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DEVELOPMENT AND VALIDATION OF RP–HPLC METHOD FOR ESTIMATION OF DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE AND TENELIGLIPTIN HYDROBROMIDE HYDRATE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A straightforward, precise, and validated Reverse Phase-High Performance Liquid Chromatographic (RP-HPLC) method was established for the determination of Dapagliflozin propanediol monohydrate (DAPA) and Teneligliptin hydrobromide hydrate (TENA) in tablet formulation Separation was performed using a Shimadzu Shim-pack C8 column (4.6 × 250 mm, 5 µm) with a mobile phase comprising HPLC-grade acetonitrile and Phosphate buffer (60:40 %v/v), adjusted to pH 4 with 1% o-phosphoric acid, at a flow rate of 1.0 ml/min. Detection was carried out at 220 nm for both analytes, yielding retention times of 3.9 min for DAPA and 2.9 min for TENA. The method demonstrated excellent linearity over the concentration ranges of 5-25 µg/ml for DAPA and 10-50 µg/ml for TENA, with correlation coefficients of 0.9992 and 0.9994 respectively. Limits of detection and quatification were found to be 0.49766 µg/ml and 1.50806 µg/ml for DAPA, and 0.66921 and 2.02791 µg/ml for TENA respectively. Validation parameters including accuracy, precision, and robustness complied with ICH Q2 (R2) guidelines, confirming the method's suitability for routine quality control of combined

pharmaceutical dosage forms.

KEYWORDS: DAPA, TENA, Validation, RP-HPLC, Accuracy and precision, Repeatability.

1. INTRODUCTION

Dapagliflozin propanediol monohydrate (Dapagliflozin):- These sodium-glucose co-transport-2 (SGLT-2) inhibitors have been given to treat people with type 2 diabetes. They cause constant glycosuria and reduce blood sugar levels after a single daily dose. It was approved by FDA in January 2014.

The chemical name of Dapagliflozin propanediol monohydrate is (2S)-propane-1,2-diol(2S,3R,4R,5S,6R)-2-{4-chloro-3-[(4-ethoxy phenyl)methyl]phenyl}-6-(hydroxymethyl) oxane-3,4,5-triol hydrate.[4]

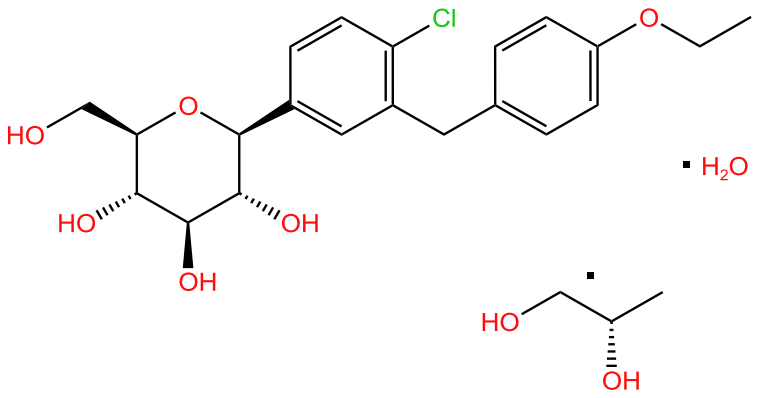

Figure 1: Structure of Dapagliflozin propanediol monohydrate

Teneligliptin hydrobromide hydrate (Teneligliptin): - Teneligliptin hydrobromide hydrate is a pharmaceutical drug which is used to treat type 2 diabetes mellitus. It belongs to the class of DPP-4 inhibitors, that is commonly known as gliptins. This medication is used with diet and exercise for the patients with type 2 diabetes, mainly in adults. Teneligliptin ensures that the medication helps in the monitoring and management of blood glucose levels, allowing them to stay within a normal range. It was approved by FDA in May 2015. The chemical name of teneligliptin hydrobromide hydrate is ((2s,4s)-4-(4-(3-methyl-1-phenyl-1h-pyrazol-5-yl)-1-piperazinyl)-2-pyrrolidinyl)-3-thiazolidinyl-, hydrobromide, (2:5), hydrate.[5]

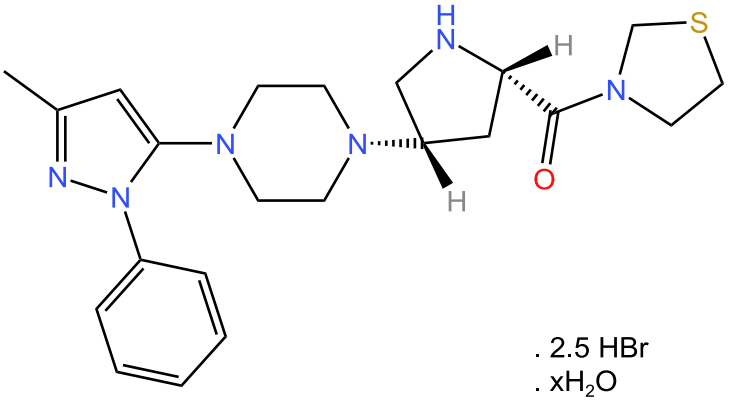

Figure 2: Structure of Teneligliptin hydrobromide hydrate.

2. MATERIALS AND METHODS

2.1 Materials

The Glassware's and Apparatus used for the Research work were made up of borosilicate and that were calibrated before used in the research. For weighing the required chemicals in the range of (10 mg – 700 mg) a calibrated digital weighing balance (sartorious-TE-214S) was utilized (max capacity – 200 gm). Ultra-Sonicator (RC system-MU1700) was used for getting the uniform mixture of solvent and the sample. DAPA and TENA API were procured as a gift sample from Synokem pharmaceuticals Ltd. Uttarakhand. Marketed formulatio Zita-D is manufactured by Glenmark pharmaceuticals Ltd.

2.2 Instruments Used

- **HPLC System Liquid Chromatography :** Shimadzu LC- 20AT
- **UV – Visible Detector :** Shimadzu SPD-20A
- **Analytical Column :** Shimadzu shim-pack 5µm C8 (4.6 × 250 mm)
- **Data Processor :** LabSolutions software Version 5.90
- **Injector :** Rheodyne – 7725i (Fixed Capacity Loop of 20µl)
- **Syringe :** Hamilton, 25 µl
- **Filter :** Nylon (25 mm, 0.2 µm) filter
- **Electronic Weighing Balance (Sartorius – TE 214 S)**
- **Ultrasonicator (RC Systems – MU 1700)**
- **UV-Visible Spectrophotometer (Shimadzu – 1700, Software Version – UVProbe 2.32)**
- **Digital pH Meter (Digisun Electronics – 7007)**
- **Vacuum Pump (Value High Reliability Vaccum Pump)**

- **Supor 200 Membrane Filter, 0.2 µm (Pall India Pvt. Ltd)**

2.3 Chemicals and Reagents

HPLC grade Methanol, Acetonitrile was used as a solvent which was procured Avantor Performance Materials India Pvt. Ltd., Thane, Maharashtra India. Double Distilled water was used throughout the analysis.

2.4 METHODOLOGY

2.4.1 Selection of Analytical Wavelength

To investigate the appropriate analytical wavelength for simultaneous estimation of DAPA, TENA, the standard solutions of DAPA (10 µg/ml), TENA (20 µg/ml) were prepared with HPLC water. These solutions were scanned separately in the UV region of 200 to 400 nm and the overlain spectra were studied for selection of analytical wavelength. Overlay spectra shown in Figure No: 3.

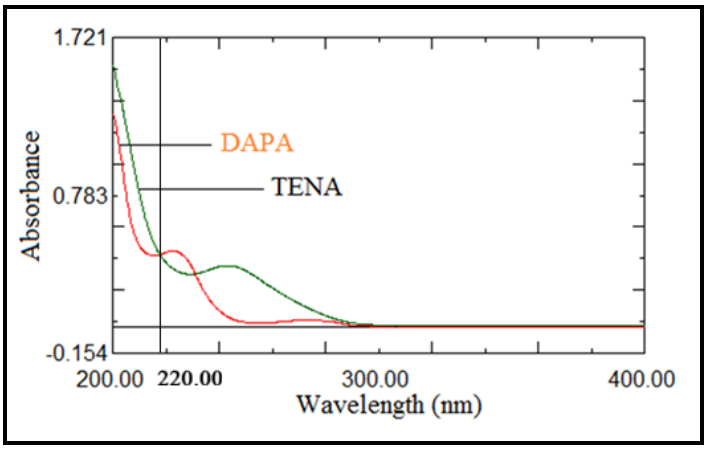

Figure No: 3: Overlay spectra of DAP (10 µg/ml) and TENA (20 µg/ml).

2.4.2. Finalized Chromatographic Conditions

✓ **Analytical Column:** Shim pack C18(250 mm×4.6 mm, 5 µm)

✓ **Mobile Phase:** ACN: Potassium di-Hydrogen Orthophosphate (Phosphate Buffer) – pH-4 adjusted (60:40 % v/v)

✓ **Injection volume:** 20 µl

✓ **Flow rate:** 1 ml/min

✓ **Detection Wavelength:** 220 nm

✓ **AUFS:** 0.1000

✓ **Pressure ~** 7.6 MPa

2.4.3. Preparation of Mobile Phase

Mobile phase was prepared by mixing 60 ml of HPLC grade Acetonitrile and 40 ml of 10mM Potassium Di-Hydrogen Phosphate Buffer and the pH was adjusted to 4 by using orthophosphoric acid. The Mobile Phase was filtered through 0.2 µm membrane using vacuum pump and sonicated for 10 min.

2.4.4. Preparation of Standard Stock Solution

I. Preparation of Standard Solution of Dapagliflozin propanediol monohydrate

Accurately weighed 10 mg Dapagliflozin propanediol monohydrate into a 10 ml volumetric flask and dissolved it in 10 ml of HPLC grade methanol to obtain final concentration of 1000 µg/ml solution of Dapagliflozin propanediol monohydrate, this was labelled as Std Stock DAPA. From this 1ml of aliquot was pippeted out into 10 ml volumetric flask and made upto the mark using HPLC grade water to obtain final concentration of 100 µg/ml solution, this was labelled as Std Stock DAPA (B).

II. Preparation of Standard Solution of Teneligliptin hydrobromide hydrate

Accurately weighed 10 mg Teneligliptin hydrobromide hydrate was transferred into a 10ml volumetric flask and dissolved it in 10 ml of HPLC grade methanol to obtain final concentration of 1000 µg/ml of Teneligliptin hydrobromide hydrate, this was labelled as Std Stock TENA. From this 1ml of aliquot was pippeted out into 10 ml volumetric flask and made upto the mark using HPLC grade water to obtain final concentration of 100 µg/ml solution, this was labelled as Std Stock TENA (B).

2.4.5 Preparation of Calibration Curve for DAPA and TENA

Pipette out 0.5, 1.0, 1.5, 2.0 and 2.5 ml of Std Stock of DAPA (B), Similarly from Std Stock of TENA (B) pipette out 1.0, 2.0, 3.0, 4.0 and 5.0 ml solution into five volumetric flasks, label them as C1, C2, C3, C4, & C5, and made up to the mark using HPLC grade water to obtain the concentration of 5-25 µg/ml of DAPA and 10-50 µg/ml of TENA respectively. These solutions were filtered through Nylon 25 mm, 0.25 µm filter using syringe and injected into the Rheodyne injector (20 µl) of HPLC system and their chromatogram were recorded under the finalized chromatographic conditions as described above after getting a stable baseline. Peak areas were recorded for both the drugs. Overlay chromatogram for each dilution is shown in Figure No: 4 and 5. Calibration curves of DAPA and TENA were constructed by plotting the peak area v/s concentration of DAPA and TENA respectively as shown in Figure No: 6 and 7. The results of calibration study are given in Table No: 1 and 2.

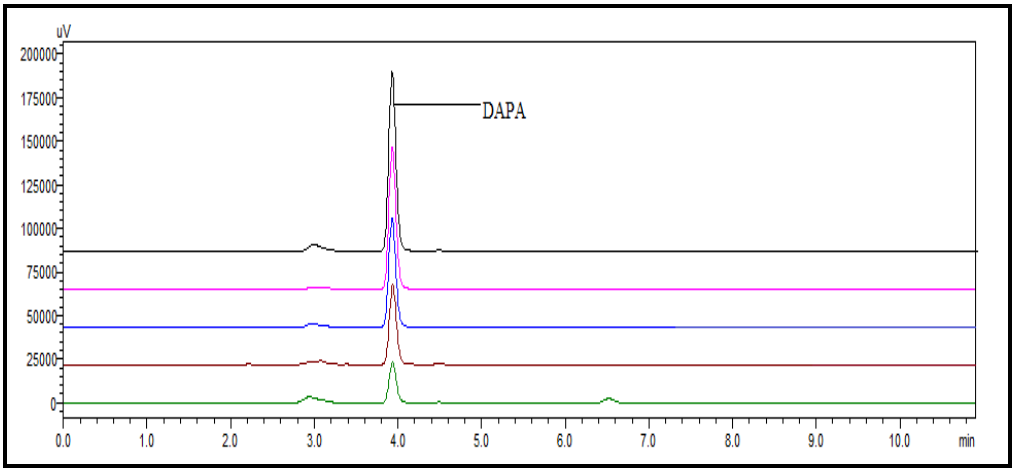

Figure No: 4. Overlain Chromatograms of Serial Dilutions of DAPA (5-25 µg/ml), in Acetonitrile: Phosphate buffer (pH4) (60:40 % v) at flow rate of 1.0 ml/min at 220 nm using C8 column.

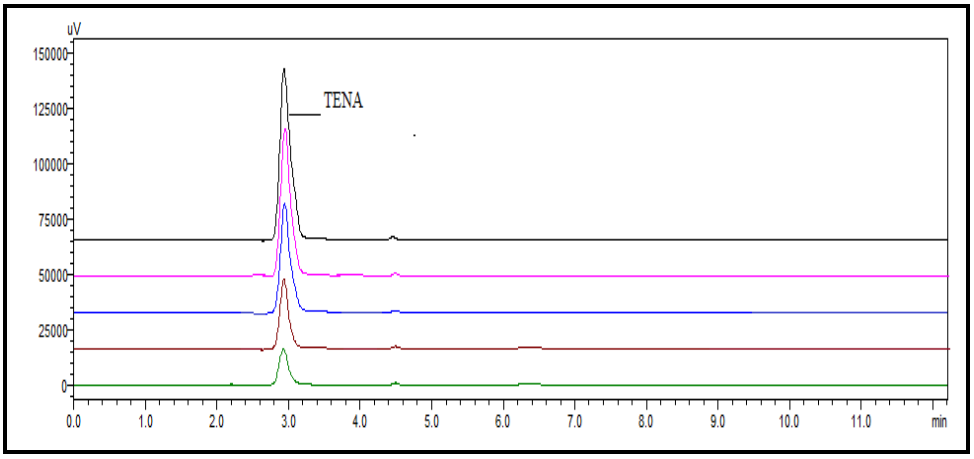

Figure No: 5. Overlain Chromatograms of Serial Dilutions of TENA (10-50 µg/ml), in Acetonitrile: Phosphate buffer (pH4) (60:40 % v) at flow rate of 1.0 ml/min at 220 nm using C8 column.

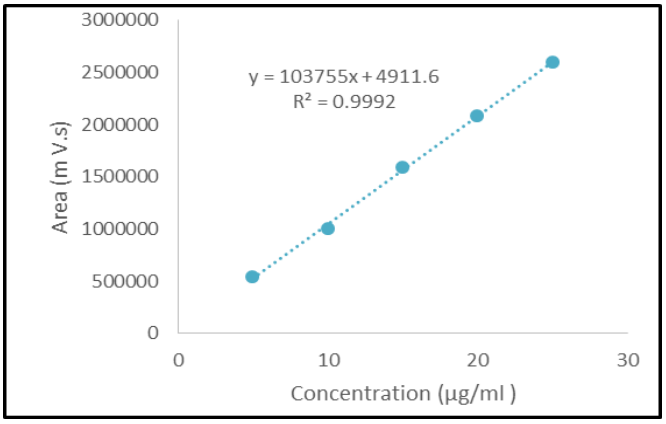

Figure No: 6. Calibration Curve of DAPA at 220 nm.

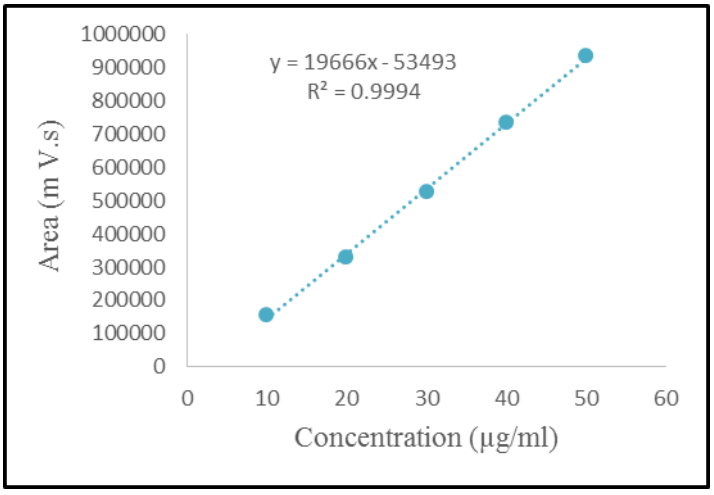

Figure No: 7. Calibration Curve of TENA at 220 nm.

2.4.6 Analysis of Tablet Formulation

20 tablets of Zita-D (DAPA-10mg and TENA-20mg) were weighed and their average weight was determined and finely powdered. Weigh tablet powder equivalent to 15 mg of DAPA and 30 mg of TENA and transfer into into a 25ml volumetric flask containing little amount of methanol and sonicate it for 20 minutes then make up the volume with methanol. Filter the solution using Whatman filter paper No 4, Label this as Sample stock A.

From the above Sample stock A pipette out 0.25ml into 10ml volumetric flask and make up the volume to 10ml with HPLC water, Label this as Sample stock B, filter the obtained solution through 0.2 µm nylon filter. The volume was made up to the mark with HPLC water to obtain a final concentration of 15 µg/ml of DAPA and 30 µg/ml of TENA.

Similarly, from the 'Std Stock DAPA' (100µg/ml) an aliquot of 1.5 ml was pipetted out into a 10ml volumetric flask along with this 3.0 ml of 'Std Stock TENA' (100µg/ml) was transferred and the volume was made up to 10ml using the water to obtain a final concentration of 15 µg/ml of DAPA and 30 µg/ml of TENA.

Both solutions (Standard and Sample) were filtered through Nylon 25mm, 0.2µm filter using syringe and followed by injection into the Rheodyne injector (20 µl) of HPLC system using the Hamilton Syringe. Both the sample and standard chromatograms were recorded under the finalized chromatographic conditions as described above after getting a stable baseline. Peak areas were recorded for all the peaks. The amount of DAPA and TENA present in the tablets was calculated using single point analysis. The results were shown in Table No:4 and overlain spectra are given in Figure No: 8 and 9.

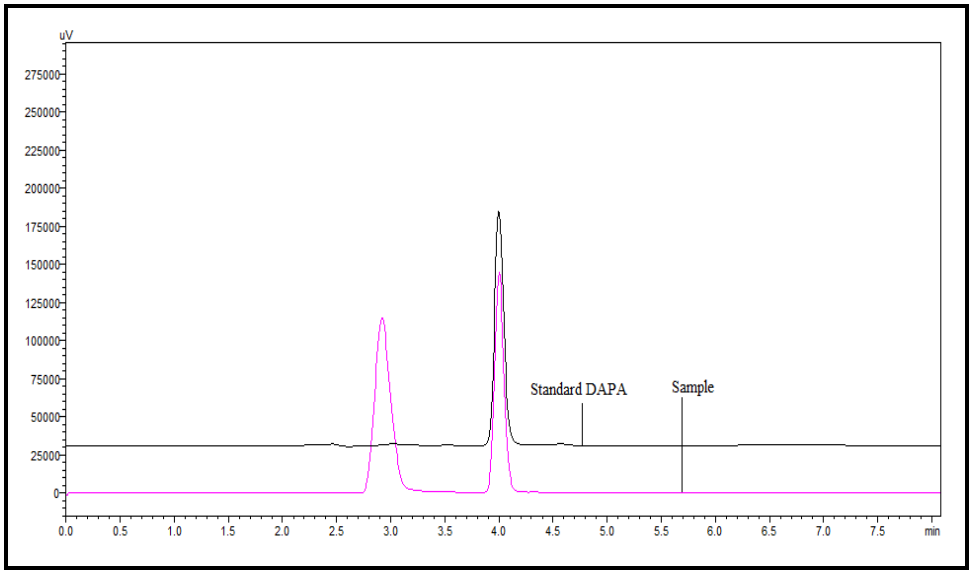

Figure No: 8. Overlay Chromatograms of Sample and Standard Solution of DAPA at 220 nm.

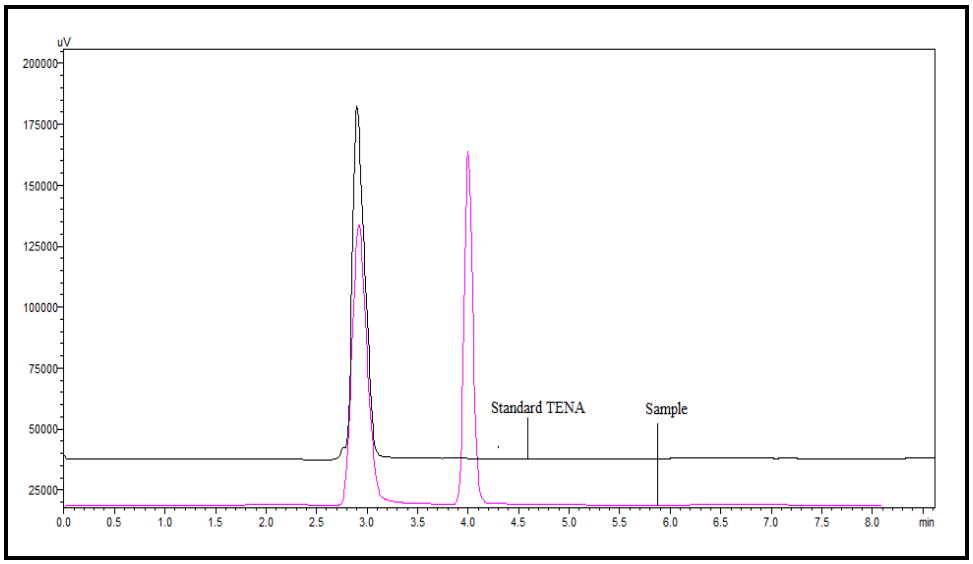

Figure No: 9. Overlay Chromatograms of Sample and Standard Solution TENA at 220 nm.

2.4.6 Validation of RP-HPLC Method.

2.4.6.1 Accuracy

Twenty tablets were weighed and powdered for the study of accuracy. Recovery studies were carried out by adding the known amount of standard DAPA (12, 15 and 18 µg/ml) and standard TENA (24, 30 and 36µg/ml) to the pre analyzed sample at three different concentration levels i.e., 80%, 100%, and 120% and percentage recoveries were calculated. The results were shown in table no: 6 and 7.

2.4.6.2 Precision

The Precision of an analytical method was studied by performing intermediate precision and repeatability.

A. Intermediate Precision

1. Intra-day precision

Intra-day precision was determined by analyzing the standard solutions of DAPA (10, 15 and 20 µg/ml) and TENA (20, 30 and 40 µg/ml) at three different time intervals on the same day. The results are shown in Table No:8 and 9.

2. Inter-day Precision

Inter-day precision was determined by analyzing the standard solutions of DAPA (10, 15 and 20 µg/ml) and TENA (20, 30 and 40 µg/ml) on three consecutive days. The results are shown in Table No: 10 and 11.

3. Variation by Different Analyst

The sample solutions of 15 µg/ml of DAPA and 30 µg/ml of TENA were prepared and analyzed three times by two different analysts. The results were compared using F-test and T-test to observe effect of different analyst in the variation of results. The results are shown in Table No:12 and 13.

B. Repeatability

Standard solutions of DAP (15 µg/ml) and TENA (30 µg/ml). were prepared and analysed six times. The standard deviation and % Relative standard deviation were calculated. The results are shown in Table No:14.

Linearity and Range

The concentration ranges 5-25 µg/ml for DAPA and 10-50 µg/ml TENA were prepared and analyzed. Linearity of the method was decided by observing r^2 value.

I. Limit of Detection and Limit of Quantitation

Detection limit and quantitation limit were determined based on the standard deviation of y-intercepts of six calibration curves and average slope of six calibration curves. The formula is as follows: -

$$LOD = 3.3 \times \frac{\text{Standard Deviation of y-Intercepts of Six Calibration curves}}{\text{Average Slope of Six Calibration Curves}}$$

$$LOQ = 10 \times \frac{Standard\ Deviation\ of\ y-Intercepts\ of\ Six\ Calibration\ curves}{Average\ Slope\ of\ Six\ Calibration\ Curves}$$

The results of LOD and LOQ are given in Table No:3.

II. Robustness

Combined standard solutions of DAP (10µg/ml) and TENA (20 µg/ml) was prepared and analyzed at different flow rates (0.98, 1.00 and 1.02 ml/min) and different Mobile phase ratio ACN: KH_2 PO_4 adjusted to pH -4 (58.8:39.2, 60:40, 61.2:40.8) the results were shown in Table No: 15, 16 and 17.

III. System Suitability

Combined standard solutions of DAP (10µg/ml) and TENA (20 µg/ml) were prepared and analyzed six times. Chromatograms were studied for different parameters such as tailing factor, resolution and theoretical plates to see that whether they comply with recommended limit or not. Results of validation parameters are shown in Table No:18.

3. RESULTS

Table No. 1: Results of Calibration Curve of DAPA at 220 nm.

Conc. (µg/ml)	Peak Area	± SD	% RSD
5	541740	2513.141	0.463902
10	1001821	15253.3	1.522556
15	1587201	7953.176	0.501082
20	2077776	26117.61	1.256998
25	2597634	26397.14	1.0162

Table No. 2: Results of Calibration Curve of TENA at 220 nm.

Conc. (µg/ml)	Peak Area	± SD	% RSD
10	155337.8	659.5327	0.42458
20	330334.3	4057.943	1.228435
30	525865	2969.708	0.564728
40	734202.8	4074.225	0.554918
50	936706.7	8196.286	0.875011

Table No: 3. Linear Regression Analysis of Calibration Curve for DAPA and TENA at 220 nm.

Parameters	DAPA	TENA
Beer's law limit (µg/ml)	5 to 25	10 to 50
Wavelength (nm)	220	220
(Correlation Coefficient) R^2	0.9992	0.9994
Slope	103755	19666
Intercept	4911.6	53493

LOD (µg/ml)	0.49766	0.66921
LOQ (µg/ml)	1.50806	2.02791

Table No. 4: Assay Results of Tablet Formulation by RP-HPLC Method at 220 nm.

Sr. No.	Amount Present (mg/tab)		Amount Found (mg/tab)		% Assay	
	DAPA	TENA	DAPA	TENA	DAPA	TENA
1	10	20	9.78	19.75	97.89	98.75
2	10	20	9.82	19.85	98.2	98.25
3	10	20	9.96	19.72	99.68	98.62
4	10	20	9.974	19.5	99.74	97.5
5	10	20	10.11	20.6	101.1	101.5
6	10	20	9.69	19.94	96.98	99.74
Mean			9.888333	19.88	98.81	99.06
± SD			0.152763	1.855907	0.153199	0.376493
% RSD			1.544886	1.871912	1.549188	1.892557

Table No: 5. Results of Chromatograms of Sample Solution (Zita-D) at 220 nm.

Drug	Area (m V.s)	Retention Time (Min)	Tailing Factor (T)	Theoretical Plates (N)
DAPA	997993	3.9	1.080	6486
TENA	332346	2.9	1.244	4259

Table 6: Results of Accuracy for RP-HPLC Method.

Level of % Recovery	Sr. No.	Amount of Standard Drug Added (µg/ml)		Total Amount Found (µg/ml)		Total Amount Recovered (µg/ml)		%Recovery	
		DAPA	TENA	DAPA	TENA	DAPA	TENA	DAPA	TENA
80 %	1	12	24	26.85	54.11	11.85	24.11	98.75	100.4
	2	12	24	27.02	53.85	12.02	23.85	100.16	99.37
	3	12	24	26.93	54.06	11.93	24.06	99.4	100.2
100 %	1	15	30	30.04	60.12	15.04	30.12	100.26	101.4
	2	15	30	29.84	59.85	14.84	29.85	98.93	99.50
	3	15	30	29.79	59.93	14.79	29.93	98.60	99.76
120%	1	18	36	32.86	66.04	17.86	36.04	99.22	100.1
	2	18	36	33.03	65.92	18.03	35.92	100.1	99.77
	3	18	36	32.84	66.03	17.84	36.03	99.11	100.08

Table 7: Statistical Validation Data for Accuracy Study.

Level of % Recovery	Mean* (% Recovery)		±SD		%RSD	
	DAPA	TENA	DAPA	TENA	DAPA	TENA
80%	99.43	99.99	0.70571	0.54617	0.70971	0.54622
100%	99.26	100.2	0.87877	1.03015	0.88529	1.02788
120%	99.47	99.98	0.54262	0.18502	0.54547	0.18505

Table 8: Results of Intra-day Precision of DAPA.

Concentration (µg/ml)	Peak Area at different time intervals (hr)			Mean	±SD	%RSD
	0	2	4			
10	995060	1019534	1020927	1011840	14548.88	1.437863
15	1594632	1602997	1592120	1596583	5694.917	0.356694
20	2092025	2098746	2129743	2106838	20118.95	0.954936

Table 9: Results of Intra-day Precision of TENA.

Concentration (µg/ml)	Peak Area at different time intervals (hr)			Mean	±SD	%RSD
	0	2	4			
20	321753	322423	321642	321939.3	422.5285	0.131245
30	527753	519896	526289	524646	4178.241	0.796392
40	734610	739387	735689	736562	2505.3	0.340134

Table 10: Results of Inter-day Precision of DAPA.

Concentration (µg/ml)	Peak Area at consecutive days			Mean	±SD	%RSD
	0	1	2			
10	1015060	1029534	1020927	1021840	7280.096	0.712449
15	1594632	1582997	1595420	1591016	6956.114	0.437212
20	2102025	2075746	2107743	2095171	17064.04	0.814446

Table 11: Results of Inter-day Precision of TENA.

Concentration (µg/ml)	Peak Area at Following Day			Mean	±SD	%RSD
	0	1	2			
20	322134	331782	322642	325519.3	5429.573	1.667972
30	527753	519896	536289	527979.3	8198.843	1.552872
40	734610	749387	735689	739895.3	8237.710	1.113361

Table 12: Results of Variation by Different Analyst Study for DAPA.

(%Assay*±SD)		Result of F-test	Result of t-test	Inference
Analyst 1	Analyst 2			
100.04± 1.0830	100.49±1.2413	0.7612	0.6180	No Significant difference

Table 13: Results of Variation by Different Analyst Study for TENA.

(%Assay*±SD)		Result of F-test	Result of t-test	Inference
Analyst 1	Analyst 2			
100.26±0.9416	100.83±0.6568	0.4865	1.7031	No Significant difference

Table No. 14: Results of Repeatability Study for DAPA and TENA.

Sr. No.	Peak Area	
	DAPA (15 µg/ml)	TENA (30 µg/ml)
1	1564533	527696
2	1585082	519958
3	1582120	526163
4	1583436	527080
5	1590895	527854
6	1607180	526439
Mean	1585541	525865
±SD	13817.327	2969.708
% RSD	0.8714582	0.564728

Table 15: Result of Robustness Study: Variation in Flow Rate (ml/min).

Flow Rate (ml/min)	Analyte	Retention Time*(min)	Tailing Factor*(T)	Theoretical Plates*(N)
0.98*	DAPA	3.98	2.590	24268
	TENA	2.89	1.394	44848
1.0*	DAPA	3.9	1.025	10519
	TENA	2.9	1.971	24681
1.02*	DAPA	3.9	1.268	10211
	TENA	3.0	2.529	24484

Table 16: Result of Robustness Study: Variation in Organic Solvent Ratio in Mobile Phase.

Mobile Phase (ACN: KH_2PO_4 buffer pH4(60:40) %v/v)	Analyte	Retention Time*(min)	Tailing Factor *(T)	Theoretical Plates*(N)
58.8:39.2*	DAPA	3.98	1.438	10539
	TENA	2.89	1.473	27766
60:40*	DAPA	3.9	1.132	11156
	TENA	2.9	1.203	31385
61.2:40.8*	DAPA	3.9	1.375	9775
	TENA	3.0	1.160	25212

* **Mean of 3 estimations**

Table 17: Result of Robustness Study: Variation in Wavelength.

Wavelength (220 nm)	Analyte	Retention Time*(min)	Tailing Factor* (T)	Theoretical Plates* (N)
218*	DAPA	3.98	1.438	10539
	TENA	2.89	1.473	27766
220*	DAPA	3.90	1.132	11156
	TENA	2.90	1.203	31385
222*	DAPA	3.90	1.375	97755
	TENA	3.10	1.160	25212

Table No. 18: System Suitability Results of the Proposed Method (n=6).

Analyte	T	N	Rt	Peak Area
DAPA	9954	1.037	3.94	998993
TENA	4568	1.372	2.99	334346
Required limits	N>2000	T<2	RSD < 2%	

N-Number of theoretical plates, T-Tailing factor

Table 19: Summary of RP-HPLC Method.

Parameters	DAPA	TENA
Retention Time (min)	3.9	2.9
Linearity Range (µg/ml)	5-25	10-60
Regression Equation (y=mx+c)	103755x + 4911.6	19666x - 53493
Correlation Coefficient (R^2)	0.9992	0.9994
LOD (µg/ml)	0.497	0.669
LOQ (µg/ml)	1.508	2.027
Analysis of Tablets (%Assay)	98.81	99.06
% Recovery	99.26-99.47 %	99.98-100.2
Intra Day Precision (%RSD)	0.3566-1.4378	0.13124-0.79639
Inter Day Precision (%RSD)	0.43721-0.81444	1.11336-1.66797
Repeatability(±RSD)	0.87145	0.56472
Variation by different analyst study (t-test)	0.6180	1.7031
Robustness (%RSD*)	<2%	<2%

4. CONCLUSION

The validated RP-HPLC method provides a reliable, reproducible, and economical solution for the concurrent quantification of Dapagliflozin propanediol monohydrate and Teneligliptin hydrobromide hydrate in pharmaceutical formulations. Its demonstrated accuracy, precision, and adherence to ICH standards support its application in routine quality control and analytical procedures within the pharmaceutical sector.

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