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Original Article

DEVELOPMENT AND STABILITY INDICATING HPLC METHOD FOR DAPAGLIFLOZIN IN API AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

Objective: To develop precise, accurate and reproducible stability assay method by RP-HPLC for estimation of dapagliflozin in API and pharmaceutical dosage form.

Methods: The adequate separation was carried using agilent C18 (4.6 ml (millimeter)*150,5 µm (micromiter), mixture of acetonitrile**:** di-potassium hydrogen phosphate with pH-6.5 adjusted with OPA (40:60 %v/v) as a mobile phase with the flow rate of 1 ml/min (milliliter/minute) and the effluent was monitored at 222 nm (nanometer) using photo diode array detector. The retention time of dapagliflozin API and dapagliflozin tablet were 3.160 min (minute) and 3.067 min (minute) respectively.

Results: Linearity for dapagliflozin was found in the range of 50-150µg/ml (microgram/milliliter) (R^2 = 0.99) respectively. The accuracy of the present method was evaluated at 50 %, 100% and 150%. The % recoveries of dapagliflozin API and tablet were found to be in the range of 99.00–99.99 % and 98.50–99.99 % respectively. Precision studies were carried out and the relative standard deviation values were less than two. The method was found to be robust.

Conclusion: The proposed method was found to be specific, accurate, precise and robust can be used for estimation of dapagliflozin in API and Pharmaceutical dosage form.

Keywords: HPLC, Dapagliflozin, API, Pharmaceutical dosage form, OPA

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INTRODUCTION

Dapagliflozin is chemically a (2S,3R.4R,5S,6R)-2-[4-chloro-3-(4-ethoxybenzyl)phenyl]-6-(hydroxymethyl)tetrahydro 2H-pyran-3,4,5-triol) with molecular weight of 408.873 g/mol.

Dapagliflozin is a sodium glucose co transpoter inhibitor (antidiabetic drug), which prevents glucose reabsorption in the kidney. Thus leads to the elimination of glucose through urine [1-2].

Various analytical methods have been reported for dapagliflozin alone and in combination with metformin hydrochloride. Methods such as UV spectroscopy for estimation of dapagliflozin alone or in combination with metformin hydrochloride [3-7, 9], HPLC method for estimation of dapagliflozin and metformin hydrochloride [8] and alone dapagliflozin in API [10], LC MS/MS for dapagliflozin [11] has been reported.

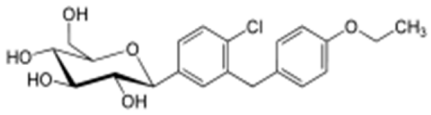

Fig. 1: Structure of dapagliflozin from pubmed

However, an extensive literature search didn't reveal any estimation method for dapagliflozin in API and Pharmaceutical dosage form. Therefore an attempt has been made to develop and validate simple, precise, accurate HPLC method for estimation of dapagliflozin in API and Pharmaceutical dosage form.

MATERIALS AND METHODS

Drugs, chemicals and solvents: Dapagliflozin in API was kindly given by advanced analytical research and training institute, gujarat. All the chemicals and solvents used were of analytical grade.

Instruments

The analysis was performed on agilent HPLC fitted with a gradient pump photo diode array detector and agilent C18 (4.6 mm150,5 µm) column which is maintained at an ambient temperature. The optimized mobile phase composition was a mixture of acetonitrile**:** dipotassium hydrogen phosphate with pH 6.5 adjusted with OPA (40:60 %v/v) with a flow rate of 1 ml/min. The injection volume was 20 µl. The chromatographic run time was adjusted to 6 min. The wavelength of the detector was set at 222 nm for analysis of the drug.

Preparation of buffer

Dissolve 0.435 gm (gram) of dipotassium hydrogen phosphate in 100 ml (milliliter) of HPLC water. Filter the solution through 0.45 µ nylon filter. Adjust the pH-6.5 with dilute orthophosphoric acid and degas before use.

Preparation of mobile phase

Prepare a mixture of buffer (dipotassium hydrogen phosphate) and acetonitrile in the ratio of 60:40. Adjust the pH 6.5 with diluted ortho phosphoric acid (OPA). This solution was sonicated for 5 min (minute) for degassing and filtered through 0.45 µ millipore filter.

Diluent

The drug was dissolved in acetonitrile.

Preparation of standard stock solution (API)

Accurately weighed 10 mg (milligram) of dapagliflozin was taken in a 10 ml standard volumetric flask and dissolved in few ml of acetonitrile. Then the volume was made up to the mark with acetonitrile. From the above solution, 5 ml was diluted to 10 ml with to get a concentration of 500 µg/ml of dapagliflozin.

Preparation of standard stock solution (tablet)

The average of 10 tablets was determined and grounded in a mortar. An accurately weighed amount of powder equivalent to 10 mg of

dapagliflozin was taken. It was transferred to 10 ml of volumetric flask. Add 5 ml of diluents and sonicated for 5 min to ensure complete solubilization of drug after sonication, volume was made up to the mark with diluents (1000 µg/ml of dapagliflozin stock solution). Pipette out 5 ml from above solution and dilute up to 10 ml with diluents (500 µg/ml of dapagliflozin).

Calibration curve

Aliquots of different concentrations of standard solution were prepared and their chromatograms were recorded at the optimized chromatographic conditions. The mean peak areas at different concentration levels were calculated from the chromatograms. Then the linearity plot was constructed using the mean peak areas at their respective concentrations fig. 14.

Forced degradation study

Forced degradation study of dapagliflozin in API and pharmaceutical dosage form was carried out under different stress conditions as mentioned in ICH guideline Q1A (R2). The standard solution containing 500 µg/ml of dapagliflozin API and 500 µg/ml of dapagliflozin tablet were subjected to acid, alkali hydrolysis, peroxide, thermal and photolytic degradation.

Acid degradation

Transfer 1 ml of standard solution to 10 ml of volumetric flask. Add 1 ml of 0.1 N HCl keep the volumetric flask in water bath at 60 °C for 2 h. After time period cool the contents to ambient temperature. Neutralized the solution with 1 ml of 0.1 N NaOH and volume was made up to 10 ml with diluent. After inject the acid degradation sample into HPLC, peak area and peak shapes were observed fig. 2.

Procedure for tablet

The average of 10 tablets was determined and grounded in mortar. An accurately weighed amount of powder equivalent to 10 mg of dapagliflozin was taken. It was transferred to 10 ml of volumetric flask. Add 5 ml of diluents and sonicated for 5 min to ensure complete solubilization of drug. After sonication, volume was made up to the mark with diluent (1000 µg/ml of dapagliflozin stock solution). Pipette out 5 ml from above solution and dilute up to 10 ml with diluent (500 µg/ml of dapagliflozin). Pipette out 1 ml from the sample solution and add 1 ml of 0.1N HCl and keep at 60 °C in water bath for 2 h. After time period cool the contents to ambient temperature. Neutralized the solution with 1 ml of 0.1 N NaOH and volume was made up to 10 ml with diluents. After inject the acid degradation sample into HPLC,peak area and peak shape were observed fig. 3.

Base degradation

Procedure for API

Transfer 1 ml of standard solution to 10 ml of volumetric flask. Add 1 ml of 0.1 N NaOH keep the volumetric flask in a water bath at 60 °C for 2 h. After time period cool the contents to ambient temperature. Neutrilized the solution with 1 ml of 0.1 N HCl and volume was made up to 10 ml with diluents. After inject the base degradation sample into HPLC, peak area and peak shape were observed fig. 4.

Procedure for tablet

The average of 10 tablet was determined and grounded in mortar. An accurately weighed amount of powder equivalent to 10 mg of dapagliflozin was taken. It was transferred to 10 ml of volumetric flask. Add 5 ml of diluents and sonicated for 5 min to ensure complete solubilization of drug. After sonication, volume was made up to the mark with diluent (1000 µg/ml of dapagliflozin stock solution). Pipette out 5 ml from above solution and dilute up to 10 ml with diluent (500 µg/ml of dapagliflozin). Pipette out 1 ml from the sample solution and add 1 ml of 0.1N NaOH and keep at 60 °C in water bath for 2 h. After time period cool the contents to ambient temperature. Neutralized the solution with 1 ml of 0.1 N HCl and volume was made up to 10 ml with diluent. After inject the base degradation sample into HPLC, peak area and peak shape were observed fig. 5.

Peroxide degradation

Procedure for API

Transfer 1 ml of standard solution to 10 ml of volumetric flask. Add 1 ml of 3 % H_2O_2, keep the volumetric flask in a water bath at 60 °C for 2 h. After time period cool the contents to ambient temperature. Dilute the volume with diluent. After inject the peroxide degradation sample into HPLC, peak area and peak shape were observed fig. 6.

Procedure for tablet

The average of 10 tablet was determined and grounded in mortar. An accurately weigh the amount of powder equivalent to 10 mg of dapagliflozin was taken. It was transferred to 10 ml of volumetric flask. Add 5 ml of diluents and sonicated for 5 min to ensure complete solubilization of drug. After sonication, volume was made up to the mark with diluent (1000 µg/ml of dapagliflozin stock solution). Pipette out 5 ml from above solution and dilute up to 10 ml with diluent (500 µg/ml of dapagliflozin). Pipette out 1 ml from the sample solution and add 1 ml of 3 % H_2O_2, keep the volumetric flask in water bath at 60 °C for 2 h. After time period cool the contents to ambient temperature. Dilute the volume with diluent. After inject the peroxide degradation sample into HPLC, peak area and peak shape were observed fig. 7.

Thermal degradation

Procedure for API

Transfer 1 ml of standard solution to 10 ml of volumetric flask. Keep the volumetric flask in water bath at 60 °C for 2 h. After time period cool the contents to ambient temperature. Make up the volume with diluent. After injecting the thermal degradation sample into HPLC, peak area and peak shape were observed fig. 8.

Procedure for tablet

The average of 10 tablet was determined and grounded in mortar. An accurately weigh the amount of powder equivalent to 10 mg of dapagliflozin was taken. It was transferred to 10 ml of volumetric flask. Add 5 ml of diluents and sonicated for 5 min to ensure complete solubilization of drug. After sonication, volume was made up to the mark with diluents (1000 µg/ml of dapagliflozin stock solution). Pipette out 5 ml from above solution and dilute up to 10 ml with diluent (500 µg/ml of dapagliflozin). Pipette out 1 ml of the sample solution to 10 ml of volumetric flask. Keep the volumetric flask in water bath at 60 °C for 2 h. After time period cool the contents to ambient temperature. Make up the volume with diluent. After inject the thermal degradation sample into HPLC, peak area and peak shape were observed fig. 9.

Photolytic degradation

Procedure for API

Transfer 1 ml of standard solution to 10 ml of volumetric flask. It was exposed to direct sunlight for 1 h, make up the volume with diluent. After inject the photolytic degradation sample into HPLC, peak area and peak shape was observed fig. 10.

Procedure for tablet

The average of 10 tablet was determined and grounded in mortar. An accurately weigh the amount of powder equivalent to 10 mg of dapagliflozin was taken. It was transferred to 10 ml of volumetric flask. Add 5 ml of diluents and sonicated for 5 min to ensure complete solubilization of drug. After sonication, volume was made up to the mark with diluents (1000 µg/ml of dapagliflozin stock solution). Pipette out 5 ml from above solution and dilute up to 10 ml with diluents (500 µg/ml of dapagliflozin). Pipette out 1 ml of the sample solution to 10 ml of volumetric flask. It was exposed to direct sunlight for 1 h, make up the volume with diluent. After inject the photolytic degradation sample into HPLC, peak area and peak shape were observed fig. 11.

Method validation

System suitability was carried out by injecting standard solutions of API and tablet 5 times into the chromatographic system. The system

suitability parameters were then evaluated for tailing factor, retention time and theoretical plates of standard chromatograms.

Accuracy

The accuracy of the test method was demonstrated by % recovery across its range by making three different concentrations at 50%, 100% and 150 % level using standard addition method.

Intraday precision

Intraday precision was performed by injecting standard preparations three times on the day by maintaining the optimized chromatographic conditions and calculate % relative standard deviation of retention time and peak areas for dapagliflozin.

Inter-day precision

Inter-day precision was performed by injecting standard preparations three times into chromatographic system on 2 different days by maintaining the optimized chromatographic conditions and calculate % relative standard deviation of retention time and peak areas for dapagliflozin.

Repeatability

Method precision of experiment was performed by preparing the standard solutions of Dapagliflozin (500 µg/ml) for six times and analysed as per proposed method and % RSD was calculated.

Linearity

Transfer an accurately weighed quantity about 100 mg of dapagliflozin in 100 ml volumetric flask, dissolve and dilute the volume with diluents. Prepare different linearity concentration solutions in the range of 250–750 µg/ml.

Robustness

The robustness was studied by analyzing the sample of dapagliflozin by deliberate variation in method parameters. The change in response of dapagliflozin was noted. Robustness of the method was studied by changing flow rate±0.2 ml, mobile phase composition and column temperature. The change in the response of dapagliflozin was noted and compared with the original one.

Limit of detection and limit of quantification

LOD and LOQ were determined by using the formula based on the standard deviation of the response and the slope. LOD and LOQ were calculated by using equations:

LOD = 3.3 σ/S

LOQ = 10 σ/S

Where, σ = Standard deviation of response

S = Slope of calibration curve

RESULTS AND DISCUSSION

The detection wavelength was carried out in the UV range of 222 nm. Chromatographic separation was carried out using mobile phase composed 1 molar dipotassium hydrogen phosphate and acetonitrile (60:40 % v/v) and pH was adjusted to 6.5 with orthophophoric acid on agilent C18 (4.6 mm150,5 µm) at a flow rate of 1 ml/min using PDA detector.

(1) Acid degradation for API and tablet

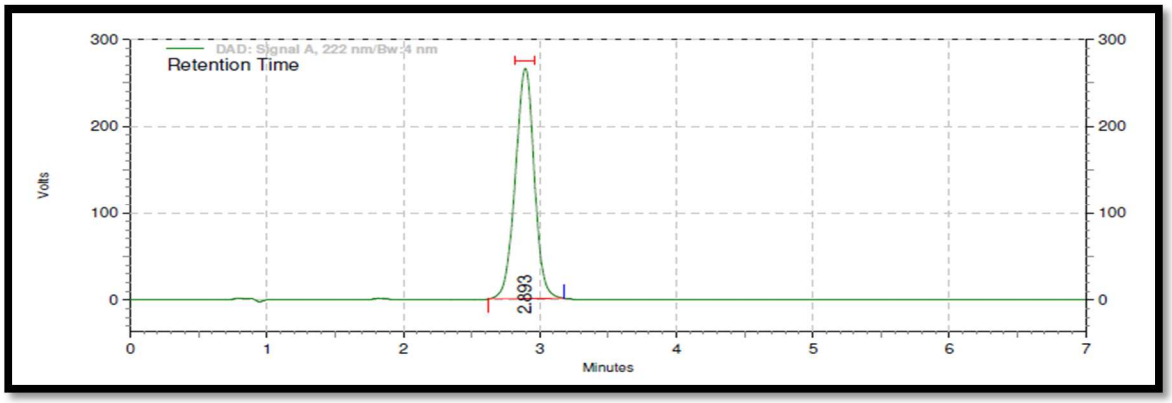

Fig. 2: Acid degradation for dapagliflozin in API

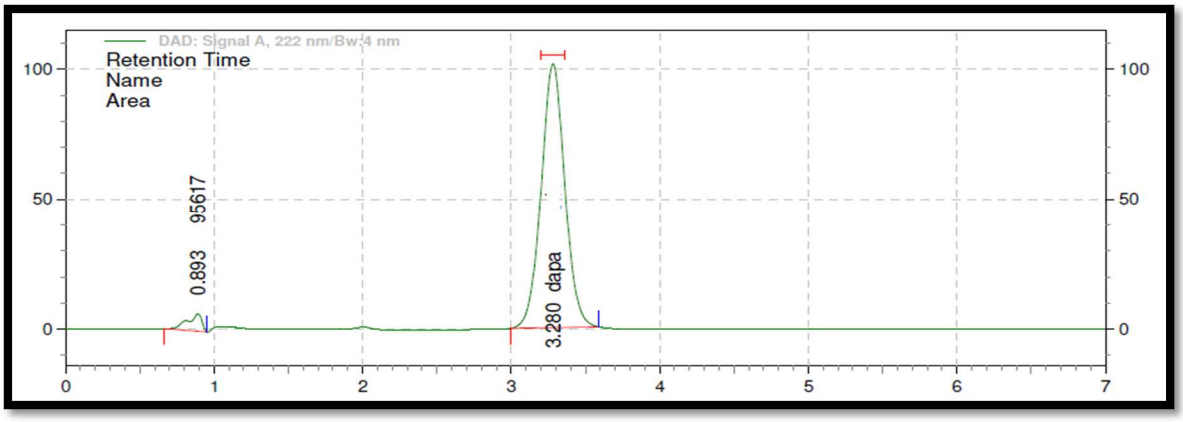

Fig. 3: Acid degradation for dapagliflozin in tablet

(2) Base degradation for API and tablet

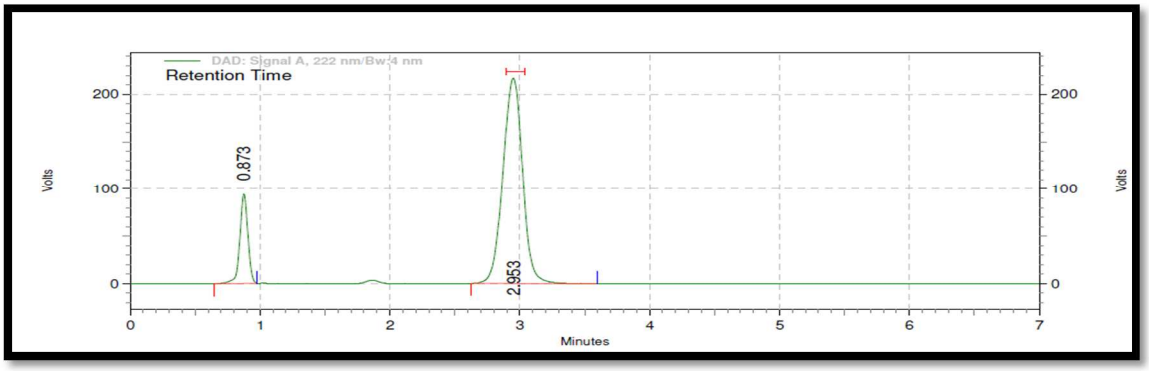

Fig. 4: Base degradation for dapagliflozin in API

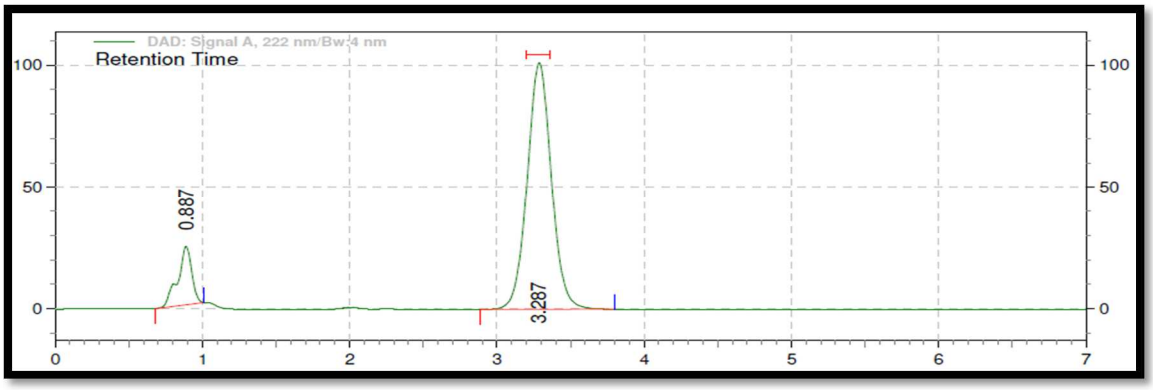

Fig. 5: Base degradation for dapagliflozin tablet

(3) Peroxide degradation

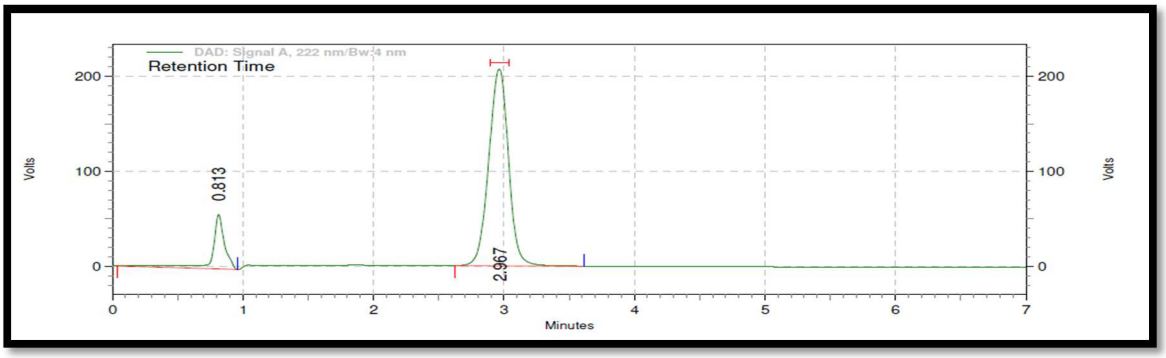

Fig. 6: Peroxide degradation for dapagliflozin API

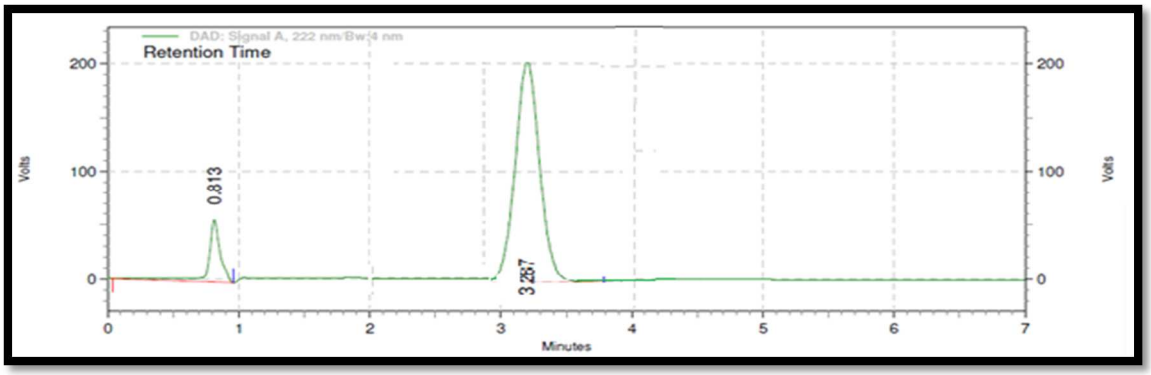

Fig. 7: Peroxide degradation for dapagliflozin tablet

(4) Thermal degradation

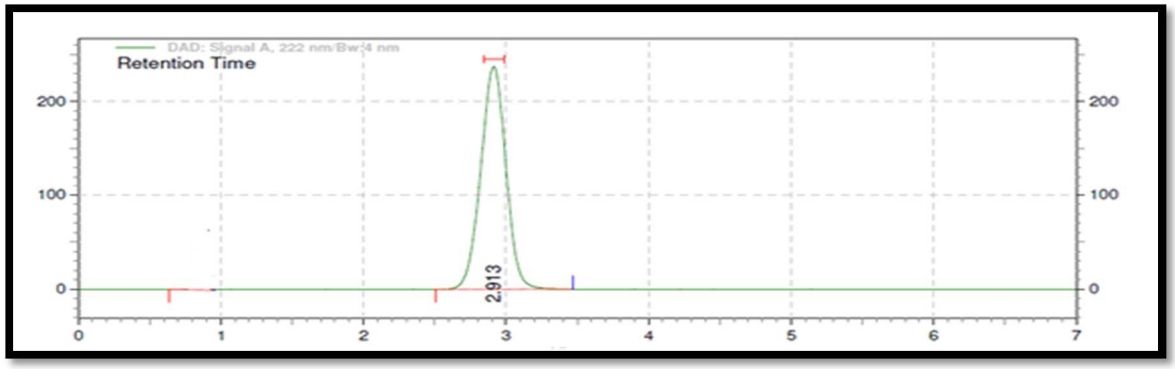

Fig. 8: Thermal degradation for dapagliflozin API

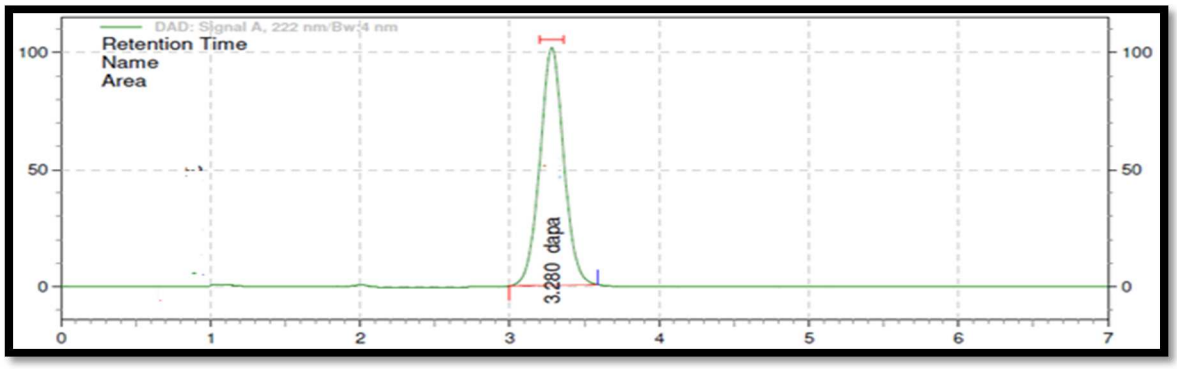

Fig. 9: Thermal degradation for dapagliflozin tablet

(5) Photolytic degradation

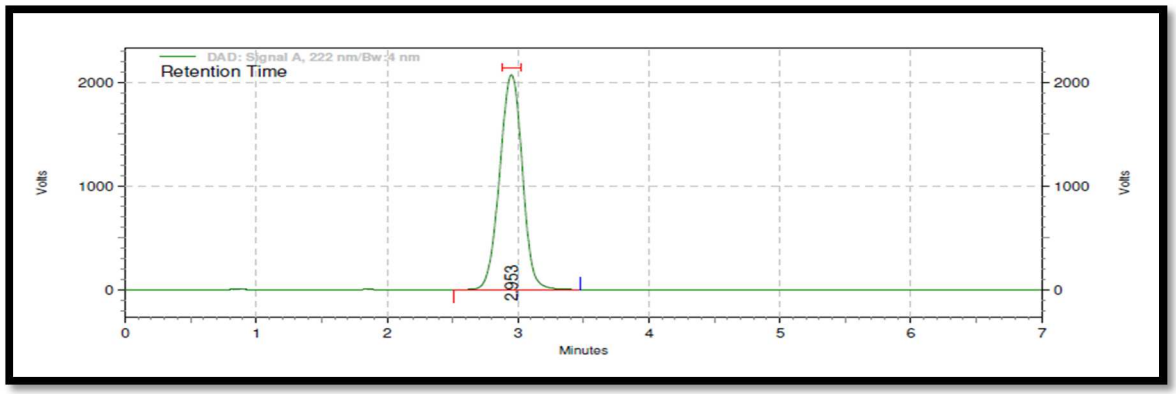

Fig. 10: Photolytic degradation for dapagliflozin API

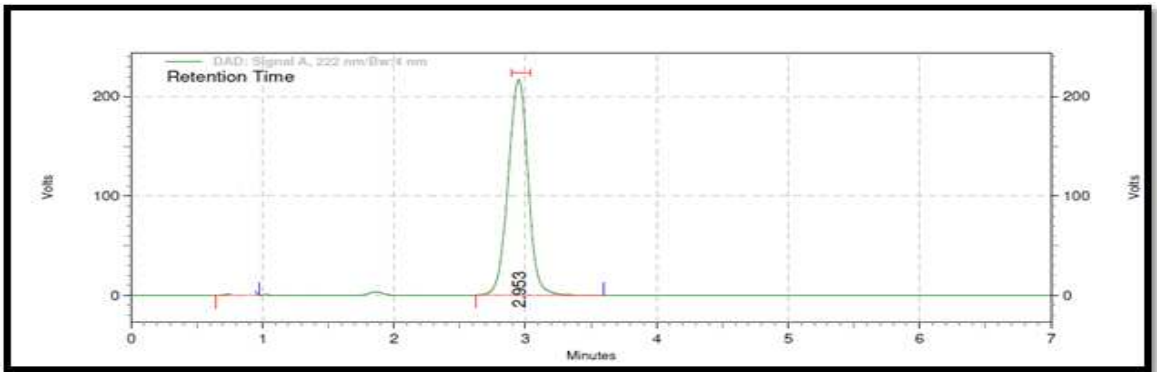

Fig. 11: Photolytic degradation for dapagliflozin

Tablet 1: Degradation summary for API

Type	Solution	Area	%Degradation
As such	Dapagliflozin	52331398	-
Acid			
0.1 N* HCL* at 60 °C for 2 h in water bath	Dapagliflozin	3270712	6.25%
Base			
0.1 N NaOH* at 60 °C for 2 h in water bath	Dapagliflozin	27787835	5.31%
Peroxide			
3% H_2O_2* at Room Temperature for 3 h	Dapagliflozin	5059869	9.66%
Thermal			
At 60 °C for 3 h	Dapagliflozin	6116184	11.68%
Photolytic			
in sun light for 1 h	Dapagliflozin	7849709	9.23%

N*-normal, HCl*-hydrochloric acid, NaOH*-sodium hydroxide, H_2O_2*-hydrogen hydroxide

Table 2: Degradation summary for tablet

Type	Solution	Area	% Degradation
As such	Dapagliflozin	18920313	-
Acid			
0.1 N* HCL* at 60 °C for 2 h in water bath	Dapagliflozin	1500380	7.93%
Base			
0.1 N* NaOH* at 60 °C for 2 h in water bath	Dapagliflozin	1738776	9.19%
Peroxide			
3% H_2O_2* at Room Temperature for 3 h	Dapagliflozin	1920411	10.15%
Thermal			
At 60 °C for 3 h	Dapagliflozin	1651743	8.73%
Photolytic			
in sun light for 1 hr	Dapagliflozin	2104050	11.12%

N*-normal, HCl*-hydrochloric acid, NaOH*-sodium hydroxide, H_2O_2*-hydrogen hydroxide

Validation data

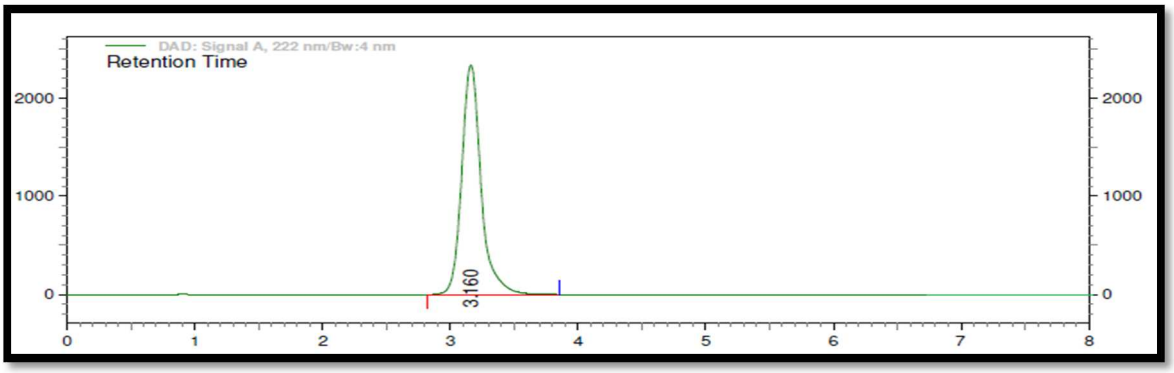

Fig. 12: Chromatogram of API

Table 3: System suitability results (API)

S. No.	System suitability parameter	Results
1	Tailing	1.28
2	Retention Time	3.160 min
3	Plate count	2350
4	Area	5165316
5	Correlation coefficient	0.99
6	LOD*	5.14 µg/ml
7	LOQ*	15.6 µg/ml

LOD*-Limit of detection, LOQ*-Limit of quantification

Table 4: System suitability results (tablet)

S. No.	System suitability parameters	Results
1	Tailing	1.20
2	Retention time	3.067
3	Plate count	2030
4	Area	18920313

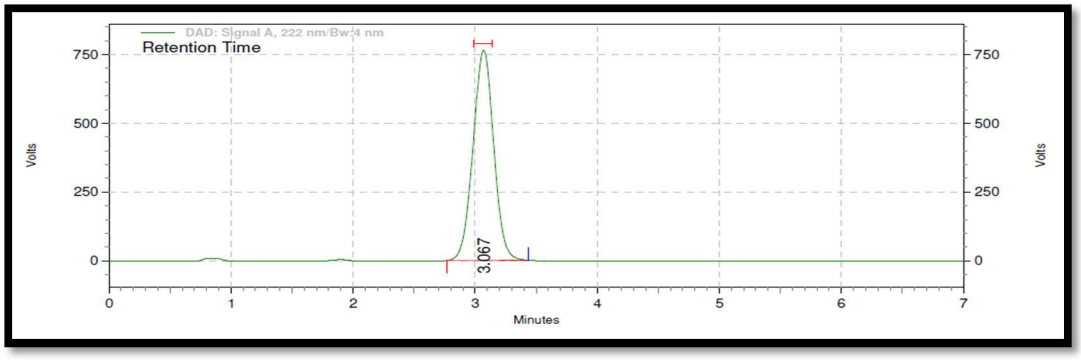

Fig. 13: Chromatogram of tablet

Table 5: System suitability data

Parameters	Observation		Specification
	API	Tablet	
% RSD of Area	0.26	0.411	RSD<2%
Resolution(Rs)	0.00	0.00	Rs>2
Tailing Factor(T)	1.28±0.04	1.02±0.09	T ≤ 2
Theoritical plates(N)	2350±185.02	2115.4±200.36	≥2000

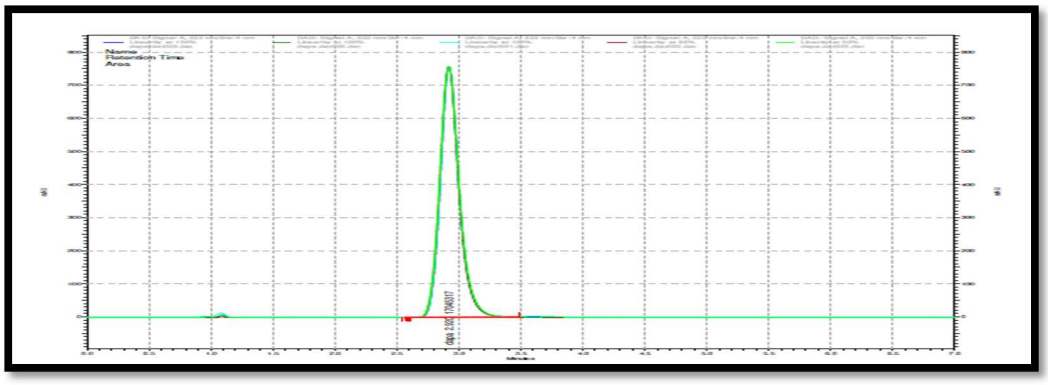

Fig. 14: Overlay spectra of dapagliflozin

Table 6: Linearity data for dapagliflozin

Conc*	Peak area±SD* (n=5)	%RSD*
250	5274844.2±11182.6	0.21
400	8958845.32±10236.58	0.12
500	11198557.8±30236.23	0.27
600	13438268.54±50923.2	0.38
750	16797835.69±99983.5	0.59

Number of experiment (n)-5, Conc*-concentration, SD*-standard deviation, %RSD*-relative standard deviation

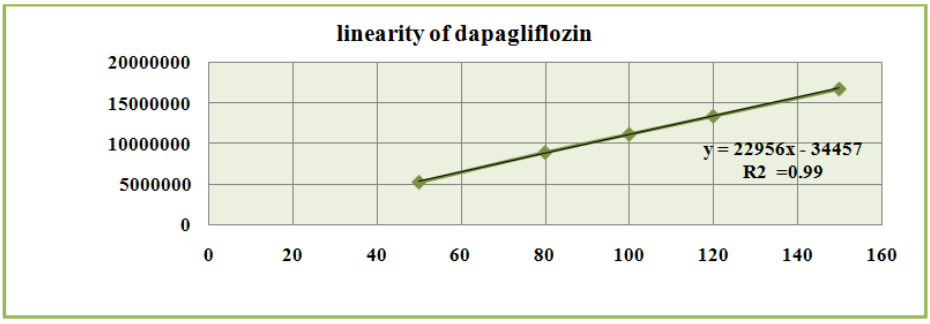

Fig. 15: Calibration plot of dapagliflozin

Table 7: Accuracy for API and tablet

Sample	Level (%)	Amount recovered (µg/ml)	Mean % recovery±SD*
Dapagliflozin API	50	402.96±0.507	99.72±0.12
	100	503.28±0.55	99.65±0.109
	150	601.12±0.24	99.19±0.03
Dapagliflozin tablet	50	398.65±0.55	98.67±0.13
	100	501.98±0.871	99.40±0.17
	150	605.89±0.98	99.98±0.16

Number of experiment (n)=3, SD*-standard deviation, precision study results

Table 8: Intraday precision

Conc* (µg/ml)	Area±SD*	% RSD*
400	11304882.67±45662.51	0.40
500	11205269±27555.81	0.26
600	11368903.33±23214.27	0.204

Conc*-concentration, Number of experiment (n)-3, SD*-standard deviation, RSD*-relative standard deviation

Table 9: Interday precision

Conc* (µg/ml)	Area±SD*	% RSD*
400	11386283±25806.57	0.23
500	11174585.67±46710.12	0.42
600	11192177±38642.96	0.34

Conc*-concentration, Number of experiment (n)-3, SD*-standard deviation, RSD*-relative standard deviation

Table 10: Repeatability data

S. No.	Dapagliflozin (500 µg/ml)
1	11448945
2	11367925
3	11382354
4	11283925
5	11356486
6	11345685
Mean	11364220
SD*	11596.78
% RSD*	0.102

Number of experiment (n)-6, SD*-standard deviation, RSD*-relative standard deviation

Table 11: Robustness study

Conc*(500 µg/ml)	Flow rate		Temperature(°C)		Mobile Phase	
	0.8 ml	1.2 ml	25 °	35 °	+5 ml	-5 ml
Avg. area	66176464	5234741	1456537.3	1856685	18478292.3	43198353
SD*	78967.96	5998.1	12044.42	102585	132229.6	20341.1
% RSD*	0.11	0.11	0.83	0.55	0.83	0.12

Conc*-concentration, Number of experiment (n)-3, SD*-standard deviation, RSD*-relative standard deviation

Table 12: LOD and LOQ

Parameter	Dapagliflozin
LOD* (µg/ml)	5.14
LOQ* (µg/ml)	15.6

LOD*-limit of detection, LOQ*-limit of quantification

DISCUSSION

A new stability indicating RP-HPLC method has been developed for estimation of Dapagliflozin in API and Tablet dosage form was rapid, accurate, precise, specific, sensitive and robust.

From the above study, we can conclude that the dapagliflozin was subjected to acid, alkali hydrolysis, and oxidation, thermal and photolytic degradation. The degradation studies indicate that dapagliflozin is more susceptible to thermal degradation and Forxiga is more susceptible to photolytic degradation.

From the peak purity study, it was confirmed that the peak of degradation product and excipient was not interfering with the peak of the drug. Hence this method was used for the analysis of Dapagliflozin in API and tablet dosage form in quality control department for routine analysis.

Linearity of the developed method follows beer's law and was near to 0.99. It found to be linear in the range 250–750 µg/ml. % RSD was found to be less than 2 for precision. The method is robust since by deliberate variation in method, % RSD was found to be less than 2. So the is found to be robust.

% Recoveries was found to be 99.65 %. Hence this method can be used for analysis of dapagliflozinin API and Tablet dosage form in quality control department for routine analysis.

CONCLUSION

In the present study, we have developed a new, rapid RP-HPLC method and validated for different parameters (system suitability, linearity, accuracy, precision, LOD, LOQ robustness). By studying all these we have concluded that the method was linear, accurate, precise, robust and rapid for determination of dapagliflozin in API and Pharmaceutical dosage form. Hence the method was successfully applied for the estimation of dapagliflozin in API and Pharmaceutical dosage form.

ACKNOWLEDGEMENT

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CONFLICT OF INTERESTS

Declare none

REFERENCES

1. Drug Profile; 2016. http://www.drugbank.ca/drugs/DB06292. [Last accessed on 10 Mar 2017].
2. Obermeier M, Yao M, Khanna A, Koplowitz B, Zhu M, Li W, *et al*. *In vitro* characterization and pharmacokinetics of dapagliflozin (BMS-512148), a potent sodium-glucose cotransporter type II inhibitor, in animals and humans. Drug Metab Dispos 2010;38:405-14.
3. Sanagapati Manasa, Dhanlakshmi K, G Nagarjuna, B Kavitha. Method development and validation of dapagliflozin API by UV spectroscopy. Int J Pharm Sci Res 2014;27:270-7.
4. KP Chitra, Eswaraiah MC, Rao Basoveswara MV. Unique UV spectrophotometric method for the reckoning of dapagliflozin in bulk and pharmaceutical dosage form. J Chem Pharm Res 2015;7:45-5.
5. Jani Br, Shah KV, Kapupara PP. Development and validation of UV spectroscopic method for simultaneous estimation of dapagliflozin and metformin hydrochloride in the synthetic mixture. Int J Res Dev Pharm Life Sci 2015**;**4:1569-7.
6. Jani BR, Shah KV, Kapupara PP. Development and validation of UV spectroscopic first derivative method for simultaneous estimation of dapagliflozin and metformin hydrochloride in the synthetic mixture. J Bioequv 2015;1:1-8.
7. Sanagapati Manasa, Dhanlakshmi K, G Nagarjunareddy, Sreenivasa S. Development and validation of a RP-HPLC method for the estimation of dapagliflozin in API. Int J Pharm Sci Res 2014:5394-3.
8. Yunoos Mohammad, DS Gowri. A validated stability indicating HPLC method for simultaneous determination of metformin hydrochloride and dapagliflozin in bulk drug and tablet dosage form. A J Pharm Clin Res 2015;8:320-6.
9. Sanagapati Manasa, Dhanlakshmi K, G Nagarjunareddy. Method development and validation of dapagliflozin in API by RP-HPLC and UV spectroscopy. Int J Pharm Sci Drug Res 2014;6:250-2.
10. Sanagapati Manasa, Dhanlakshmi K, G Nagarjunareddy, S Sreenivasa. Development and validation of stability indicating RP-HPLC method for determination of dapagliflozin. J Adv Pharm Edu Res 2014;4:350-3.
11. Aubry Af, Gu H, Magnier R, Morgan L, Xu X, Tirmenstein M, *et al*. Validated LC-MS/MS methods for the determination of dapagliflozin a sodium glucose co-transporter 2 inhibitors in normal and ZDF rat plasma. Bioanalysis 2010;2:1.

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