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Development And Validation Of RP-HPLC Method For The Estimation Of Dapagliflozin In Tablet Dosage Form Using Azelnidipine As An Internal Standard

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ABSTRACT
A simple, sensitive, precise, and accurate RP-HPLC (Reverse-Phase High-Performance Liquid Chromatography) method was developed and validated for the selective determination of Dapagliflozin using Azelnidipine as an internal standard (IS). An isocratic mode was used through Qualisil-5 BDS-C8(250×4.6mm,5µm) column, packed with 5µm particle utilizing mobile phase composition of Acetonitrile and 0.1% Ortho Phosphoric Acid (OPA), pH adjusted to 3 with Triethylamine (TEA) with a proportion of 50: 50% (v/v). The detection of the analyte was performed at a maximum wavelength of 232 nm and with a flow rate of 1 ml/min of the mobile phase. The run time was 10 mins with retention time of 4 mins for Dapagliflozin. Dapagliflozin was found to be linear in the range of 10-50 µg/ml with correlation coefficient (r^2) of 0.9991. The results of the analysis were verified for linearity, accuracy, precision, robustness, limit of detection, and limit of quantification in the developed method. The percentage recovery was found to in the range of 98.40% – 101.11%. Assay of marketed formulation was found to be 99.84%. Method was found to be reproducible with relative standard deviation (%RSD) for intraday and interday precision less than 2. The assessment of robustness of the method indicates that method remains unaffected by slight changes in chromatographic conditions. Thus, the developed RP-HPLC method was found to be simple, specific, rapid, reliable and reproducible.
KEYWORDS: *Dapagliflozin, Azelnidipine, Validation, RP-HPLC, Isocratic.*

INTRODUCTION

Dapagliflozin is mainly used to treat type 2 diabetes. Dapagliflozin is a selective inhibitor of the renal sodium-glucose cotransportor-2(SGLT- 2) & has an anti- hypoglycemic effect by reducing renal glucose reabsorption, leading to increased urinary glucose excretion. Dapagliflozin helps to improve glycemic control by inhibiting glucose and causing glycosuria. Dapagliflozin has been investigated either as a monotherapy or as an adjunct treatment with insulin or other oral hypoglycemic agents. Dapagliflozin inhibits the sodium-glucose cotransporter 2(SGLT2) which is primarily located in the proximal tubule of the nephron. SGLT2 facilitates 90% of glucose reabsorption in the kidneys and so its inhibition reabsorption in the proximal tubule of the nephron allows for glucose to be excreted in the urine. This excretion allows for better glycemic control and potentially weight loss in patients with type 2 diabetes mellitus. Dapagliflozin is used together with proper diet and exercise to treat type 2 diabetes. It works in the kidneys to prevent absorption of glucose (blood sugar). This helps lower the blood sugar level. Dapagliflozin does not help patients who have insulin-dependent or type 1 diabetes.

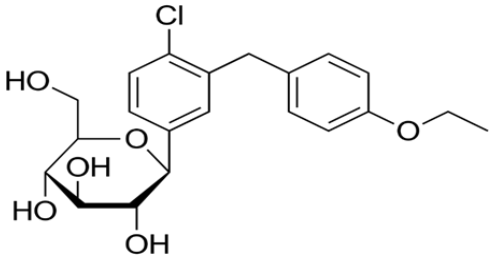

Fig 1: Structure of Dapagliflozin

Experimental work-

Materials and methods

Dapagliflozin (DAPA) was acquired from Alkem Laboratories, Navi Mumbai, India and Azelnidipine (AZEL) was acquired from Glenmark Pharmaceuticals, Sinner, India. Reagents like Methanol (AR grade), Acetonitrile (HPLC grade) were procured from Merck Life Science Pvt. Ltd., Mumbai, India. Triethylamine (TEA) and *o*-phosphoric acid (OPA) were provided by Research Lab Fine Chem. Industries, Mumbai and India and Thermosil Fine Chem. Industries, Pune, India respectively. HPLC grade water (Milli Q) was In-house supply.

Instrumentation and Chromatographic conditions:

High Performance Liquid Chromatography (HPLC) system, Jasco UV-2075 Plus, PU 2080 Plus (Low-pressure gradient Pump and a UV detector) was used. The column utilized was a Qualisil 5 BDS C8 Column (250mm×4.6mm) with a particle size of 5 µm. The software employed for operation was Borwin.

Selection of analytical wavelength

Methanol as a blank and Dapagliflozin standard solution (30 ppm) was scanned from 400 nm to 200 nm. Absorption maxima was determined for the drug. Dapagliflozin showed maximum absorbance at 232 nm.

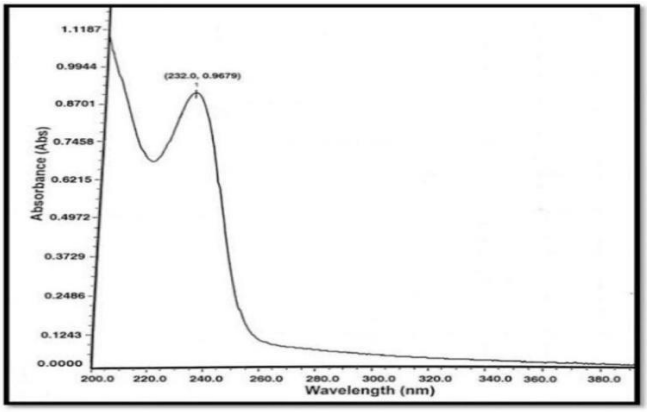

Fig 2: UV Spectrum of Dapagliflozin

METHOD DEVELOPMENT BY RP- HPLC

Preparation of mobile phase:

The HPLC grade Acetonitrile was sonicated for 30 min using a digital ultrasonicator. The pH of 0.1% OPA was adjusted pH to 3 with the diluted TEA and sonicated for 30 min. The final mobile phase consists of ACN: 0.1% OPA (pH 3) 50:50 %v/v.

Preparation of standard solution:

An accurately weighed quantity of (10 mg DAPA) was transferred it into a 100 ml volumetric flask containing 50 ml of diluent. The solution was dissolved by sonication for 30 min with intermittent shaking, volume was made up to 100 ml to get (100µg/ml of DAPA), filtered through a 0.45µm membrane. From the above filtered solution, 1 ml was further diluted to 10 ml with the same mobile phase as diluent to get the working standard solution (10 µg/ml of DAPA).

Preparation of sample solution:

Weighed 20 tablets, average weight was determined and crushed them into fine powder. Weighed accurately sample powder equivalent to 0.204 gm (10mg of DAPA), dissolved in diluent and diluted up to 100 ml in volumetric flask, filtered through 0.45µm membrane. From the above filtered solution, 1 ml was further diluted to 10 ml with same mobile phase as diluent to get the working standard solution (10 µg/ml of DAPA).

Preparation of internal standard (Azelnidipine):

Weighed Accurate quantity of AZEL (10mg), transferred it into 100 ml volumetric flask containing 50 ml of diluent. The solution was dissolved by sonication for 30 min with intermittent shaking, volume was made up to 100 ml to get internal standard (100µg/ml of AZEL). From the above filtered solution, 1 ml was further diluted to 10 ml with same mobile phase as diluent to get the working standard solution 10 µg/ml of AZEL.

Assay

Assay was performed by injecting six replicates of the sample solution containing 30µg/ml of DAPA and 10µg/ml of AZEL as IS in the HPLC system. Peak area was determined and calculated percentage assay and %RSD.

Method Validation-

1. System Suitability:

The system suitability of the method was determined by injecting the sample solution (30µg/ml of DAPA and 10µg/ml of AZEL) in six replicates. The parameters like retention time, tailing factor, number of theoretical plates, peak area and resolution were observed. The %RSD of these parameters are within the limit i.e. (<2).

2. LINEARITY & RANGE:

The linearity of the method was investigated by recording chromatograms of standard solutions in the range of 10-50 µg/ml of DAPA. A graph was plotted for the peak area ratio versus concentration, and the correlation coefficient was calculated.

3. Accuracy:

Accuracy was conducted in the range from 80%, 100% and 120% for of working concentration. Solution of each accuracy level was prepared in triplicate. Calculated % Recovery for each sample, Mean % recovery for each level and overall recovery and also calculated % RSD for each level and % RSD for overall recovery.

4. Precision:

4.1 System precision:

To determine the system precision, the standard solution containing 30µg/ml of DAPA and 10µg/ml of AZEL was prepared, and six replicates of the prepared solution were injected into the HPLC system. In this peak area of six determinations of the drug were measured and % RSD was calculated.

4.2 Method precision:

To determine method precision, six replicates of sample solution containing 30µg/ml of DAPA and 10 µg/ml of AZEL) were analyzed as per test method. In this peak area of the drug, and % assay and % RSD was calculated.

4.3 Intermediate precision:

a) Intraday Precision:

The intraday precision was determined by analyzing 20µg/ml, 30µg/ml, and 40µg/ml for DAPA each containing 10µg/ml of AZEL on three times on different time interval of the same day within the linearity range. Peak area and %RSD were calculated for DAPA.

Interday Precision:

The interday precision was determined by analyzing 20µg/ml, 30µg/ml, and 40µg/ml for DAPA each containing 10µg/ml of AZEL on three different days within the linearity range Peak area and %RSD were calculated for DAPA.

5. Specificity:

The specificity was performed by comparing the chromatograms of blank, working standard (30µg/ml of DAPA and 10µg/ml of AZEL) and sample solution (30µg/ml of DAPA and 10 µg/ml of AZEL) in triplicates

6. Robustness:

Robustness of the method was verified by deliberately changing the flow rate by ±20% of the set flow rate. The sample was analyzed in triplicates for each flow rate. The parameters like peak area, retention time, tailing factor was measured for DAPA. The %RSD for each parameter was calculated.

7. Ruggedness:

Ruggedness of the method was verified by analyzing sample solution (30µg/ml of DAPA and 10µg/ml of AZEL) by two different analysts. Calculated %RSD.

8. Limit of Detection and Limit of Quantitation:

As per ICH Q2R1 guidelines, LOD and LOQ was determined by using the approach based on the Calibration Curve in which residual standard deviation of a regression line was calculated and determined the LOD and LOQ by using following formula:

$LOD = 3.3\ \sigma / S$

$LOQ = 10\ \sigma / S$

RESULT & DISCUSSION:

Through various trials, the chromatographic parameters (mobile phase composition and pH) were improved to produce higher sensitivity and good peak shape. Various different combination ratios for mobile phase were conducted. A Qualisil 5 BDS C8 Column (250mm×4.6mm, 5µm particle size) was used for the final chromatographic separation. ACN: 0.1% OPA (50:50 % v/v) pH – 3 adjusted with TEA at the volume flow rate of 1.0mL/min with 20µl injection volume and detected wavelength at 232 nm using UV detector with 8 min

run time. Under the above described chromatographic conditions, Dapagliflozin was detected at retention time of 4 min. As per ICH recommendations, the optimized procedure was validated. The representative chromatogram of Dapagliflozin shown in the fig 3.

Fig. 3: Chromatogram of Blank

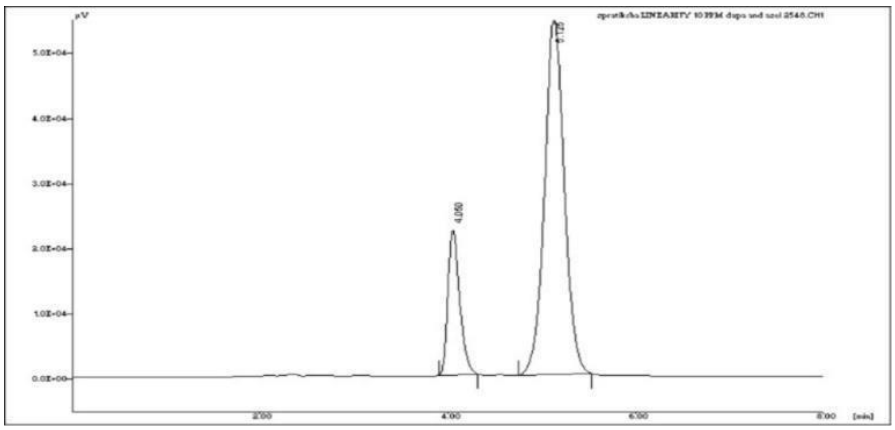

Fig.4: Chromatogram of Standard Solution

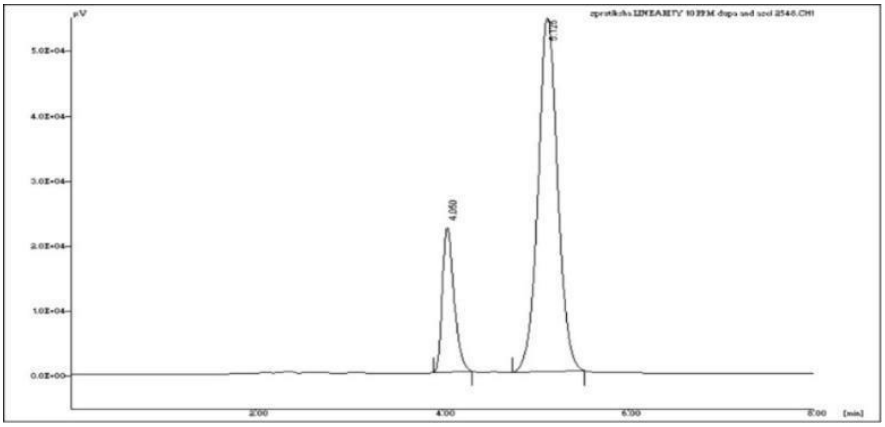

Fig. 5: Chromatogram for Sample Solution

System suitability parameters

All the system suitability parameters for DAPA were found to be within the acceptance limit (tailing factor < 2, theoretical plate count > 2000, resolution > 2). The %RSD for all parameters was within the acceptance criteria (< 2). It indicates that method is suitable for estimation of DAPA using AZEL as IS. The results of system suitability for DAPA are given in the Table-1.

Table1: System suitability parameters

Sr. No	Retention Time (Min)	Area of Std DAPA (30µg/ml)	Theoretical Plates DAPA	Tailing Factor DAPA	Retention Time (Min.) AZEL	Area of Std AZEL (10 µg/ml)	Theoretical Plates AZEL	Tailing Factor AZEL	Peak Area ratio	Resolution

	DAPA		(30µg/ml)	(30µg/ml)	(10 µg/ml)		(10 µg/ml)	(10 µg/ml)		
1	4.1	514992	5998	1.39	5.1	677232	5072	1.06	0.760	9.62
2	4.0	513748	5856	1.37	5.2	678444	5037	1.06	0.757	9.62
3	4.1	494551	5945	1.37	5.1	674308	5168	1.05	0.733	9.62
4	4.1	502267	6058	1.34	5.1	685522	5096	1.04	0.732	9.63
5	4.0	516689	5998	1.38	5.1	672208	5256	1.05	0.768	9.6
6	4.1	502992	5868	1.37	5.1	669230	5006	1.03	0.751	9.6
Mean	**4.066**	**507539.83**	**5953.83**	**1.37**	**5.11**	**676157.33**	**5105.83**	**1.048**	**0.750**	9.615
SD	**0.051**	**8887.95**	**79.71**	**0.016**	**0.04**	**5676.01**	**92.044**	**0.011**	**0.014**	0.011
%RSD	**1.269**	**1.751**	**1.338**	**1.221**	**0.79**	**0.8394**	**1.802**	**1.115**	**1.961**	**0.116**

Assay: The assay of marketed formulation was found to be 99.84%. The results of the assay are shown in Table. 2.**Table 2: Assay of DAPA**

Sr.No.	Area of test sample	Area of AZEL	Test sample peak area ratio	Area of Std. DAPA	Area of AZEL	Std. peak area ratio	% Assay
1.	496127	712599	0.6962	497114	713147	0.6970	100.12
2.	498210	713036	0.6987	499411	713698	0.6997	100.15
3.	502620	709612	0.7083	505718	729848	0.6929	97.827
4.	503147	717983	0.7007	503439	718432	0.7007	99.996
5.	503851	716842	0.7028	504776	718548	0.7024	99.946
6.	502862	718848	0.6995	503974	713284	0.7065	101.00
Mean	**501136.16**	**714820**	**0.7010**	**502405.33**	**717826.2**	**0.6999**	**99.84**
SD	**3170.11**	**3620.95**	**0.0041**	**3378.97**	**6402.81**	**0.0046**	**1.0598**
%RSD	**0.6325**	**0.5065**	**0.5951**	**0.6725**	**0.8919**	**0.6659**	**1.0615**

Specificity:

The specificity of the method was determined by comparing the chromatograms of blank working, standard, and sample solutions. No additional peak was observed at the retention time of DAPA, indicating the specificity of the method.

Linearity and Range

The method developed was found to be linear in the range of 10-50 µg/ml for DAPA.

Table3: Linearity data of DAPA

Parameter	DAPA
Linearity range	10-50 µg/ml
r^2	0.9991
Slope	0.0216
Y- intercept	0.0539
Y= mx +c	Y = 0.0216x + 0.0539

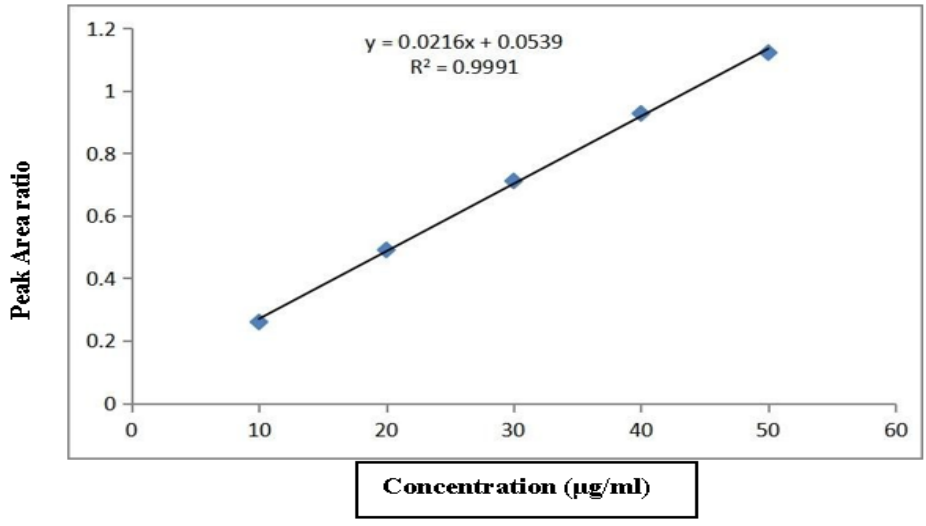

Fig.8: Linearity Curve for DAPA

Precision:

System precision

The system precision was studied for the standard solution of DAPA, the % RSD was found to be within acceptance limit (% RSD < 2). The results of system precision are given in Table 4.

Table 4: System Precision (DAPA)

Sr. No.	Area of Sample DAPA (30µg/ml)	Area of AZEL (10µg/ml)	Peak Area Ratio
1	498513	735212	0.6780
2	497843	756471	0.6581
3	498994	727842	0.6855
4	496563	725494	0.6844
5	487761	723788	0.6739
6	487145	728287	0.6688
Mean	494469.83	732849	0.6748
SD	5499.754	12211.98	0.0103
%RSD	1.1122	1.6663	1.5315

Method Precision

The results of the method's precision are given in Table 18. The % RSD for both the drugs, DAPA, was found to be within the acceptance limit (% RSD < 2).

Table 5: Method Precision (DAPA)

Sr. No.	Area of Sample DAPA (30µg/ml)	Area of AZEL (10µg/ml)	Peak Area Ratio	%Assay (w/v)
1	495718	719612	0.6888	**99.99317**
2	489411	713036	0.6863	**99.95018**
3	488704	727544	0.6717	**99.97917**
4	487761	736432	0.6623	**99.99141**
5	496570	725540	0.6844	**99.98961**
6	485831	727408	0.6678	**99.95247**
Mean	490665.83	724928.66	0.6769	**99.97600**
SD	4418.61	7942.16	0.0110	**0.01973**
%RSD	0.9005	1.0955	1.6313	**0.01973**
Acceptance Criteria - % RSD <2				

Intermediate Precision:

a) Interday Precision

The results of inter-day precision for DAPA are given in the Table. The %RSD for the DAPA was found to be within the acceptance limit (% RSD < 2).

Table 6: Interday Precision (DAPA)

Sr. No	Conc. Of DAPA (µg/ml)	Time Interval	Peak Area of DAPA	Peak Area of AZEL (10µg/ml)	Peak Area Ratio	Mean	SD	%RSD
1	20	Day 1	340683	716268	0.475	**0.477**	**0.3024**	**0.5053**
		Day 2	345890	719987	0.480			
		Day 3	342544	717521	0.477			
2	30	Day 1	498951	736181	0.677	**0.270**	**0.3523**	**1.1076**
		Day 2	496885	7371212	0.067			
		Day 3	496649	7371168	0.067			
3	40	Day 1	640930	744065	0.861	**0.8596**	**0.3641**	**0.4236**
		Day 2	634850	742137	0.855			
		Day 3	644397	747522	0.862			

b) Intraday Precision

The results of intraday precision for DAPA are given in Table 20. The %RSD for DAPA was found to be within acceptance criteria (%RSD < 2).

Table 7: Intraday Precision (DAPA)

Sr. No	Conc. of DAPA (µg/ml)	Time Interval	Peak Area of DAPA	Peak Area of AZEL (10µg/ml)	Peak Area Ratio	Mean	SD	%RSD
1	20	After 4hr	345890	718402	0.4814	0.4740	0.3064	1.361
		After 8hr	337400	715781	0.4713			
		After12hr	335754	715200	0.4694			
2	30	After 4hr	489321	726021	0.6739	0.6660	0.3077	1.160
		After 8hr	482076	724397	0.6654			
		After12hr	480824	730128	0.6585			
3	40	After 4hr	640499	733321	0.8734	0.8740	0.310	1.174
		After 8hr	649218	733865	0.8846			
		After12hr	636478	736537	0.8641			

LOD and LOQ

The LOD and LOQ were found to be 0.967 µg/ml and 2.931µg/ml for DAPA, which indicate that the method is suitable for the determination of lower concentration and confirm that the proposed method is sensitive for the determination of DAPA by using AZEL as an internal standard.

Drug	Limit of detection (µg/mL)	Limit of quantitation (µg/mL)
DAPA	0.967 (µg/mL)	2.931 (µg/mL)

Accuracy

The results of the accuracy study were found to be within an acceptable limit for DAPA, as shown in the Table. The % recovery calculated for DAPA was in the range of 98.40% – 101.11% and the % RSD was found to be within the acceptance limit (% RSD < 2).

Table 8: Accuracy (Recovery values)

Level of Recovery	Amt of drug from sample (µg/ml)	Amt of std added (API) (µg/ml)	Peak area ratio of spiked sample (A)	Peak area ratio of unspiked sample (B)	Peak area ratio of drug API (C)	B+C	Amt Recovery (µg/ml)	% Recovery	Avg	SD	%RSD
80%	15	12	0.6551	0.3628	0.2998	0.6626	11.86	98.87	98.96	0.4431	0.448
			0.6520	0.3606	0.2950	0.6557	11.93	99.44			
			0.6494	0.3612	0.2976	0.6588	11.83	98.57			
100%	15	15	0.7270	0.3621	0.3569	0.7191	15.17	101.11	100.45	0.7665	0.763
			0.7245	0.3606	0.3593	0.7200	15.10	100.63			
			0.7140	0.3612	0.3555	0.7168	14.94	99.61			
120%	15	18	0.8070	0.3626	0.4422	0.8049	18.05	100.26	99.58	1.0264	1.031
			0.8070	0.3606	0.4456	0.8063	18.02	100.09			
			0.8002	0.3612	0.4519	0.8132	17.71	98.40			

Robustness:

The results for robustness are given in Table 23 for DAPA. The % RSD for the robustness study was found to be within acceptance criteria (%RSD < 2) indicating the robustness of method.

Table 9: Robustness

Flow Rate (ml)	Retention Time (Min.) DAPA	Theoretical Plates (DAPA)	Peak Area (DAPA)	Retention Time (Min.) AZEL	Theoretical Plates (AZEL)	Peak Area (AZEL)	Peak Area Ratio
0.8	3.1	51436	486319	6.3	52835	711006	0.6839
	3,1	50764	495311	6.3	5147	721200	0.6867
	3	51463	495713	6.2	51475	711088	0.6971
1	4	51476	504992	5.1	50476	715578	0.7057
	4.2	50264	493748	5.2	51487	718444	0.6872
	4.1	52578	494549	5.1	50148	714524	0.6921
1.2	5	51346	491695	4.7	51386	719024	0.6838
	5.1	51857	493222	4.6	51496	706430	0.6981
	5	51436	482464	4.7	51457	707134	0.6822
MEAN	-	-	**493112.55**	-	-	**713825.33**	**0.690**
SD	-	-	**6292.350**	-	-	**5258.45**	**0.008**
%RSD	-	-	**1.276**	-	-	**0.7366**	**1.161**

Ruggedness

The results of ruggedness are given in Table 22. The % RSD for the DAPA was found to be within the acceptance limit (%RSD < 2).

Table 10: Ruggedness

Drug	Parameter	Peak Area DAPA (µg/ml)	Peak Area AZEL (10µg/ml)	Peak Area Ratio	Mean	SD	%RSD
DAPA	Analyst 1	503992	725518	0.6946			
		514652	715610	0.71917			
		516601	724971	0.71258	**0.7088**	**0.0126**	**1.789**
DAPA	Analyst 2	513872	732114	0.70190			
		503987	729810	0.6905			
		516468	729517	0.7079	**0.70014**	**0.008**	**1.2604**

CONCLUSION:

The literature survey reveals that several UV, HPLC methods have been reported for the estimation of DAPA in different dosage forms. But, no analytical method was reported for the estimation of the DAPA by using Internal Standard. Therefore, this work aimed to develop and validate an RP HPLC method for the determination of DAPA in tablet dosage form. The separation was achieved on column Qualisil-5 BDS-C8 250×4.6mm using a UV detector at a detection wavelength of 232 nm. Various trials were conducted for optimization of mobile phase. The optimized mobile phase consisted of ACN:0.1% OPA pH adjusted with TEA to 3 (50:50 % v/v). The flow rate was 1 ml/min with the injection volume of 20µL and run time for analysis was 08 minutes. The DAPA was satisfactorily eluted with retention time 4 min. No interference of any component of the pharmaceutical dosage form was observed. Thus, a simple, precise, fast, sensitive, accurate RP-HPLC method was developed. The linearity range was 10-50 µg/ml for DAPA, and the correlation coefficient was 0.9991 for DAPA. The method has been checked for validation parameters like Linearity, Precision, Accuracy, Specificity, Robustness, LOD, & LOQ. The mobile phase used was simple and economical.

Therefore, the new analytical method developed for estimation of DAPA by using AZEL as an Internal Standard in tablet dosage form was found to be specific, accurate, precise, sensitive, reproducible, and cost-effective.

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REFERENCES:

1. List F. J., Woo V., Morales E., Tang W., and Fiedorek F. T., 2009, "Sodium-Glucose Cotransport Inhibition with Dapagliflozin in Type 2 Diabetes," Diabetes Care, 32(4), pp. 650.
2. Manasa S., Dhanalakshmi K., Reddy N. G., and Sreenivasa S., 2014, "Method Development and Validation of Dapagliflozin in API by RP-HPLC and UV-Spectroscopy," International Journal of Pharmaceutical Sciences and Drug Research, 6(3), pp. 250.
3. Sanagapati M., Lakshmi D. K., Reddy N. G., and Sreenivasa S., 2014, "Development and Validation of a Stability-Indicating RP-HPLC Method for the Determination of Dapagliflozin," Journal of Advanced Pharmacy Education & Research, 4(3).
4. Karuna P. C., China E., and Basaveswara Rao M. V., 2015, "Unique UV Spectrophotometric Method for Reckoning of Dapagliflozin in Bulk and Pharmaceutical Dosage Forms", Journal of Chemical and Pharmaceutical Research, 7(9), pp. 45–49.
5. Debata J., Kumar S., Jha S. K., and Khan A., 2017, "A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form," International Journal of Drug Development and Research, 9(2), pp. 48–51.
6. Madhavi S., and Rani A. P., 2017, "Development and Validation of a Method for Simultaneous Determination of Dapagliflozin and Saxagliptin in a Formulation by RP-UPLC", World Journal of Pharmaceutical Research, 6(12), pp. 904–916.
7. Mante G. V., Hemke A. T., and Umekar M. J., 2018, "RP-HPLC Method for Estimation of Dapagliflozin from Its Tablet", International Journal of Chem Tech Research, 11(01), pp. 242–248.
8. Deepan T., and Dhanaraju M. D., 2018, "Stability Indicating HPLC Method for the Simultaneous Determination of Dapagliflozin and Saxagliptin in Bulk and Tablet Dosage Form," Current Issues in Pharmacy and Medical Sciences, 31(1), pp. 39–43.
9. Ghode P. D., Baradkar S. S., Sayare A. S., Pachauri A. D., and Khandelwal K. R., 2019, "Stability Indicating HPTLC Method Development and Validation for the Estimation of Saxagliptin in Bulk and Its Dosage Form," Journal of Pharmaceutical Sciences and Research, 11(7), pp. 2485–2489.
10. Bhokare M., and Ige P., 2024, "Analytical Method Development and Validation of Dapagliflozin by RP-HPLC Method in Tablet Dosage Form," International Journal of Pharmacy Sciences, 2(7), pp. 1718–1728.
11. Ghode P., Kapse R, Sayare A. Pachauri A. "RP-HPLC Method Development and Validation for the Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Linagliptin in Tablet Dosage Form," 2024, African Journal of Biomedical Research, 27(3S), pp. 242–249.
12. International Conference on Harmonization (ICH), 2005, ICH Q2(R1): Validation of Analytical Procedure: Text and Methodology, IFMA, Geneva.