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A NEW RAPID ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTITATIVE DETERMINATION OF EDOXABAN IN PURE FORM AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT:

An Analytical, accurate, precise, efficient and simple RP-HPLC method has been developed and validated for the determination of Edoxaban in bulk and marketed pharmaceutical dosage forms. The mobile phase used for the chromatographic runs consisted of Acetonitrile and Phosphate buffer (0.01M, pH-3.2) in the ratio of 30:70% v/v. The Chromatographic Separation was achieved on a Symmetry C18 ODS (4.6mm × 250mm) 5µm particle size column using isocratic mode. Drug peak was well separated and were detected by a UV detector at 246 nm. The developed method was linear at the concentration range 6–14 µg/ml for Edoxaban. The method has been validated according to ICH guidelines with respect to system suitability, specificity, precision, accuracy and robustness. Edoxaban Limit of detection (LOD) and Limit of Quantification (LOQ) were 0.487µg/ml and 1.477µg/ml respectively. As a result, the suggested method with excellent specificity, accuracy, precision, linearity and robustness as well as economical was useful for the regular quality control analysis of Edoxaban in bulk and pharmaceutical dosage forms.

Key Words: Edoxaban, RP-HPLC, Accuracy, Precision, Robustness, ICH Guidelines.

INTRODUCTION

Edoxaban is a novel oral anticoagulant used for reducing the risk of stroke and systemic embolism (SE) in patients with nonvalvular atrial fibrillation (NVAF). Edoxaban is indicated for reducing the risk of stroke and systemic embolism (SE) in patients with nonvalvular atrial fibrillation (NVAF). However, it should not be used in patients with creatinine clearance (CrCL) > 95 mL/min because of increased risk of ischemic stroke compared to warfarin at the highest dose studied (60 mg)1. It is also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5-10 days of initial therapy with a parenteral anticoagulant. Edoxaban (brand name Savaysa) is a direct oral anticoagulant (DOAC) used to prevent blood clots and stroke2. It is primarily indicated to reduce the risk of stroke in nonvalvular atrial fibrillation (NVAF) and to treat deep vein thrombosis (DVT) and pulmonary embolism (PE), often following initial injectable anticoagulant therapy. The IUPAC name of Edoxaban is 2-[1-ethyl sulfonyl-3-[4-(7H-pyrrolo [2, 3-d] pyrimidin-4-yl) pyrazol-1-yl] azetidin-3-yl] acetonitrile3. The Chemical Structure of Edoxaban is shown in following figure-1.

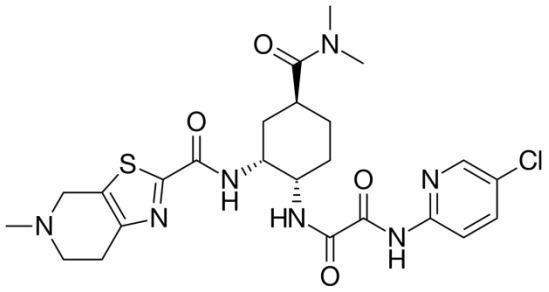

Fig-1: Chemical Structure of Edoxaban

MATERIALS AND METHODS

The following are the list of instruments/Equipment's, chemicals/reagents and standards to perform the HPLC Analysis of the drug Edoxaban.

Equipments:

Table-1: List of Equipments

S. No.	Instruments/Equipment's/Apparatus
1.	HPLC WATERS with Empower2 Software with Isocratic with UV-Visible Detector.
2.	T60-LABINDIA UV – Vis spectrophotometer
3.	High Precision Electronic Balance
4.	Ultra Sonicator (Wensar wuc-2L)
5.	Thermal Oven
6.	Symmetry C18 Column, 250 mm x 4.6 mm and 5µm particle size
7.	PH Analyser (ELICO)
8.	Vaccum Filtration Kit (Labindia)

Chemicals and Reagents:

Table-2: List of Chemicals Used

S. No.	Name	Grade	Manufacturer/Supplier
1.	HPLC grade water	HPLC	Sd fine-Chem ltd; Mumbai
2.	Methanol	HPLC	Loba Chem; Mumbai.
3.	Ethanol	A.R.	Sd fine-Chem ltd; Mumbai
4.	Acetonitrile	HPLC	Loba Chem; Mumbai.
5.	DMSO	A.R.	Sd fine-Chem ltd; Mumbai
6.	DMF	A.R.	Sd fine-Chem ltd; Mumbai

Method Development:

HPLC Instrumentation & Conditions: The HPLC system employed was HPLC WATERS with Empower2 Software with Isocratic with UV-Visible Detector.

Standard Preparation for UV-Spectrophotometer Analysis:

The Standard Stock Solutions – 10 mg of Edoxaban standard was transferred into 10 ml volumetric flask, dissolved & make up to volume with Methanol. Further dilutions were done by transferring 1 ml of the above solution into a 10ml volumetric flask and make up to volume with methanol to get 10ppm concentration4.

It scanned in the UV spectrum in the range of 200 to 400nm. This has been performed to know the maxima of Edoxaban, so that the same wave number can be utilized in HPLC UV detector for estimating the Edoxaban.

Selection of Wavelength:

The detection wavelength was selected by dissolving the drug in mobile phase to get a concentration of 10µg/ml for individual and mixed standards. The resulting solution was scanned in U.V range from 200-400nm. The UV spectrum of Edoxaban was obtained and the Edoxaban showed absorbance's maxima at 246nm5. The UV spectra of drug are follows:

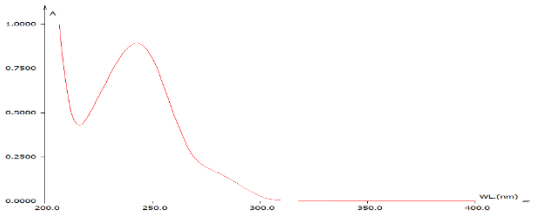

Fig-2: UV Spectrum of Edoxaban (246nm)

Observation: While scanning the Edoxaban solution we observed the maxima at 246nm. The UV spectrum has been recorded on T60-LAB INDIA make UV – Vis spectrophotometer model UV-2450.

Selection of chromatographic methods:

The proper selection depends upon the nature of the sample, (ionic or ion stable or neutral molecule) its molecular weight and stability. The drugs selected are polar, ionic and hence reversed phase chromatography was selected6.

Optimization of Column:

The method was performed with various columns like Hypersil C18 column, X- bridge column and X-terra (4.6 ×150mm, 5µm particle size), Symmetry C18 ODS (4.6mm×250mm) 5µm particle size Column was found to be ideal as it gave good peak shape and resolution at 1.0ml/min flow.

Mobile Phase Optimization:

Initially the mobile phase tried was Water: Methanol and Water: Acetonitrile and Methanol with TEA Buffer with varying proportions. Finally, the mobile phase was optimized

to Acetonitrile: Phosphate buffer (0.01M, pH-3.2) in the ratio of 30:70 respectively7.

Preparation of Mobile Phase:

Accurately measured 300 ml (300%) of HPLC Grade Acetonitrile and 700 ml of Phosphate buffer (70%) were mixed and degassed in a digital ultra sonicater for 15 minutes and then filtered through 0.45 µ filter under vacuum filter.

Preparation of 0.01M Potassium dihydrogen orthophosphate Buffer Solution:

About 1.36086grams of Potassium dihydrogen orthophosphate was weighed and transferred into a 1000ml beaker, dissolved and diluted to 1000ml with HPLC Grade water. The pH was adjusted to 3.20 with diluted orthophosphoric acid.

Diluent Preparation:

Accurately measured 300 ml (300%) of HPLC Grade Acetonitrile and 700 ml of Phosphate buffer (70%) were mixed and degassed in a digital ultra sonicater for 15 minutes and then filtered through 0.45 µ filter under vacuum filter8.

Assay

Preparation of the Edoxaban standard solution:

Preparation of standard solution: (Edoxaban)

Accurately weigh and transfer 10 mg of Edoxaban, working standard into a 10ml of clean dry volumetric flasks add about 7ml of diluent and sonicate to dissolve and removal of air completely and make volume up to the mark with the diluent.

Further pipette 0.1ml of Edoxaban from stock solution in to a 10ml volumetric flask and dilute up to the mark with diluent.

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 guidelines9-15.

Preparation of Sample Solution:

Take average weight of Tablet and crush in a mortar by using pestle and taken weight 10 mg equivalent weight of Edoxaban 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.

Procedure:

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

Inject the three replicate injections of standard and sample solutions and calculate the assay by using formula16:

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

Analytical Method Validation

Validation:

Validation is a process of establishing documented evidence which provide a high degree of assurance that specific activity will consistently produce a desired result or product meeting its predetermined specification and quality characteristics17.

System Suitability

System suitability is the evaluation of the components of an analytical system to show that the performance of a system meets the standards required by a method. A system suitability evaluation usually contains its own set of parameters. For chromatographic assays, these may include tailing factor, resolution, precision, capacity factor time and theoretical plates.

Accuracy:

For preparation of 50% Standard stock solution:

Further pipette 0.05ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

For preparation of 100% Standard stock solution:

Further pipette 0.1ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

For preparation of 150% Standard stock solution:

Further pipette 0.15 ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

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 Edoxaban and calculate the individual recovery and mean recovery values.

Acceptance criteria:

The %RSD for each level should not be more than 2 .

Precision:

Repeatability

Preparation of Edoxaban for Precision:

Further pipette 0.1 ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent

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 limits18.

Ruggedness

To evaluate the intermediate precision of the method, Precision was performed on different days by maintaining same conditions.

Procedure:

DAY 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.

DAY 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 limits19.

The % RSD for the area of five standard injections results should be not more than 2%.

Linearity:

Preparation of Level – I (6µg/ml of Edoxaban):

Further pipette 0.06 ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

Preparation of Level – II (8µg/ml of Edoxaban):

Further pipette 0.08 ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

Preparation of Level – III (10µg/ml of Edoxaban):

Further pipette 0.1ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

Preparation of Level – IV (12µg/ml of Edoxaban):

Further pipette 0.12ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

Preparation of Level – V (14µg/ml of Edoxaban):

Further pipette 0.14ml of Edoxaban from stock solutions in to a 10ml volumetric flask and dilute up to the mark with diluent.

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 coefficient20-21.

Acceptance Criteria: Correlation coefficient should be not less than 0.999.

Limit of Detection:

The detection limit is determined by the analysis of samples with known concentration of analyte and by establishing that minimum level at which the analyte can reliably detected22.

Limit of Quantitation

The quantification limit is generally determined by the analysis of sample with known concentrations of analyte and by establishing the minimum level at which the analyte can be quantified with acceptable accuracy and precision23.

Robustness:

The analysis was performed in different conditions to find the variability of test results. The following conditions are checked for variation of results24.

Effect of Variation of flow Rate:

The sample was analyzed at 0.9 ml/min and 1.1 ml/min instead of 1ml/min, remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded.

Effect of Variation of Mobile Phase Organic Composition:

The sample was analyzed by variation of mobile phase i.e. Acetonitrile: Phosphate Buffer was taken in the ratio and 70:30, 75:25 instead of 65:35, remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded25.

RESULTS AND DISCUSSION

Optimization of Method:

Optimized Chromatographic Condition:

Mobile phase : Acetonitrile: Phosphate buffer (0.01M, pH-3.2) (30:70v/v)

Column : Symmetry C18 ODS (4.6mm×250mm) 5µm particle size

Flow rate : 1.0 ml/min

Wavelength : 246 nm

Column temp : Ambient

Injection Volume : 20 µl

Run time : 10 minutes

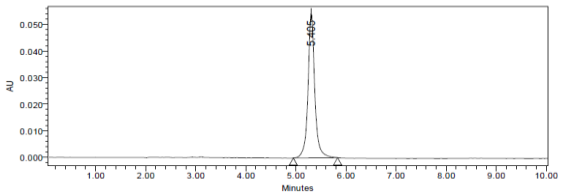

Fig-3: Optimized Chromatographic Condition

Validation of Analytical Method:

System Suitability:

Table-3: Observation of System Suitability Parameters

S.No.	Parameter	Edoxaban
1.	Retention Time (min)	5.453
2.	Theoretical Plates	6967
3.	Tailing factor	1.12
4.	Peak Area (AUC)	647856

The system suitability parameters were found to be within the specified limits for the proposed method.

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. Analytical method was tested for specificity to measure accurately quantitates Edoxaban in drug product.

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

Observation: The % purity of Edoxaban in present in the marketed pharmaceutical dosage form was found to be 99.85%.

Linearity:

Table-4: Chromatographic Data for Linearity Study of Edoxaban

Concentration µg/ml	Average Peak Area
6	468784
8	615798
10	768759
12	925748
14	1078765

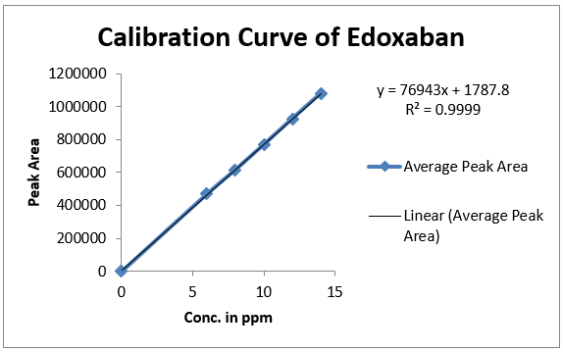

Fig-4: Calibration Curve of Edoxaban

Linearity Plot: The plot of Concentration (x) versus the Average Peak Area (y) data of Edoxaban is a straight line.

Y = mx + c

Slope (m) = 76943

Intercept (c) = 1787

Correlation Coefficient (r) = 0.99

Validation Criteria: The response linearity is verified if the Correlation Coefficient is 0.99 or greater.

Conclusion: Correlation Coefficient (r) is 0.99, and the intercept is 76943. These values meet the validation criteria.

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.

Repeatability: Obtained Six (6) replicates of 100% accuracy solution as per experimental conditions. Recorded the peak areas and calculated % RSD.

Table-5: Results of Repeatability for Edoxaban:

S. No.	Peak Name	Retention time	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Edoxaban	5.419	645784	83685	6825	1.05
2	Edoxaban	5.405	642589	84932	6849	1.09
3	Edoxaban	5.478	643658	85847	6845	1.08
4	Edoxaban	5.466	648759	86295	6839	1.09
5	Edoxaban	5.493	649657	86587	6895	1.07
6	Edoxaban	5.466	647854	87853	6874	1.10
Mean			**646383.5**			
Std. Dev			**2853.319**			
%RSD			**0.441428**			

Intermediate Precision/Ruggedness:

Analyst - 1:

Table-6: Results of Intermediate Precision for Edoxaban

S. No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Edoxaban	5.484	636854	84863	6758	1.09
2	Edoxaban	5.493	637489	84759	6726	1.08
3	Edoxaban	5.406	635762	84685	6749	1.09
4	Edoxaban	5.419	636984	84697	6698	1.07
5	Edoxaban	5.446	634856	84258	6728	1.08
6	Edoxaban	5.452	639689	84753	6699	1.08
Mean			636939			
Std. Dev.			1649.149			
% RSD			0.258918			

Analyst 2:

Table-7: Results of Intermediate Precision Analyst 2 for Edoxaban

S. No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Edoxaban	5.491	628985	85698	6985	1.09
2	Edoxaban	5.482	624879	85479	6899	1.07
3	Edoxaban	5.416	625846	85748	6928	1.06
4	Edoxaban	5.482	623568	85647	6874	1.09
5	Edoxaban	5.495	628985	85246	6984	1.07
6	Edoxaban	5.427	628473	85924	6872	1.08
Mean			626789.3			
Std. Dev			2340.636			
% RSD			0.373433			

Accuracy: Accuracy at different concentrations (50%, 100%, and 150%) was prepared and the % recovery was calculated.

Table-8: The Accuracy Results for Edoxaban

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	386559	5	5.00	100.000%	100.130%
100%	768536	10	9.965	99.650%	
150%	1164522	15	15.111	100.740%	

Limit of Detection for Edoxaban

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.

LOD= 3.3 × σ / s

Were,

σ = Standard deviation of the response

S = Slope of the calibration curve

Result: = 0.487µg/ml

Quantitation Limit

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

LOQ = 10×σ/S

Where,

σ = Standard deviation of the response

S = Slope of the calibration curve

Result: = 1.477µg/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 Edoxaban. The method is robust only in less flow condition. The standard of Edoxaban 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: Results for Robustness

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	648759	5.484	6845	1.08
Less Flow rate of 0.9 mL/min	635248	5.599	6786	1.09
More Flow rate of 1.1 mL/min	659865	4.576	6528	1.05
Less organic phase	625986	7.415	6689	1.03
More organic phase	615869	3.827	6354	1.01

CONCLUSION

The analytical method was developed by studying different parameters. First of all, maximum absorbance was found to be at 246nm and the peak purity was excellent. Injection volume was selected to be 20µl which gave a good peak area. The column used for study was Symmetry C18 ODS (4.6mm×250mm) 5µm particle size because it was giving good peak. Ambient temperature was found to be suitable for the nature of drug solution. The flow rate was fixed at 1.0ml/min because of good peak area and satisfactory retention time. Mobile phase is Acetonitrile: Phosphate buffer (0.01M, pH-3.2) (30:70 v/v) was fixed due to good symmetrical peak. So, this mobile phase was used for the proposed study. Methanol was selected because of maximum extraction sonication time was fixed to be 10min at which all the drug particles were completely soluble and showed good recovery. Run time was selected to be 10min because analyze gave peak around 5.405min and also to reduce the total run time. The percent recovery was found to be 98.0-102 was linear and precise over the same range. Both system and method precision was found to be accurate and well within range. The analytical method was found linearity over the range of 6-14ppm of the Edoxaban target concentration. The analytical passed both robustness and ruggedness tests. On both cases, relative standard deviation was well satisfactory.

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