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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ANTI-DIABETIC AGENT DAPAGLIFLOZIN IN BULK FORM AND MARKETED PHARMACEUTICAL DOSAGE FORM

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ABSTRACT
A novel, simple, accurate, precise, sensitive and specific analytical RP-HPLC method was developed and validated for the quantitative estimation of Dapagliflozin in bulk drugs and pharmaceutical dosage form. Chromatographic separation was achieved on an Symmetry ODS C18 (4.6×250mm, 5µm) analytical column using mobile phase composition of methanol and Phosphate Buffer in ratio of (35: 65 v/v) that was set at a flow rate of 1.0µl/min with detection of 235 nm. The retention time of Dapagliflozin was found to be 3.006min. The drug was analyzed by following the guidelines of International conference on Harmonization (ICH). This drug showing linearity in the concentration range of 6-14µg/ml and the correlation coefficient showing R2 = 0.9996. The % Recoveries showing within the limits. The presentation of the method was validated according to the present ICH guidelines for accuracy, precision and robustness, Linearity, limit of quantification, limit of detection linearity.

KEYWORDS: Dapagliflozin, RP-HPLC, Method Development, Accuracy, Precision.

INTRODUCTION
Dapagliflozin is a C-glycosyl comprising beta-D-glucose in which the anomeric hydroxy group is replaced by a 4-chloro-3-(4-ethoxybenzyl) phenyl group. Used (in the form of its Propanediol monohydrate) to improve glycemic control, along with diet and exercise, in adults with type 2 diabetes. It has a role as a hypoglycemic agent and a sodium-glucose transport protein subtype 2 inhibitor.[1] It is a C-glycosyl compound, aromatic ether and a member of monochlorobenzenes. Dapagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and it was the first SLGT2 inhibitor to be approved. Indicated for managing diabetes mellitus type 2. When combined with diet and exercise in adults, Dapagliflozin helps to improve glycemic control by inhibiting glucose reabsorption in the proximal tubule of the nephron and causing glycosuria. Dapagliflozin has been investigated either as monotherapy or as an adjunct treatment with insulin or other oral hypoglycemic agents.[2] Dapagliflozin was originally approved by the FDA on Jan 08, 2014, to improve glycemic control in adults with type 2 diabetes in conjunction with diet and exercise. It was later approved to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease in April 2021. Dapagliflozin is a Sodium-Glucose Cotransporter 2 Inhibitor.[3] The mechanism of action of Dapagliflozin is as a Sodium-Glucose Transporter 2 Inhibitor. The IUPAC Name of Dapagliflozin is (2S, 3R, 4R, 5S, 6R)-2-[4-chloro-3-[(4-ethoxyphenyl) methyl] phenyl]-6-(hydroxy methyl) oxane-3, 4, 5-triol. The Chemical Structure of Dapagliflozin is shown in following figure-1.

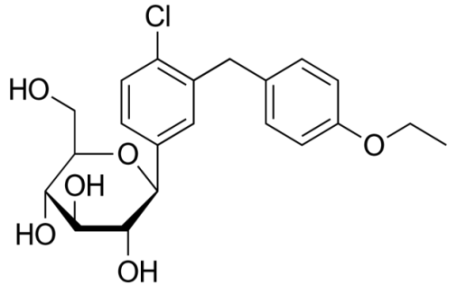

Fig. 1: Chemical Structure of Dapagliflozin.

EXPERIMENTAL

Table 1: Instruments Used.

S.No	Instruments And Glass wares	Model
1	HPLC	HPLC with Empower2 Software with Isocratic with UV-Visible Detector (Waters).
2	pH meter	Lab India
3	Weighing machine	Sartorius
4	Volumetric flasks	Borosil
5	Pipettes and Burettes	Borosil
6	Beakers	Borosil
7	Digital Ultra Sonicator	Labman

Table 2: Chemicals Used.

S.No.	Chemical	Brand Names
1	Dapagliflozin (Pure)	Oxra 10mg Tablet
2	Water and Methanol for HPLC	LICHROSOLV (MERCK)
3	Acetonitrile for HPLC	Merck

HPLC Method Development

Preparation of Standard Solution

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7ml of Methanol and sonicate to dissolve and removal of air completely and make volume up to the mark with the same Methanol. Further pipette 0.1ml of the above Dapagliflozin stock solutions into a 10ml volumetric flask and dilute up to the mark with Methanol.

Procedure

Inject the samples by changing the chromatographic conditions and record the chromatograms, note the conditions of proper peak elution for performing validation parameters as per ICH guidelines.[13,14,25,30]

Mobile Phase Optimization

Initially the mobile phase tried was Methanol and Methanol: Water with varying proportions. Finally, the mobile phase was optimized to Methanol: Phosphate Buffer in proportion 35:65% v/v.

Optimization of Column

The method was performed with various C18 columns like, X- bridge column, Xterra, and C18 column.[4] Symmetry ODS C18 (4.6 x 250mm, 5µm) was found to be ideal as it gave good peak shape and resolution at 1ml/min flow.

Preparation of Buffer and Mobile Phase

Preparation of Potassium dihydrogen Phosphate (KH_2PO_4) buffer (pH-3.6)

Dissolve 6.8043 of potassium dihydrogen phosphate in 1000 ml HPLC water and adjust the pH 3.6 with diluted orthophosphoric acid. Filter and sonicate the solution by vacuum filtration and ultra-sonication.

Preparation of Mobile Phase

Accurately measured 350 ml (35%) of Methanol, 650 ml of Phosphate buffer (65%) were mixed and degassed in digital ultra sonicater for 15 minutes and then filtered through 0.45 µ filter under vacuum filtration.[5]

Diluent Preparation

The Mobile phase was used as the diluent.

Method Validation Parameters

System Suitability

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.1ml of the above Dapagliflozin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Procedure

The standard solution was injected for five times and measured the area for all five injections in HPLC. The %RSD for the area of five replicate injections was found to be within the specified limits.[6]

Specificity

Preparation of Standard Solution

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent.[7] (Stock solution). Further pipette 0.1ml of the above Dapagliflozin stock solutions into a 10ml volumetric flask and dilute up to the mark with diluents.

Preparation of Sample Solution

Weight 10 mg equivalent weight of Dapagliflozin sample into a 10mL clean dry volumetric flask and add about 7mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent. Further pipette 0.1ml of Dapagliflozin above stock solution into a 10ml volumetric flask and dilute up to the mark with diluent.

Procedure

Inject the three replicate injections of standard and sample solutions and calculate the assay[8] by using formula:

%ASSAY =

$$\frac{\text{Sample area}}{\text{Standard area}} \times \frac{\text{Weight of standard}}{\text{Dilution of standard}} \times \frac{\text{Dilution of sample}}{\text{Weight of sample}} \times \frac{\text{Purity}}{100} \times \frac{\text{Weight of tablet}}{\text{Label claim}} \times 100$$

Linearity

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Preparation of Level – I (6ppm of Dapagliflozin)

Take 0.6ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – II (8ppm of Dapagliflozin)

Take 0.8ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – III (10ppm of Dapagliflozin)

Take 0.1ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – IV (12ppm of Dapagliflozin)

Take 0.12ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – V (14ppm of Dapagliflozin)

Take 0.14ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Procedure

Inject each level into the chromatographic system and measure the peak area. Plot a graph of peak area versus concentration (on X-axis concentration and on Y-axis Peak area) and calculate the correlation coefficient.[9]

Precision

Repeatability

Preparation of Dapagliflozin Product Solution for Precision

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.1ml of the above Dapagliflozin stock solutions into a 10ml volumetric flask and dilute up to the mark with diluents.

Method: The standard solution was injected for five times and measured the area for all five injections in HPLC. The %RSD for the area of five replicate injections was found to be within the specified limits.

Intermediate Precision

To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different days by maintaining same conditions.[10]

Procedure

Analyst 1

The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.

Analyst 2

The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.[11]

ACCURACY

For Preparation of 50% Standard Stock Solution

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.05ml of the above Dapagliflozin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

For Preparation of 100% Standard Stock Solution

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.1ml of the above Dapagliflozin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.[12]

For Preparation of 150% Standard Stock Solution

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to

dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.15ml of the above Dapagliflozin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Procedure

Inject the Three replicate injections of individual concentrations (50%, 100%, 150%) were made under the optimized conditions. Recorded the chromatograms and measured the peak responses. Calculate the Amount found and Amount added for Dapagliflozin and calculate the individual recovery and mean recovery values.

Robustness

The analysis was performed in different conditions to find the variability of test results. The following conditions are checked for variation of results.[15]

For Preparation of Standard Solution

Accurately weigh and transfer 10 mg of Dapagliflozin working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.1ml of the above Dapagliflozin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Effect of Variation of Flow Conditions

The sample was analyzed at 0.9 ml/min and 1.1 ml/min instead of 1ml/min, remaining conditions are same. 10µl of the above sample was injected and chromatograms were recorded.[16]

Effect of Variation of Mobile Phase Organic Composition

The sample was analyzed by variation of mobile phase i.e. Methanol: Phosphate Buffer was taken in the ratio and 40:60, 30:70 instead (35:65), remaining conditions are same.[17] 10µl of the above sample was injected and chromatograms were recorded.

RESULTS AND DISCUSSION

Method Development

The analytical procedure for the estimation of Dapagliflozin in bulk and marketed formulation was optimized with a view to develop a precise and accurate assay method. Agilent Eclipse XDB (4.6x150mmx3.5mic), Agilent Zorbax C8 (4.6x150mmx5mic) and Inertsil-ODS (4.6x250mmx5mic) were used to provide an efficient separation but appropriate chromatographic separation was achieved on An Symmetry ODS C18 (4.6×250mm, 5µm). Various mobile phase systems were prepared and used to provide an appropriate chromatographic separation, but the proposed mobile phase containing Methanol and Phosphate Buffer in the ratio of 35:65% v/v gave a better resolution. Using UV-visible PDA detector at 235 nm carried out the detection.[18] Amongst the several flow rates tested, the flow rate of 1.0 ml/min was the best suited for both the drugs with respect to location and resolution of peaks. The retention time of Dapagliflozin was found to 3.006min. The chromatograms of Standard Solution of Dapagliflozin were shown in Figure-2. The tailing factor of Dapagliflozin was 1.24 found, which indicates symmetrical nature of the peak.[19] The USP plate count of Dapagliflozin was 6569 found, which indicates column efficiency for separation. System suitability parameters such as Peak asymmetry, Resolution and Number of theoretical plates are meeting ICH requirements.[13,14,25,30] The percentage label claim of individual drugs found in formulations were calculated and provided in Table 10. The results of analysis shows that the amount of drug estimated were in good agreement with the label claim of the formulations.

Optimized Chromatographic Conditions

Mobile phase ratio	: Methanol: Phosphate Buffer (35:65) V/V
Column	: Symmetry ODS C18 (4.6×250mm, 5µm)
Column temperature	: Ambient
Wavelength	: 235nm
Flow rate	: 1ml/min
Injection volume	: 10µl
Run time	: 8min

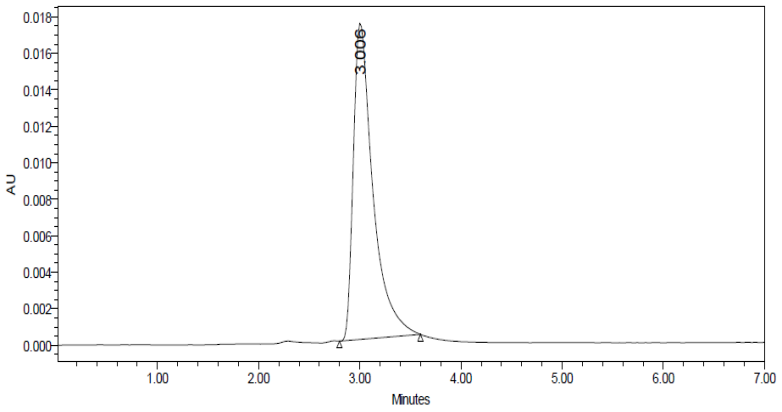

Fig. 2: Optimized Chromatographic Condition.

Table 3: Results of Optimized Chromatographic Condition.

S. No.	Name	RT	Area	Height	USP Tailing	USP Plate Count
1	Dapagliflozin	3.006	1658242	185421	1.24	6569

Method Validation

The method was validated according to ICH guidelines[25,30] for the parameters including accuracy, precision, linearity, specificity and robustness in analytical solution.

System Suitability

The system suitability test was performed to check the various parameters such as column efficiency, resolution, peak tailing and retention time. The number of theoretical plates for Dapagliflozin was 6589. All these parameters were evaluated with the background of regulatory requirements, which also suggest good chromatographic condition.[20] The results were shown in Table 4.

Table 4: Results of system suitability for Dapagliflozin.

S.No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Dapagliflozin	3.008	1652847	185647	6589	1.24
2	Dapagliflozin	3.005	1653658	186254	6587	1.26
3	Dapagliflozin	3.001	1654521	185475	6584	1.28
4	Dapagliflozin	3.000	1653564	186594	6582	1.29
5	Dapagliflozin	3.001	1658745	185684	6895	1.24
Mean			1654667			
Std. Dev.			2355.764			
% RSD			0.142371			

Specificity

The ICH documents define specificity as the ability to assess unequivocally the analyte in the presence of components that may be expected to be present, such as impurities, degradation products, and matrix components.[21] Analytical method was tested for specificity to measure accurately quantitates Dapagliflozin in drug product.

$$\%ASSAY = \frac{\text{Sample area}}{\text{Standard area}} \times \frac{\text{Weight of standard}}{\text{Dilution of standard}} \times \frac{\text{Dilution of sample}}{\text{Weight of sample}} \times \frac{\text{Purity}}{100} \times \frac{\text{Weight of tablet}}{\text{Label claim}} \times 100$$

The % purity of Dapagliflozin in pharmaceutical dosage form was found to be 99.86%.

Linearity and Range

The linearity of the method was determined at five concentration levels (6, 8, 10, 12% and 14µg/ml). Linearity test solutions were prepared by diluting the stock solutions to the required concentrations. The calibration curves were plotted between the responses of peak area versus concentration of analyte. The slope and intercept value for calibration curve was y = 185008 x - 16179 (r2=0.9996) for Dapagliflozin.[22] The result (Table 5) shows that an excellent correlation exists between area and concentration of drug within the concentration range. Calibration curve is presented in Figure 3.

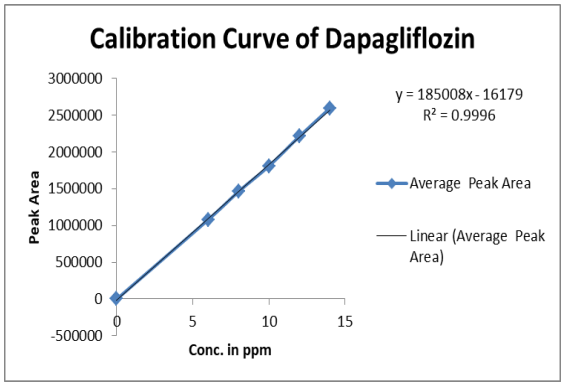

Fig-3: Linearity Curve of Dapagliflozin.

Table 5: Data for Linearity of Dapagliflozin.

Concentration µg/ml	Average Peak Area
6	1078475
8	1461129
10	1808358
12	2211573
14	2593778

Precision

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.[23]

Repeatability: Obtained Five (5) replicates of 100% accuracy solution as per experimental conditions. Recorded the peak areas and calculated % RSD.

Table 6: Results of Repeatability for Dapagliflozin.

S. No.	Peak name	Retention time	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Dapagliflozin	3.008	1658954	186958	1.26	6785
2	Dapagliflozin	3.000	1658745	187548	1.27	6854
3	Dapagliflozin	3.013	1659865	189854	1.26	6852
4	Dapagliflozin	3.006	1653254	186985	1.25	6784
5	Dapagliflozin	3.001	1654781	189542	1.24	6895
Mean			1657120			
Std. Dev			2913.592			
%RSD			0.175823			

Intermediate Precision

The Intermediate Precision consists of two methods:-

Intra Day: In Intra Day process, the 50%, 100% and 150% concentration are injected at different intervals of time in same day.

Inter Day: In Inter Day process, the 50%, 100% and 150% concentration are injected at same intervals of time in different days.

Table 7: Results of Intra-Assay & Inter-Assay.

Conc. of Dapagliflozin (API) (µg/ml)	Observed Conc. of Dapagliflozin (µg/ml) by the proposed method			
	Intra-Day		Inter-Day	
	Mean (n=6)	% RSD	Mean (n=6)	% RSD
50	49.38	0.56	49.45	0.56
100	100.17	0.71	99.70	0.77
150	150.89	0.89	149.91	0.85

Observations: The intra & inter day variation of the method was carried out for standard deviation & % RSD (% RSD < 2%) within a day & day to day variations for Dapagliflozin revealed that the proposed method is precise.

Accuracy

The accuracy of the method was determined by recovery experiments.[24] The recovery studies were evaluated in triplicate using three concentration levels 50%, 100% and 150%. The percentage recovery data was obtained, added recoveries of standard drugs were found to be accurate (Table-8).

Table 8: The Accuracy Results for Dapagliflozin.

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	109068.3	5	5.021	100.420%	100.72%
100%	202187	10	10.054	100.540%	
150%	297032.3	15	15.181	101.206%	

Limit of Detection for Dapagliflozin

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.[25]

$$LOD = 3.3 \times \sigma / s$$

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

Result

= 1.2µg/ml.

Quantitation Limit for Dapagliflozin

The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined.[26]

$$LOQ = 10 \times \sigma / S$$

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

Result

= 3.6µg/ml.

Robustness

The robustness was performed for the flow rate variations from 0.9 ml/min to 1.1ml/min and mobile

phase ratio variation from more organic phase to less organic phase ratio for Dapagliflozin. The method is robust only in less flow condition.[27] The standard of Dapagliflozin was injected by changing the conditions of chromatography. There was no significant change in the parameters like resolution, tailing factor, asymmetric factor, and plate count.

Table 9: Result of Method Robustness Test.

Change in Parameter	% RSD
Flow (1.1 ml/min)	0.68
Flow (0.9 ml/min)	0.39
Temperature (27^0C)	0.54
Temperature (23^0C)	0.63
Wavelength of Detection (280 nm)	0.91
Wavelength of detection (270 nm)	0.93

Acceptance Criteria: The tailing factor should be less than 2.0 and the number of theoretical plates (N) should be more than 2000.

Estimation of Dapagliflozin in Pharmaceutical Dosage Form

Oxra 10mg Tablet

Twenty tablets were taken and the I.P. method was followed to determine the average weight. Above weighed tablets were finally powdered and triturated well. A quantity of powder equivalent to 10 mg of drug were transferred to 10 ml volumetric flask, and 8 ml of mobile phase was added and solution was sonicated for 15 minutes, there after volume was made up to 10 ml with same solvent. Then 1ml of the above solution was diluted to 10 ml with HPLC grade methanol. The solution was filtered through a membrane filter (0.45 µm) and sonicated to degas. From this stock solution (1.0 ml) was transferred to five different 10 ml volumetric flasks and volume was made up to 10 ml with same solvent system.[28]

The solution prepared was injected in five replicates into the HPLC system and the observations were recorded.

A duplicate injection of the standard solution was also injected into the HPLC system and the peak areas were recorded. The data are shown in Table-10.

ASSAY

% Assay=AT/AS×WS/DS×DT/WT×P/100×AW/LC×100

Where:

AT = Peak Area of Dapagliflozin obtained with test preparation

AS = Peak Area of Dapagliflozin obtained with standard preparation

WS = Weight of working standard taken in mg

WT = Weight of sample taken in mg

DS = Dilution of Standard solution

DT = Dilution of sample solution

P = Percentage purity of working standard

Results obtained are tabulated below:

Table-10: Assay of Dapagliflozin Tablets.

Brand Name of Tablets	Labelled Amount of Drug (mg)	Mean (±SD) Amount (mg) Found by the Proposed Method (n=5)	Assay + % RSD
Oxra 10mg Tablet (Sun Pharmaceutical Industries Ltd)	10mg	9.386 (± 0.527)	99.128 % (± 0.289)

Result & Discussion: The %Purity of Oxra 10mg Tablet containing Dapagliflozin was found to be 99.128 % (± 0.289).

Forced Degradation Studies

Results of Degradation Studies: The results of the forced degradation studies indicated the specificity of the developed method that has been developed.[29-30] Dapagliflozin were stable only in oxidation, photolytic and acidic stress conditions. The results of stability studies are given in the following Table-11.

Table 11: Results of Forced Degradation Studies of Dapagliflozin API.

Stress Condition	Time (hours)	Assay of Active Substance	Assay of Degraded Products	Mass Balance (%)
Acid Hydrolysis (0.1N HCl)	24Hrs.	96.854	3.146	100.00
Basic Hydrolysis (0.IN NaOH)	24Hrs.	81.632	18.368	100.00
Thermal Degradation (60 ^{0}C)	24Hrs.	86.475	13.525	100.00
UV (254nm)	24Hrs.	97.866	2.134	100.00
3% Hydrogen Peroxide	24Hrs.	98.654	1.346	100.00

SUMMARY

To develop a precise, linear, specific & suitable stability indicating RP-HPLC method for analysis of Dapagliflozin, different chromatographic conditions were applied & the results observed are presented in previous chapters. Isocratic elution is simple, requires only one pump & flat baseline separation for easy and reproducible results. So, it was preferred for the current

study over gradient elution. In case of RP-HPLC various columns are available, but here Symmetry ODS C_{18} (4.6mm×250mm, 5µm) column was preferred because using this column peak shape, resolution and absorbance were good. Detection wavelength was selected after scanning the standard solution of drug over 200 to 400nm. From the U.V spectrum of Dapagliflozin it is evident that most of the HPLC work can be accomplished in the wavelength range of 235 nm conveniently. Further, a flow rate of 1.0 ml/min & an injection volume of 10µl were found to be the best analysis. The result shows the developed method is yet another suitable method for assay which can help in the analysis of Dapagliflozin in different formulations.

CONCLUSION

In the present research, a fast, simple, accurate, precise, and linear HPLC method has been developed and validated for Dapagliflozin, and hence it can be employed for routine quality control analysis. The analytical method conditions and the mobile phase solvents provided good resolution for Dapagliflozin. In addition, the main features of the developed method are short run time and retention time around 3 min. The method was validated in accordance with ICH guidelines. The method is robust enough to reproduce accurate and precise results under different chromatographic conditions. Hence the proposed RP-HPLC method proved to be simple, accurate and reproducible for the determination of Dapagliflozin in a reasonable run time. The method was validated showing satisfactory data for all the method validation parameters tested. The developed method can be conveniently used by quality control laboratories.

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