozin was achieved on RP-HPLC equipped with C18 (150 mm×4.6 mm, 5 µm) column. Mobile phase (Buffer Solution: ACN) composed of 55 volumes of buffer solution and 1.36 gram of potassium dihydrogen orthophosphate was dissolved in 1000 ml HPLC water and then pH was balanced utilizing weaken phosphoric acid to a pH of 2.0 and 45 volumes of acetonitrile. Then it was mixed well and sonicated to degas and then filtered. The retention time of the Dapagliflozin was found to be 3.38 with excellent absorbance sensitivity at 225 nm wavelength. The linear regression equation was found to be (y = 28916x + 16389) with a correlation coefficient R^2 = 1.0000 which shows excellent linear correlation. Specificity, linearity, precision, accuracy robustness, degradation was determined for method validation and results were found to be well within recommended limits as per ICH guidelines..

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Keywords: Dapagliflozin; Type 2 diabetes; RP-HPLC; Method Development; Validation

1. INTRODUCTION

1.1 Drug Description

Dapagliflozin belongs to class of medications called as sodium-glucose co transporter-2 inhibitor which is commonly used for the treatment of Type-2 mellitus diabetes. Type-2 diabetes mellitus (T2DM) is a condition in which there is persistently high blood sugar (Hyperglycaemia) since the body stops itself from using insulin property. It's a prevalent, progressive disease and the rising prevalence of type 2 diabetes (T2D) is a severe concern in healthcare all over the world. Dapagliflozin is an innovative restorative agent which is as of late being utilized for the treatment of T2DM. Moreover, it has been found that it is beneficial for the people who cannot take metformin. This Drug works by reducing the reabsorption of the glucose and also sodium in the proximal tubule of kidney thus enhancing glucose and sodium excretion. Moreover, it's also found that along with having glucose lowering effect dapagliflozin also has diuretic effects and also plays role in decreases blood pressure and weight of the respective individual.

2. MATERIALS AND METHODS

2.1 Drug Profile

Structure:

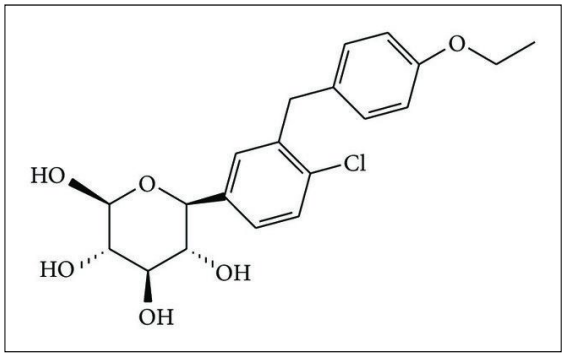

Figure 1: Structure of Dapagliflozin

General profile of Dapagliflozin:

Category: Anti-diabetic Agent

Chemical Name: (2*S*,3*R*,4*R*,5*S*,6*R*)-2-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-6- (hydroxymethyl)oxane-3,4,5-triol

Molecular Formula: $C_{21}H_{25}ClO_6$

Molecular Weight: 408.873 g/mol

pKa: 12.6

Mechanism of Action: Dapagliflozin restrains the sodium-glucose cotransporter 2(SGLT2) which is basically found in the proximal tubule of the nephron. This excretion permits for superior glycemic control and possibly weight loss in patients with type 2 diabetes mellitus SGLT2 encourages 90% of glucose reabsorption in the kidneys and so its hindrance permits for glucose to be excreted in the urine.

2.2 Initialization of RP-HPLC Method

2.2.1 Identification of Dapagliflozin by FTIR

Dapagliflozin powder (1–2 mg) was triturated with spectroscopic grade potassium bromide (300–400 mg). The mixture was ground thoroughly in an agate mortar to obtain a uniform blend. Pellet was prepared by compressing the mixture under high pressure and was mounted in the sample holder. FTIR spectrum was recorded for analysis.

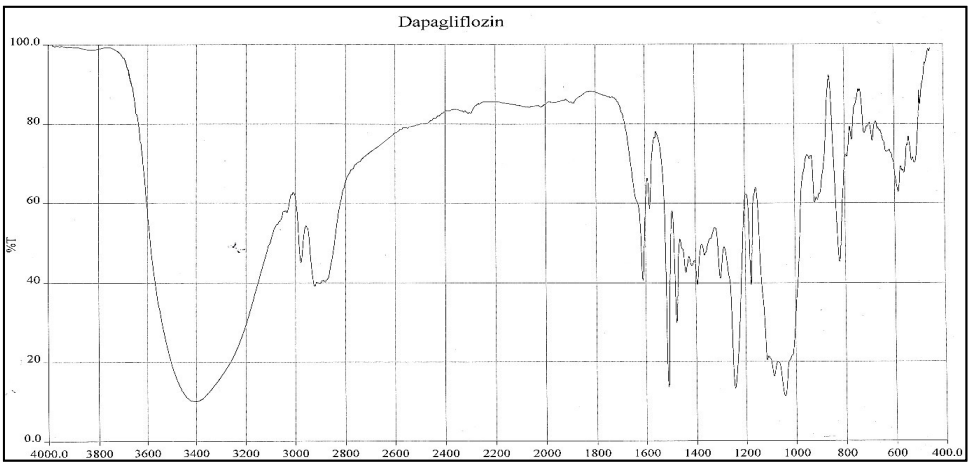

Figure 2: FTIR spectrum for Dapagliflozin

2.2.2 Selection of mobile phase

Table 1: Solubility of Dapagliflozin

Solvents	Dapagliflozin
Water	Freely soluble
Methanol	Soluble
Acetonitrile	Soluble
Ethanol	Soluble
0.1M NaOH	Sparingly soluble

Solubility of API of Dapagliflozin was checked in various solvents like water, acetonitrile, methanol, ethanol, water: acetonitrile, ortho phosphoric acid, water: methanol, etc. Acetonitrile and HPLC water were selected as the mobile phase not only because of the best drug solubility, but also due to the easy availability and low cost.

2.2.3 Preparation of Mobile Phase

Mixture of Buffer Solution and Acetonitrile in the proportion (55: 45) was prepared and utilized as the mobile phase.
Buffer Solution: 1.36 gram of Potassium Dihydrogen Phosphate was dissolved in 1000 ml HPLC water and then pH was adjusted to 2.0 by dilute phosphoric acid. Then it was mixed well and sonicated to degas and then filtered with 0.45µ membrane filter.

2.2.4 Preparation of diluent

Mixture of HPLC Water and Acetonitrile in the proportion (50 : 50) was prepared and utilized as the diluent.

2.2.5 Preparation of Blank

Diluent was used as blank.

2.2.6 Preparation of standard stock solution

A 1000 PPM solution of Dapagliflozin API was prepared and used as the standard stock solution. 100 mg drug was weighed and transferred to a 100 ml volumetric flask. Then 15ml of diluent was added to it, and the volumetric flask was shaken for thorough mixing and kept in the sonicator for 10 minutes. Finally, volume makeup was done using the diluent.

2.2.7 Preparation of standard solution

A 1000 PPM solution of Dapagliflozin was prepared as the standard stk. solution. 5 ml of the above standard stock solution was taken in 100 ml volumetric flask. Some amount of diluent around 10 ml was added to it and sonicated for 10 minutes. Finally, volume was made up to 100 ml using the diluent.

2.2.8 Preparation of test solutions

- **25 ppm:** 2.5 ml solution was taken from the standard stock solution in 100 ml volumetric flask. Small amount of diluent around 5 ml was added to it and sonicated for 10 minutes. Finally, volume was made up to 100 ml using the diluent.
- **37.5 ppm:** 3.75 ml solution was taken from the standard stock solution in 100 ml volumetric flask. Small amount of diluent around 5 ml was added to it and sonicated for 10 minutes. Finally, volume was made up to 100 ml using the diluent.
- **50 ppm:** 5.0 ml solution was taken from the standard stock solution in 100 ml volumetric flask. Small amount of diluent around 5 ml was added to it and sonicated for 10 minutes. Finally, volume was made up to 100 ml using the diluent.
- **62.5 ppm:** 6.25 ml solution was taken from the standard stock solution in 100 ml volumetric flask. Small amount of diluent around 5 ml was added to it and sonicated for 10 minutes. Finally, volume was made up to 100 ml using the diluent.
- **75 ppm:** 7.5 ml solution was taken from the standard stock solution in 100 ml volumetric flask. Small amount of diluent around 5 ml was added to it and sonicated for 10 minutes. Finally, volume was made up to 100 ml using the diluent.

2.2.9 Selection of Detection Wavelength

Solution of Dapagliflozin was prepared in methanol. UV spectrum was obtained by scanning solution over the entire range (200-400). Dapagliflozin showed maximum absorbance at 225 nm and was selected as the detection wavelength.

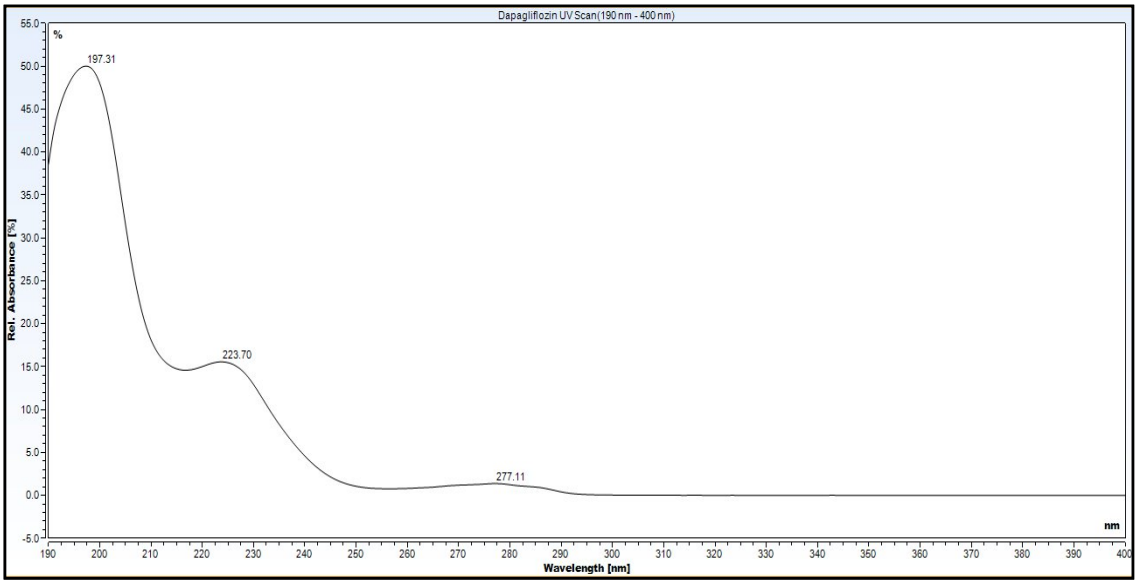

Figure 3: Chromatogram for Scanned UV Range

2.3 Chromatographic conditions

Table 2: Optimized chromatographic conditions used to validate the proposed method.

Sr. No.	Parameters	Chromatographic conditions
1.	**HPLC System**	ThermoScientific Dionex 3000
2.	**Software used**	Chromeleon 7
3.	**Column**	C18 (150 mm×4.6 mm, 5 µm)
4.	**Column Temperature**	25 C
5.	**Flow Rate**	1 ml/min
6.	**Injection Volume**	10 µL
7.	**Wavelength**	225 nm
8.	**Run Time**	15 min
9.	**Mobile Phase**	Buffer : ACN
10.	**Elution Mode**	Isocratic

3. RESULTS AND DISCUSSION

Validation of optimized method of Dapagliflozin by RP-HPLC method.

3.1 System Suitability

System suitability was checked for the drug of concentration 50µg/ml of Dapagliflozin. The retention time (RT), theoretical plates, asymmetry factor, % Relative SD were calculated and was found to be above acceptance criteria.

Table 3: System Suitability Study Result of Dapagliflozin

Parameter	Achieved Value	Acceptance Criteria
Theoretical plates	4874	> 2000
Tailing factor	1.07	≤ 2
%RSD of Area	0.10	≤ 2

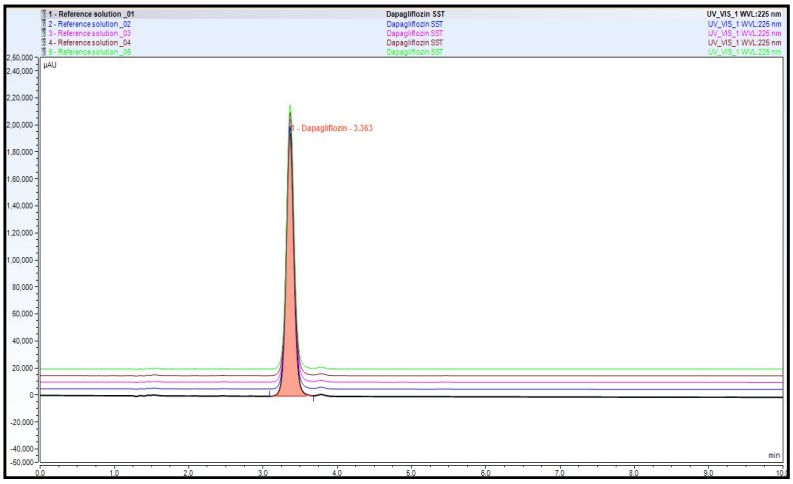

Figure 4: Overlayed Chromatogram for SST

3.2 Specificity:

The specificity of the method was performed by injecting diluent as blank and drug solution in concentration 50µg/ml of Dapagliflozin. No interference from the diluent at RT of Dapagliflozin was detected when comparing both blank and standard solution. The method was found to be workable and specific to detect dapagliflozin.

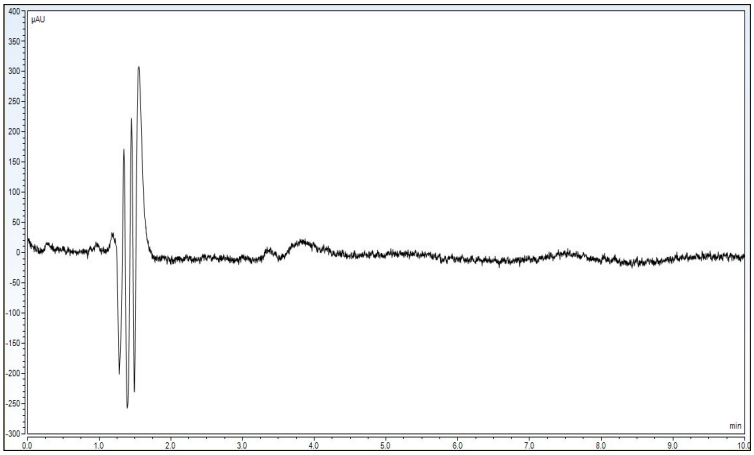

Figure 5: Chromatogram for blank

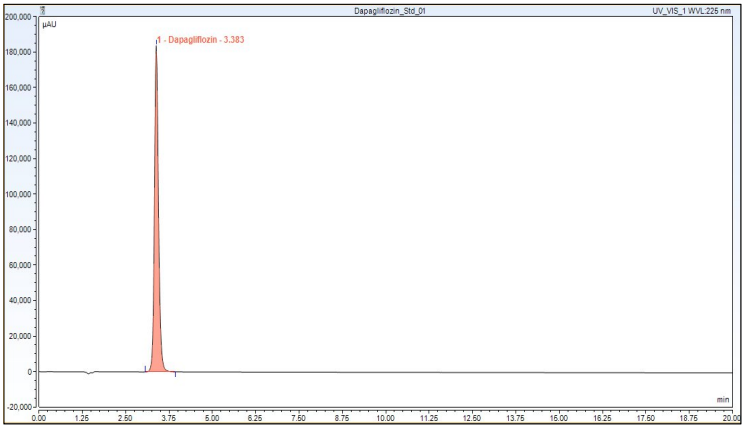

Figure 6: Chromatogram for standard Dapagliflozin

3.3 Accuracy:

To determine the accuracy of the method 3 different levels of concentration (50 %, 100 %, & 150 %) was injected in triplicate (3 times) according to ICH guidelines. Standard addition method was used for this analysis and accuracy determination. The results obtained were in complete compliance with the prescribed range and were demonstrated in the terms of % Recovery.

Table 4: Result of Accuracy of Dapagliflozin (50 - 150 % Concentration)

Sr. No.	Accuracy Levels	Accuracy (%)	Mean	SD	RSD (%)
1.	At 50% Level -01	98.10	98.44	0.36	0.37
2.	At 50% Level -02	98.82			
3.	At 50% Level -03	98.40			
4.	At 100% Level -01	100.20	100.67	0.77	0.76
5.	At 100% Level -02	101.55			
6.	At 100% Level -03	100.25			
7.	At 150% Level -01	100.82	100.82	0.48	0.48
8.	At 150% Level -02	101.31			
9.	At 150% Level -03	100.34			
Overall Mean			**99.98**	**1.25**	**1.25**

The method passed the test, and RSD was found to be less than 2.0 %.

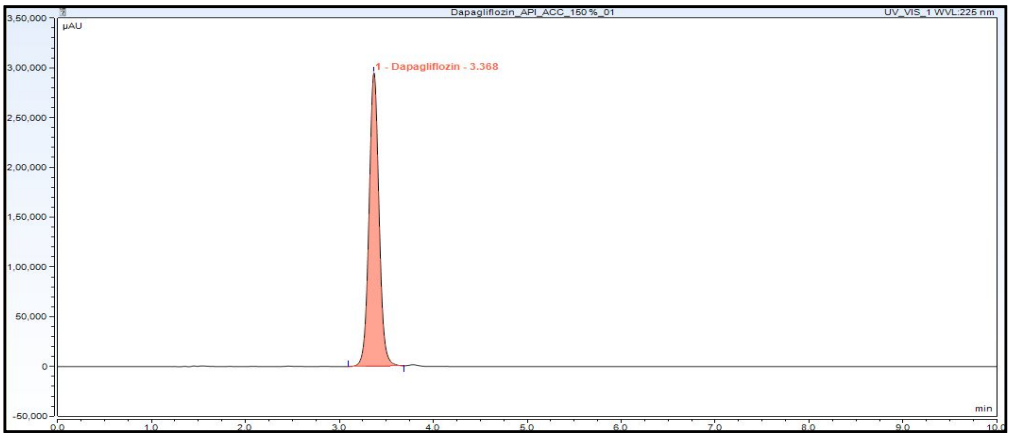

Figure 7: Chromatogram for blank

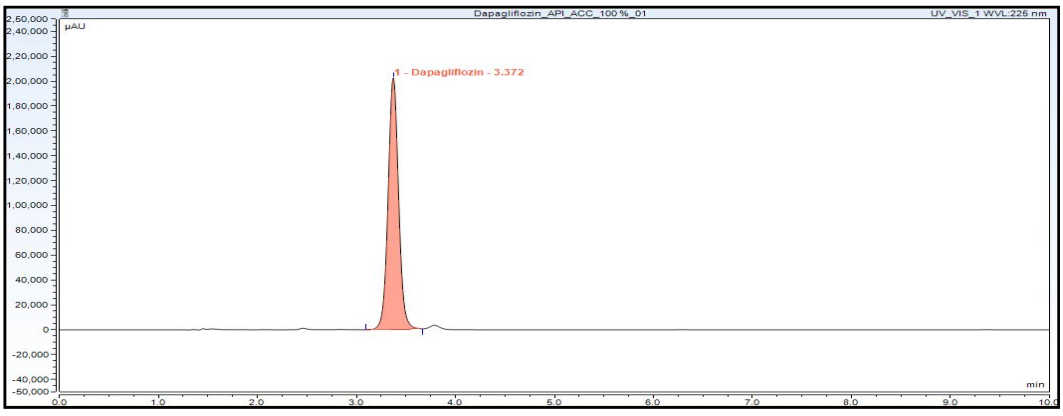

Figure 8: Chromatogram for blank

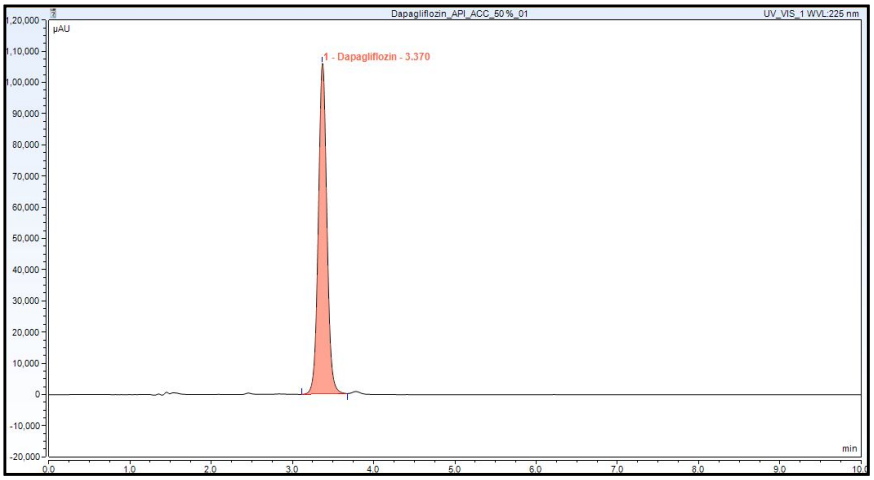

Figure 9: Chromatogram for blank

3.4 Linearity:

Linearity was established along the standard curve. Five different volumes 25, 37.5, 50, 62.5, 75µg/ml were injected in the HPLC. The regression coefficient and correlation coefficient (R square value) were calculated. The calibration curve was plotted between the concentration (µl/ml) and average area response. A linear relationship between peak responses vs. concentration was observed in the range of study.

Table 5: Result of Linearity of Dapagliflozin (25-75 PPM)

Sr. No.	Conc. (µg/ml)	Dapagliflozin Area Count
1.	25	733887
2.	37.5	1103649
3.	50	1466335
4.	62.5	1828154
5.	75	2178872

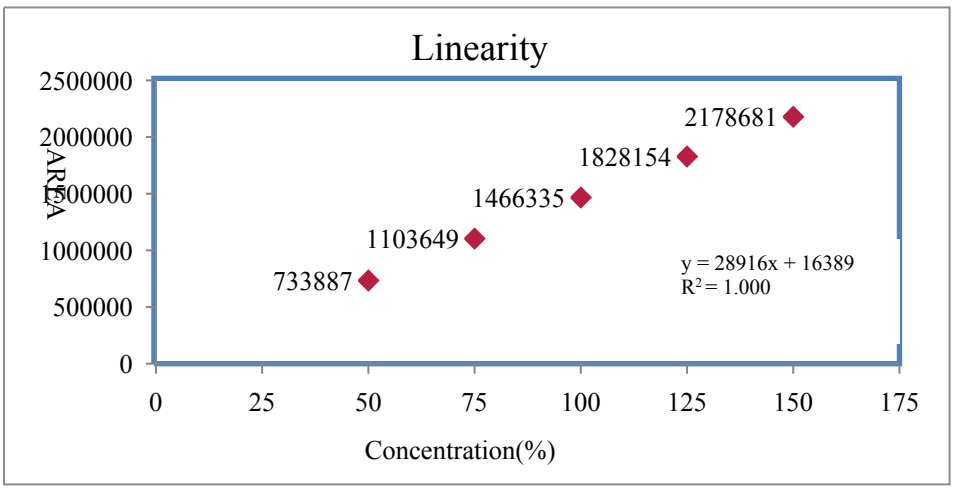

Figure 10: Linearity graph of Dapagliflozin API

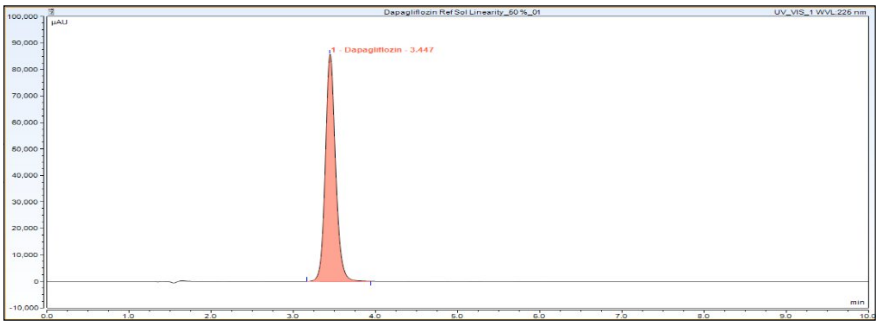

Figure 11: Linearity 25 PPM Solution (50%)

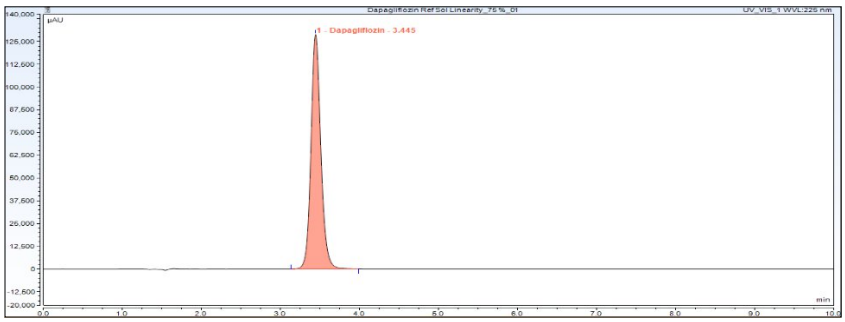

Figure 12: Linearity 37.5 PPM Solution (75%)

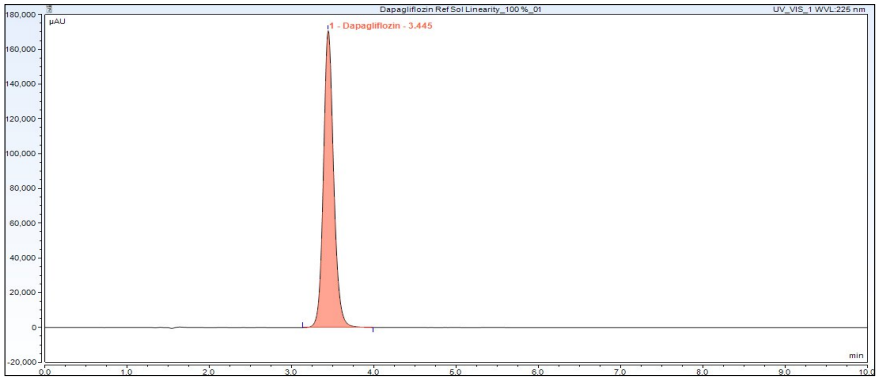

Figure 13: Linearity 50 PPM Solution (100%)

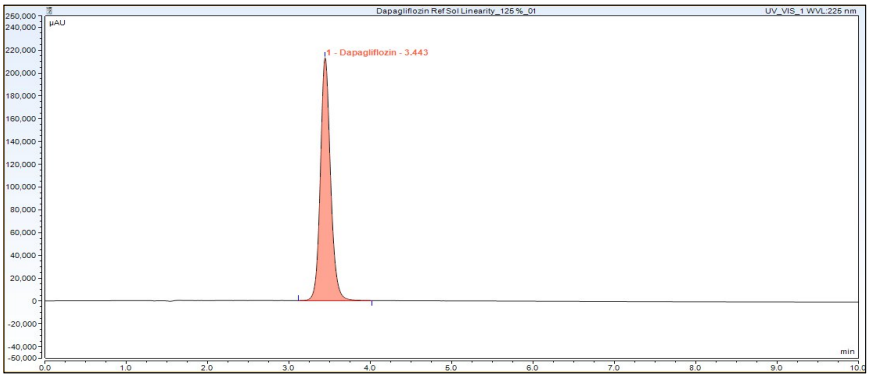

Figure 14: Linearity 62.5 PPM Solution (125%)

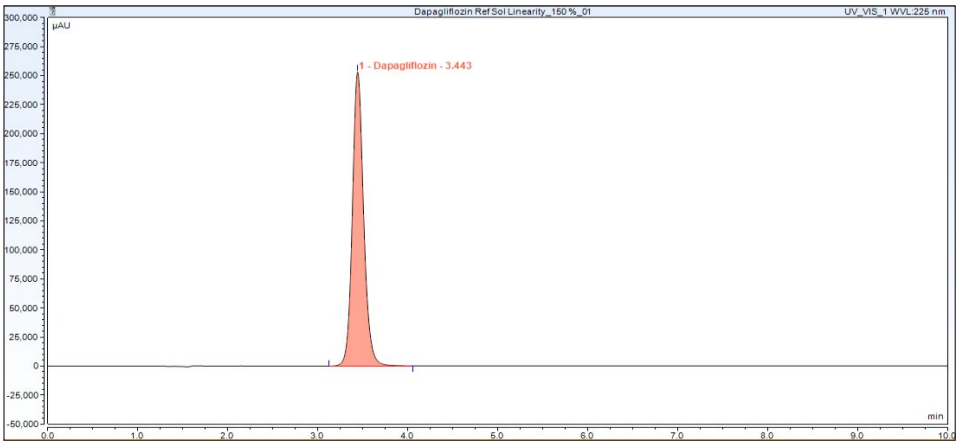

Figure 15: Linearity 75 PPM Solution (150%)

The method passed the test and RSD value was found less than 2.0 %.

A regression coefficient of 1.000 between the standard drug concentration and corresponding mean area under the curve show a good linearity of the standard curve. The other parameters under the regression analysis also support a good linearity of the regression curve and a most optimal linear range of 25 to 75µg/ml.

3.5 Precision

A solution of 50µg/ml solution of Dapagliflozin was prepared and Precision was carried out. Procedure followed for Intraday precision and Inter-day precision are given. The analytical method is precise when the values of a multiple sampled series of the same analyte are very close to each other.

3.5.1 Repeatability

Repeatability expresses the accuracy beneath the same working conditions over a brief interval of time. Repeatability is also termed intra-assay precision. Repeatability was assessed by analysing 50 PPM concentration 6 times on same day. Six Reps of Dapagliflozin was performed and %RSD was calculated as follows:

Table 6: Result of Repeatability Study (Intra Day) of Dapagliflozin (50 PPM)

Sr. No	Area	% Assay
1.	1516045	98.60
2.	1521315	98.24
3.	1540558	99.37
4.	1529940	99.40
5.	1534987	100.45
6.	1533714	100.03
AVG	1529427	99.35
STD	9147	0.84
%RSD	**0.60**	**0.84**

The method passed the test as the RSD was less than 2%.

3.5.2 Intermediate Precision

Intermediate precision achieved when an analytical procedure produces the same results within-laboratories variations: different days, different analysts, different equipment, etc. Intermediate Precision was assessed by analysing 50 PPM concentration 6 times on two different days.

Day 1: Six Reps of Dapagliflozin was performed for inter-day precision and %RSD was calculated as follows:

Table 7: Result of Intermediate Precision (Inter Day-1) of Dapagliflozin (50 PPM)

Sr. No.	Area	% Assay
1.	1511245	98.29
2.	1515462	98.65
3.	1525478	98.41
4.	1512450	98.27
5.	1514586	99.13
6.	1513244	98.71
AVG	1515411	98.58
STD	5155	0.33
%RSD	**0.34**	**0.33**

The method passed the test as the RSD was less than 2%.

Day 2: Six Reps of Dapagliflozin was performed for inter-day precision and %RSD was calculated as follows:

Table 8: Result of Intermediate Precision (Inter Day-2) of Dapagliflozin (50 PPM)

Sr. No.	Area	% Assay
1.	1501313	98.53
2.	1501245	98.08
3.	1515782	99.25
4.	1501450	98.91
5.	1513436	99.06
6.	1512245	98.65
AVG	1507579	98.75
STD	6933	0.42
%RSD	**0.46**	**0.42**

The method passed the test as the RSD was less than 2%.

3.6 Robustness

The Robustness of method validated for the slight change in flow rate, slight change in mobile phase composition and change in wavelength. From the observations it was found that method is robust with slight change in chromatographic parameter as shown in Table 8.

Table 9: Result of Robustness of Dapagliflozin

Change in Flow Rate						
Sr. No.	**Flow Rate (ml/min)**	**Retention Time**	**Area**	**Mean**	**SD**	**RSD (%)**
1.	**0.8**	3.410	1506044	1502316	10445	**0.70**
2.	**1.0**	3.385	1510385			
3.	**1.2**	3.326	1490518			
Change in Mobile Phase Ratio						
Sr. No.	**Ratio (Buffer: ACN)**	**Retention Time**	**Area**	**Mean**	**SD**	**RSD (%)**
1.	**68.5: 31.5**	3.421	1496015	1495958	4645	**0.31**
2.	**55: 45**	3.381	1491285			
3.	**41.5: 58.5**	3.378	1500575			
Change in Mobile Phase pH						
Sr. No.	**pH (± 0.5)**	**Retention Time**	**Area**	**Mean**	**SD**	**RSD (%)**
1.	**1.5**	3.411	1531241	1531988	7813	**0.51**
2.	**2.0**	3.388	1524575			
3.	**2.5**	3.332	1540148			
Change in Wavelength						
Sr. No.	**Wavelength (nm)**	**Retention Time**	**Area**	**Mean**	**SD**	**RSD (%)**
1.	**223**	3.381	1496458	1500942	9536	**0.64**
2.	**225**	3.382	1511894			
3.	**227**	3.382	1494474			

3.7 Force degradation study

Force degradation studies are carried out under four stress conditions acidic condition, alkali condition, H_2O_2 and thermal stress. Using the Dapagliflozin standard, different forced degradation conditions were used to partially degrade the medication. According to ICH Q1A (R2) requirements, the proposed research has been conducted to design an appropriate analytical method that separates pure drug peak from degradation compounds. Furthermore, the investigations outline the circumstances in which the medication is unstable, offering further details so that suitable safety measures can be implemented throughout the formulation process to prevent any instabilities. The procedure followed during Force degradation is given below:

Table 10: Results of Force Degradation studies of Dapagliflozin

Mode of Degradation	Condition	Assay (%)	Degradation (%)
Control	No Treatment	98.6	-
Acidic degradation	Add 5ml 0.1N HCl in mixed test solution+ stand for 1 hour+ neutralize with same concentration of alkali.	97.8	0.8
Alkali degradation	Add 5ml 0.1N NaOH in mixed test solution+ stand for 1 hour+ neutralize with same concentration of acid.	98.5	0.1
Peroxide degradation	Add 30% - 5mL H2O2	92.1	6.5
Thermal degradation	Treated at increased temperature (80°C) for 24 hours.	95.2	3.4
Photolytic Degradation (Light)	Light exposure of sample – 24 hours	96.1	2.5

3.8 Filter Compatibility study

Force Sample Solutions were filtered using different Syringe filters and the percent difference in their areas were compared to centrifuged sample. The method will pass the test if the Absolute Percent (%) Area Difference was less than 2%.

Table 11: Result of Filter Compatibility Study

Difference in Area (%)		
Filter Type	**Area (Average)**	**% Area Difference**
Centrifuged	1465514	**0.00**
PVDF Filter	1482925	**-1.19**
NYLON Filter	1452304	**0.90**

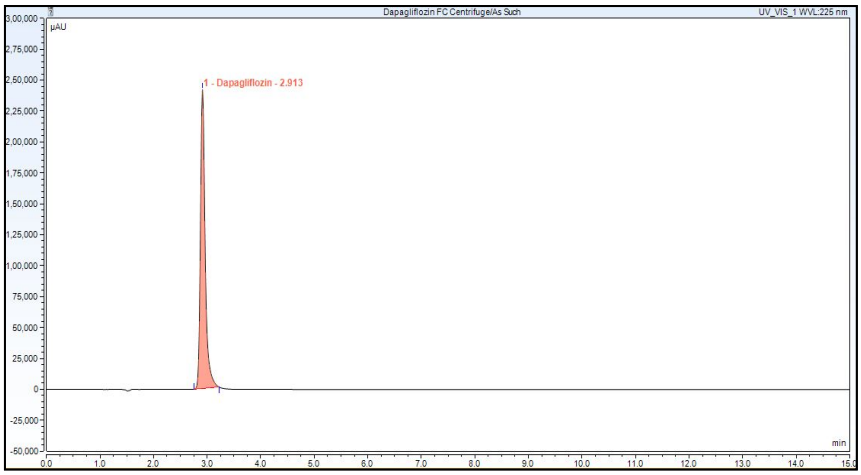

Figure 16: Chromatogram for standard Dapagliflozin

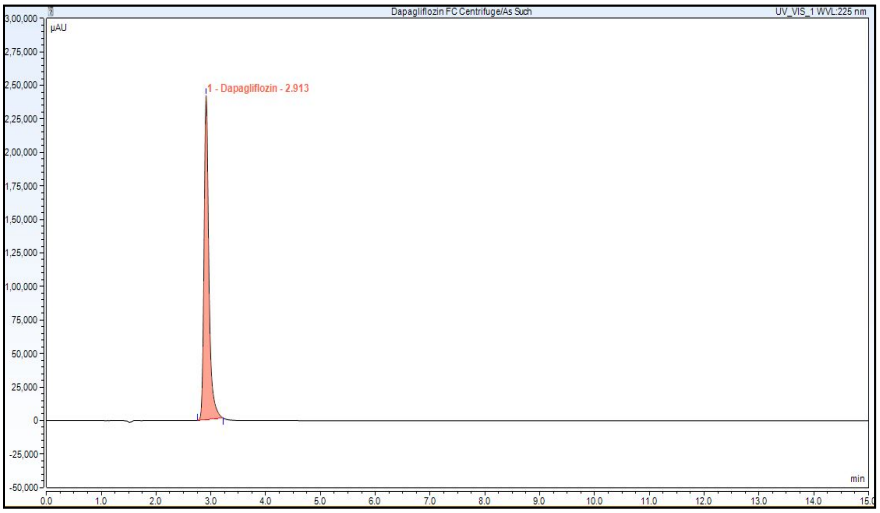

Figure 17: Chromatogram for standard Dapagliflozin

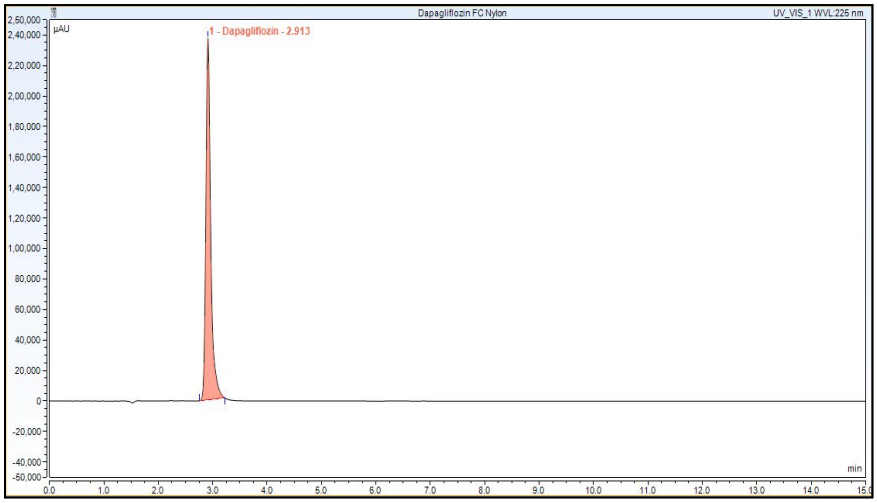

Figure 18: Chromatogram for standard Dapagliflozin

3.9 Stability Study

Standard solution samples were kept at room temperature in order to test the stability of Dapagliflozin. The experimental investigation demonstrated that under the specified storage conditions, Dapagliflozin stayed stable for at least 36 hours.

Table 12: Result of Solution Stability Study

Solution Stability for Dapagliflozin				
Time	**Area**	**Cumulative Mean**	**Cumulative SD**	**Cumulative % RSD**
Initial	1419029	1419029	0	0.00
After 4 hr	1432093	1425561	9238	0.65
After 8 hr	1460510	1437211	21209	1.48
After 12 hr	1438431	1437516	17328	1.21
After 16 hr	1437593	1437531	15006	1.04
After 20 hr	1454858	1440419	15172	1.05
After 24 hr	1459866	1443197	15680	1.09
After 28 hr	1465588	1445996	16535	1.14
After 32 hr	1456070	1447115	15827	1.09
After 36 hr	1526009	1455005	29070	2.00
After 40 hr	1598639	1468062	51343	3.50

4. CONCLUSION

ThermoScientific RP-HPLC technology was utilised in the development and validation of a dependable and expeditious method for measuring and testing Dapagliflozin. Although this method was straightforward, it was original and had never been published before. Comparing the proposed research effort to previously submitted research work, it is determined to be more promising and require less time and solvent usage for technique development. The approach that was developed shown that it is robust, accurate, exact, and specific for dapagliflozin. The designed procedure for the estimate of Dapagliflozin API is straightforward, quick, and affordable, as demonstrated by the developed approach and the statistical data that was acquired. This study developed and validated a sensitive, straightforward, and cost-effective HPLC technique using a PDA detector to detect Dapagliflozin API in accordance with ICH recommendations. The process was simple, accurate, fast, and trustworthy. Additionally, it was found to comply with the ICH requirements for robustness, accuracy, precision, linearity, specificity, and system suitability. Therefore, Dapagliflozin may be routinely analysed using this approach. Because of its accurate % RSD values, linear curve, excellent peak separation, and enhanced resolution, this method is preferred for determining dapagliflozin.

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AUTHORS CONTRIBUTION

Kshitiz Sahu. Writing–Original Draft, Formal Analysis and Validation, Himanshu. Conceptualization, Writing Reviewing and Editing, Ishika Bindal and Yasheeka Shaswat. Resources, Visualization and Assistance in Literature Survey, Anshika Niranjan. Formal Evaluation of the draft, Virendra Singh. Methodology and Final Evaluation of the Draft...

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